Alternative & Integrative Medicine
ISSN: 2327-5162

Silva et al., Altern Integ Med 2016, 5:2
DOI: 10.4172/2327-5162.1000216

Research Article Open Access

# One- And Two-year Outcomes of Treating Preschool Children with Autism with a Qigong Massage Protocol: An Observational Follow-along Study

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## Abstract

**Background:** Randomized controlled trials have repeatedly demonstrated that treatment with a five-month qigong massage protocol significantly reduces the severity of autism. The treatment protocol is known as Qigong Sensory Training (QST) autism massage and is given daily by parents and weekly by therapists for five months. Treatment reduces the tactile abnormalities that are universal in young children with autism and results in improved social skills, language and behavior. At five months, tactile abnormalities are reduced by 1/2, autistic behavior is reduced by 1/3, autism severity is reduced by 16%, and 6% of children have moved off the spectrum. What has not yet been done is to measure outcomes with longer-term treatment. This observational study investigates outcomes with up to 24 months of treatment.

**Methods:** 75 children entered this observational study upon completion of five months of treatment with the QST protocol. They received daily parent treatment and monthly therapist treatment for the balance of the first year, and daily parent treatment without therapist support for the second year. Sequential evaluations were conducted at baseline (n=75), five months (n=75), 12 months (n=67) and 24 months (n=31).

**Results:** Continued treatment resulted in continued improvement. At 12 and 24 months, mean tactile responses normalized by 57% and 72%, with 24% and 32% falling into the normal range; mean autism severity decreased by 27% and 44%, with 12% and 26% of children moving out of autistic range.

**Conclusions:** Results demonstrated that longer-term treatment resulted in resolution of tactile impairment and continued improvement of social skills, language and behavior. The rate of coming off the spectrum (1 in 4 children by year-2) was far higher than the natural history of ASD would predict. Results support earlier recommendations to treat tactile abnormalities at the time of autism diagnosis in order to improve autism outcomes.

**Keywords:** Autism treatment; Tactile anormalities; Qigong; QST massage

**Abbreviations:** ASD: Autism Spectrum Disorder; CARS: Childhood Autism Rating Scale; ABC: Autism Behavior Checklist; SSC: Sense and Self-Regulation Checklist; PLS: Preschool Language Scale; QST: Qigong Sensory Treatment; EIBI: Early Intensive Behavioral Intervention; ABA: Applied Behavioral Analysis

## Introduction

Autism is the most common developmental disability in the United States and is currently estimated to affect 1 in 45 children [1]. Its cause remains unknown. Clinically, it is defined by the appearance of social/language delay, unusual and repetitive behavior, and abnormal sensory responses by the age of three [2]. Autism occurs on a spectrum of severity in the lack of social/communication skills, behavioral flexibility, and cognitive ability. As of yet there is no clear explanation for why autism occurs on a spectrum of severity, and no research-based treatment that reliably improves all symptoms of autism across the spectrum [3].

A new direction for autism research and treatment was opened in 2013 when abnormal sensory responses were reclassified from co-morbid symptoms to core diagnostic autism symptoms [2]. At that point, it was recognized that abnormal responses to touch are among the earliest and most prevalent of sensory symptoms [4,5], that severity of tactile abnormalities is related to severity of autism [6], and that the sense of touch had not been proven to be intact in autism. Research as to the specific nature of tactile abnormalities in autism is ongoing. Children with autism were first described by Kanner to lack interest in affective/affiliative touch [7]. Since then, qualitative research has shown that children with autism are distinguished by a pattern of abnormal responses to light touch and pain [8]. New research from mammalian studies indicates that affectionate/affiliative touch is mediated by small unmyelinated tactile fibers (known as C-tactile fibers), and that loss of fibers presents as discomfort with light touch and decreased pain responsivity [9,10]. Diagnosis of small fiber tactile loss is by skin biopsy and specialized staining [11]. This year, the first four biopsies reported in children with autism demonstrated 50% loss of small fibers [12]. This was the first study to report skin biopsy results in children with autism and much work remains to be done to definitively diagnose the cause of tactile abnormalities in autism.

In tandem with research investigating the nature of tactile abnormalities in autism, randomized control studies investigating the effect of qigong massage treatment on severity of tactile abnormalities and severity of autism were conducted [13-15]. The protocol known as Qigong Sensory

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**Received** April 01, 2016; **Accepted** April 20, 2016; **Published** April 29, 2016

**Citation:** Silva LMT, Schalock M, Gabrielsen KR, Gretchen HD (2016) One- And Two-year Outcomes of Treating Preschool Children with Autism with a Qigong Massage Protocol: An Observational Follow-along Study. Altern Integ Med 5: 216. doi:10.4172/2327-5162.1000216

Treatment (QST) massage for autism, is based on Chinese medicine. Treatment is delivered daily by parents and weekly by trained therapists.

The QST intervention has a defined theory and methods described in a manual. Autism is theorized to be due, at least in part, to early partial loss of the sense of touch. Loss of the affective/affiliative component of touch in the early developmental period is theorized to explain the specific social/communication delay and abnormal behaviors characteristic of autism. Treatment uses a massage protocol to stimulate recovery and growth of tactile fibers by increasing circulation to the skin. The effectiveness of Chinese medical approaches to increasing skin circulation has been previously documented [16,17].

This is the second arm of a three-year study that replicated and extended earlier studies investigating the effect of qigong massage on children with autism. The first arm replicated results reported by earlier RCTs in 103 preschool children with autism: at five months, tactile responses had normalized by 49% (based on the Sense and Self-regulation Checklist [18], autistic behavior was reduced by 32% (based on the Autism Behavior Checklist [19], and severity of autism, as measured by a stable measure of autism (based on the Childhood Autism Rating Scale [20] was reduced by 12% [21]. Improvements occurred across the spectrum of autism severity.

With confirmation that five months of the qigong massage intervention is powerfully effective on measures of autism, we wished to determine the effect of longer-term treatment. The literature assessing the natural history of autism indicates that the severity of core autism features can be expected to remain stable in childhood with only a small percentage of children improving slightly and a similar small percentage of children worsening slightly over 8-12 years [22-24]. This second study arm was an observational follow-along study investigating the effect of one and two years of treatment on tactile abnormalities and severity of autism in children who participated in the first study arm. In addition, we investigated factors influencing parent fidelity with daily treatment, and whether longer-term outcomes were influenced by initial severity of tactile abnormalities. The main research questions included:

1. How do tactile abnormalities and severity of autism change over time in response to QST massage treatment?

2. How does behavior and general development change over time in response to QST massage treatment?

3. How does intensity of the parent support program influence parent fidelity (adherence to the massage protocol)? What reasons do parents give for missing treatment?

4. How does parent fidelity with ongoing treatment influence outcomes over time?

5. Does pre-treatment severity of tactile impairment influence treatment outcomes over time?

Additional research questions include:

6. Do parents perceive a change in their children's affective and affiliative responses to touch?

7. How do cost and efficacy of this intervention compare with more widely known early intervention for autism?

## Materials and Methods

### Study design

This study was the second arm of a two-part study. The first arm was a five-month replication study that evaluated efficacy of the QST massage protocol [21]. This second study arm was a 19-month observational follow-along study of children who participated in the first study and completed the five-month treatment protocol. There was no control group for the second study arm.

Standardized assessments of autism, language, and development were carried out pre-treatment and at five, 12 and 24 months post onset of treatment by three qualified professionals Additional evaluations were conducted with validated parent/caregiver questionnaires.

### Participants and recruitment

Inclusion/exclusion criteria for entry into the study included age of 2-5 years; formal diagnosis of autism; no additional chronic disability; no psychoactive medication or pharmaceutical chelation therapy; and not receiving intensive Applied Behavioral Analysis (ABA) treatment for autism. Two study participants were identified as receiving non-intensive ABA treatment at 8 and 10 hours/week, respectively. Parents agreed to give their children the daily massage treatment for the duration of the study and to follow through with training and support visits. Parents were asked about additional interventions for autism at the one-year and two-year assessments.

### Verifying and confirming the diagnosis of autism

Children were required to have a diagnosis of autism by formal autism evaluation as a condition of entry into the study. Records were reviewed and diagnoses confirmed by neurodevelopmental pediatricians using DSM-IV criteria.

### Demographic information

At post-treatment the average age of participants was 57.7 months. At 12 months the average age was 64.1 months and at 24 months the average age was 78 months. Boys made up 90% of the sample at 12 months and 87% of the sample at 24 months. Overall prevalence of autism in boys is 4.5 times that of girls [25]. Lower income families were 33% of the participants at 12 months and 36% at 24 months. Families of cultural minorities were 28% of the participants at 12 months and 39% at 24 months. Eighty percent of parents involved had no previous experience with massage or Chinese medicine. Families who withdrew from the study did not have different demographics.

### Study completion

A total of 75 children entered this follow-along study. Of these 75 children, 67 participated in the year 1 post-testing, and 31 completed the year 2 post-testing.

### The tactile stimulation protocol

The QST massage protocol is a whole body protocol that takes about 15 minutes and is usually done at bedtime. It is formalized in a parent training manual and DVD with flexible constraints [26]. The parent is taught not to avoid areas that are uncomfortable but instead to adjust the techniques to the child's responses within the comfort zone of the child. Over the course of treatment, tactile responses undergo predictable changes from hyposensitive to hypersensitive to normosensitive. The protocol requires adjustment of manual technique with each transition.

The protocol has 12 parts that follow the acupuncture channels down the front and back of the body. Massage is carried out towards the hands and feet in the direction of capillary blood flow. Both patting and pressure are used according to the child's response. Generally, a

quicker, lighter, patting technique is used to begin with, especially in areas of numbness. In areas where the child withdraws from touch or is ticklish, slower pressing techniques are used. Additional options are available when neither patting nor pressure resolves the difficulty. For a summary of the massage movements, go to http://qsti.org/wp-content/uploads/2014/06/12MovementsAutism.pdf.

Therapists providing the parent training and support program graduated from a 60-hour training and supervision [27,28]. At support visits, therapists provided treatment, coached parents in the massage and evaluated parent fidelity with massage implementation. During the first five months, weekly therapist visits were provided. For the balance of the first year monthly visits were provided. No therapist visits were provided in the second year.

### Measures

The following measures were used to evaluate baseline, five-month, 12 months, and 24 months outcomes.

**Childhood Autism Rating Scale, 2nd edition, standard version (CARS):** The CARS is a reliable and widely used rating scale for the diagnosis of autism. CARS scores do not vary significantly by age between toddler and preschool-aged children indicating that it is a stable, repeated-outcomes measure in that age range [20,24]. The CARS rates children on 15 core components of autism, and yields a composite score ranging from non-autistic to mildly, moderately, or severely autistic. Studies indicate that the CARS demonstrates high concordance with clinical diagnosis by DSM-IV criteria [29]. Independent psychometric support for the CARS reports high criterion-related validity, interrater and test-retest reliability, and internal consistency. A score of 25.5 serves as the cutoff for a diagnosis of autism on the mild end of the autism spectrum; 30 to 36 is scored as moderate; 36 and higher is scored as severe [30]. A decrease in score represents a decrease in severity of autism. The pre-treatment median score of 39 was used as the criteria in the analyses to determine effects on language development by level of severity. The CARS was administered by blinded professional examiners.

**Preschool Language Scale, 5th edition (PLS):** The PLS is a measure of global language skills and standardized subscales evaluating relative ability in receptive and expressive language in children under seven years old. Internal consistency (split-half reliability) ranges from 0.91 to 0.93 for the subscale scores and 0.95 for the total score. Independent psychometric support for the PLS indicates high criterion-related validity, interrater and test–retest reliability, and that it is a valid measure of language in children with ASD [31,32]. An increase in score represents improved language skills. The PLS was administered by blinded professional examiners.

**Vineland adaptive behavior scales, 2nd edition (Vineland-II):** The Vineland is a validated parent interview that assesses socialization, communication, motor skills, and daily living skills. Cronbach's alpha is 0.97 for the composite scale and ranges from 0.83 to 0.95 for the domains. An increase in score represents an increase in developmental skills and abilities. The Vineland parent interview was conducted by blinded professional examiners [33].

**Autism Behavior Checklist (ABC):** The ABC is a validated measure of autism and a component of the Autism Screening Instrument for Educational Planning. The ABC is a sensitive measure of change in response to classroom interventions [19]. It measures behaviors typical of autism in multiple domains: sensory, relating, body and object use, language, social and self-help. Crohbach's alpha is 0.89. The mean value for typically developing children is reported at 17.81 [34]. A decrease in scores represents a reduction in autistic behavior. The Autism Behavior Checklist was completed by parents.

**Sense and Self-regulation Checklist (SSC):** The SSC is a validated parent/caregiver measure of sensory and self-regulatory difficulties and delays in children with autism [18]. It evaluates signs of peripheral impairment of touch (pain and numbness) by location and severity, and confirms severity of tactile impairment by evaluating touch-dependent self-regulatory delay. Cronbach's alpha is 0.83. SSC scores differentiate between children with ASD and typical development; mean scores are 39.6 (SD 10.6) and 18.4 (SD 9.5), respectively. Mean oral/tactile scores for ASD and typical children are 29.2 (SD 7.9) and 14.5 (SD 7.2). Mean "Other Sensory" scores for ASD and typical children are 17.5 (SD 6.1) and 6.9 (SD 5.0). Mean self-regulatory difficulty scores for ASD and typical children are 56.8 (SD 14.1) and 25.8 (SD 11.3). The overall SSC mean scores for ASD and typical children are 89.5 (SD 21.4) and 38.4 (SD 18.0). A decrease in scores represents a decrease in sensory abnormalities and self-regulatory difficulties.

**Fidelity and social validation testing** : Therapists monitored parent fidelity with massage procedures. For the first year of treatment, parents completed a daily log recording fidelity with daily massage, reasons for missing the massage, and problems or concerns. In addition, parents completed surveys at 12 months and 24 months with open-ended questions related to implementation of the treatment and observed changes in their child.

### Data collection

Pre- and post-intervention data collection was conducted within a one-month window both prior to beginning of treatment and after the 5 month protocol was completed. Twelve months and 24 months data collection also was conducted within a one-month window. Trained professionals administered the Vineland, CARS and PLS in the home.

Parents completed an online set of surveys and background questionnaires that included the Sense and Self-Regulation Checklist and the Autism Behavior Checklist. Parents offer the singular advantage of providing information about specific types of behaviors, in a variety of settings and over a much longer time than is available to the examiner during the typical evaluation [35]. Parent reports on specific behavioral and developmental responses have been found to be valid and reliable when compared with professional evaluations [36,37].

### Data analysis

Initial analyses were conducted to detect any potential attrition bias at 12 months and 24 months testing using 2-way ANOVA and MANOVA on outcome measures. To test whether the treatment effects maintain, intensify or recede over time when parents continue to provide treatment, within group one-way repeated measures ANOVAs were conducted on dependent measures at pre-treatment, post-treatment, one-year follow-up and two-year follow-up. Post-hoc pairwise Bonferroni-corrected comparisons were conducted to further test the nature of effects over time on each outcome measure. Separate unbalanced two-way repeated measure ANOVAs were conducted on pre-post follow-up scores to determine whether important differences in longitudinal effects by level of continued treatment fidelity or initial tactile abnormalities occur. Separate repeated measure ANOVA analyses were conducted and reported on the two intact cohorts of pre-post-12 months assessments (n=67) and the pre-post-12 months-24 months assessments (n=31).

## Results

### Sample size adequacy and power analysis

Power analyses to determine adequacy of sample size for this study were conducted using pre- to post-treatment published outcomes. Using the least significant treatment effects as a conservative effect size, power was estimated for both within-group repeated measures ANOVA and within-between group repeated measure ANOVA analyses. Allowing for attrition, a final n of 24 and a $p<0.05$, a power analysis yielded a power of 0.96 on both within and within-between interaction repeated measure ANOVAs. The cohort sizes of 67 and 31 provide adequate power.

### Attrition bias

Based on two-way ANOVA and MANOVA no differences were found between completers and non-completers at post-treatment or at 12 months. F values ranged from 0.018 to 3.57 at post and 0.002 and 1.47 at 12 months, with associated p. values ranging from 0.979 to 0.057. At 24 months, completers had higher levels of abnormal sensory response at baseline than did those who did not complete two-year testing.

### Longitudinal effects of intervention

**Tactile abnormalities and severity of autism:** Results from the repeated measures ANOVA for pre-post and one-year assessments are shown in Table 1. Overall there were significant reductions in tactile abnormalities and severity of autism from the pre-treatment to one-year assessments. In both cases, there was a significant change from pre- to post-treatment. Significant changes from post to one-year testing were also seen in severity of autism as measured by the CARS.

From pre-treatment to 12 months, the decrease in tactile abnormalities from 28.5 to 20.5 represented a mean normalization of 56.9%; that is, the decrease from 28.5 to 20.5 represents 56.9% of the improvement toward the score of 14.49 of typically developing children. Almost one quarter of the children (23.9%) obtained a score of 14 or lower on tactile abnormalities by the end of 12 months. The decrease in autism severity as measured by the CARS scores represented a mean normalization of 26.8% toward the score of 25.5. Overall, 12.3% of children reached the score of 25.5 which represents the threshold for autism on the CARS by the end of 12 months.

**Behavior and general development:** Overall significant positive differences were found for all outcomes except Other Sensory responses. Significant changes from post to one-year testing were seen on measures of self-regulation, language development, social development and in daily living skills. As can be seen in Table 1, the decrease on the ABC from 77.9 to 57.1 represented a 34.7% mean normalization toward the score of 17.81 for typically developing children. By the end of year one, more than one in eight (13.4%) of the children reached the typical score of 17.81. The decrease in self-regulation scores also represented a 36.9% mean normalization toward the score of 25.8. Six percent of children reached this score by the end of 12 months.

Results from the repeated measures ANOVA from pre-treatment to 24 months are shown in Table 2. Looking across two years, stronger trends emerge, with continued significant improvements on all outcomes. Scores improve significantly from pre- to post-treatment, from post to 12 months and then from 12 months to 24 months.

From pre-treatment to 24 months, the decrease in tactile abnormalities from 29.8 to 18.7 represented a mean normalization of 72.3%. Almost one third of the children (32.3%) obtained a score of 14 or lower on tactile abnormalities response by the end of two years. The decrease in autism severity as measured by the CARS scores represented a mean normalization of 43.8% toward the score of 25.5, which represents the threshold for autism on the CARS. Overall, 25.8% of children reached the score of 25.5 by two years. The decrease on the ABC represented a 48.5% mean normalization toward the score of 17.81 for typically developing children. Overall 12.9% of the children reached the typical score of 17.81 by two years. The decrease in self-regulation scores also represented a 49.1% mean normalization toward the score of 25.8. Nearly one in ten (9.7%) of children reached this score by the end of two years (Figure 1).

**Fidelity:** Fidelity data for the first five months is reported in a previous article [21]. Twelve months after the parents were trained to give their children the massage, therapists once again tested parents on the 12 massage movements using a checklist. Sixty-one percent of parents demonstrated full fidelity with massage procedures. Twenty percent needed correction on one or two of the 12 parts of the massage. Eighteen percent of parents needed correction on three or more of the movements.

**Influence of intensity of the parent support program on parent fidelity:** Idelity was strongly related to the frequency of the therapist home visits $F(2,29)=41.1$, $p<0.000$. High or full fidelity was defined as receiving the massage 6-7 times a week. Fidelity remained high during the first five-months due to the weekly therapist home visits: 80% of children received the treatment 6-7 times a week and the remainder received the massage 4-5 times a week. When therapist home visits decreased to once a month during the remainder of the first year, overall fidelity dropped: 34% children received the treatment 6-7 times per week and the remainder received the massage 5 or less times a week. When therapist home visits were discontinued in the second year, fidelity dropped again: 33% received the treatment 4 or more times a week and the remainder received the treatment 3 or fewer times a week.

**Effects of treatment fidelity on treatment outcomes:** Fidelity effects were evaluated by defining full versus less than full fidelity at 5, 12 months and 24 months. At 12 months, children who experienced full fidelity (n=22) saw improved outcomes over children experiencing less than full fidelity (n=45). The most apparent effects were observed in addressing abnormal tactile response. As can be seen in Figure 2, abnormal tactile response decreased from 29.5 to 17.5 with full fidelity and from 30.1 to 23.9 with less than full fidelity. Full fidelity represented an 80.2% change toward normalization of touch while less than full implementation represented a 39.3% change toward normalization of touch. Severity of autism declined from 37.5 to 33.5 (33.3% normalization) with full fidelity and from 39.2 to 35.3 (28.4% normalization) with less than full fidelity.

At 24 months the differences were more pronounced for touch and severity of autism. Children who experienced full fidelity (n=10) saw improved outcomes over children experiencing less than full fidelity (n=21). Abnormal tactile response decreased from 29.5 to 16.3 with full fidelity and from 30.1 to 20.5 with less than full fidelity. Full fidelity represented an 87.8% change toward normalization of touch while less than full implementation represented a 61.4% change toward normalization of touch. Severity of autism declined from 37.5 to 30.9 (54.8% normalization) with full fidelity and from 39.2 to 34.2 (36.8% normalization) with less than full fidelity. These results are shown in Figure 2.

At the end of two years, 60% of children with full fidelity achieved normal touch compared to 23.8% of children with less than full fidelity. Thirty percent of participants with full fidelity achieved scores on the CARS consistent with neurotypical development compared to 23.8% of

| Pre-post-12 month Outcomes (N = 67) | Pre-treatment Mean (SD) | Post-treatment Mean (SD) | 12 months Mean (SD) | F (2,65) | p | Partial $\eta^2$ | Tukey's HSD |
|---|---|---|---|---|---|---|---|
| Abnormal Oral-Tactile Response | 28.5 (8.1) | 22.1 (8.2) | 20.5 (9.5) | 41.2 | <0.000 | 0.559 | 1>2,3 |
| Other Sensory | 10.3 4.3 | 11.0 5.6 | 12.3 6.2 | 4.9 | 0.010 | 0.132 | 1<3 |
| Childhood Autism Rating Scale | 38.5 (7.2) | 36.9 (7.2) | 35.0 (7.9) | 17.7 | <0.000 | 0.360 | 1>2,3 2>3 |
| Autism Behavior Checklist | 77.9 (26.8) | 60.0 (29.6) | 57.1 (29.2) | 30.5 | <0.000 | 0.484 | 1>2,3 |
| Self-Regulation | 55.8 (13.9) | 44.8 (13.0) | 41.6 (14.5) | 46.8 | <0.000 | 0.590 | 1>2,3 2>3 |
| PLS-Receptive Communication | 29.0 14.3 | 33.1 14.5 | 35.7 16.5 | 37.2 | <0.000 | 0.541 | 1<2,3 2<3 |
| PLS-Expressive Communication | 29.3 13.3 | 32.7 13.3 | 35.9 15.5 | 48.8 | <0.000 | 0.608 | 1<2,3 2<3 |
| Vineland Socialization | 42.0 19.8 | 51.5 22.0 | 60.4 27.6 | 55.6 | <0.000 | 0.638 | 1<2,3 2<3 |
| Vineland Daily Living Skills | 39.8 23.0 | 48.2 24.7 | 58.3 31.5 | 60.4 | <0.000 | 0.657 | 1<2,3 2<3 |

**Table 1:** Repeated measures ANOVA results for pre-post treatment and 12 month follow-up.

| Pre-Post-12 month-24 month Outcomes | Pre Mean (SD) | 6 months Mean (SD) | 12 month Mean (SD) | 24 month Mean (SD) | F (3,28) | p | $\eta^2$ | Tukey's HSD |
|---|---|---|---|---|---|---|---|---|
| Abnormal Oral-Tactile Response | 29.8 (7.9) | 22.9 (9.2) | 21.2 (10.5) | 18.7 (8.8) | 16.16 | <0.000 | 0.634 | 1>2,3,4 2>4 3>4 |
| Other Sensory | 11.2 4.9 | 11.4 5.0 | 13.6 6.1 | 11.5 5.8 | 3.6 | 0.027 | 0.277 | NA |
| Childhood Autism Rating Scale | 38.5 (8.1) | 37.1 (8.0) | 34.6 (8.7) | 32.8 (9.1) | 11.79 | <0.000 | 0.558 | 1>2,3,4 2>3,4 3>4 |
| Autism Behavior Checklist | 81.1 (28.3) | 60.3 (31.4) | 59.6 (31.8) | 50.4 (29.2) | 10.42 | <0.000 | 0.528 | 1>2,3,4 2>4 3>4 |
| Self-Regulation | 58.2 14.9 | 46.1 14.9 | 42.0 17.7 | 38.1 16.3 | 18.1 | <0.000 | 0.660 | 1>2,3,4 2>4 |
| PLS-Receptive Communication | 29.0 15.6 | 32.9 15.8 | 35.4 17.4 | 41.3 17.6 | 23.1 | <0.000 | 0.712 | 1<2,3,4 2<4 3<4 |
| PLS-Expressive Communication | 30.1 13.5 | 32.9 13.3 | 35.4 15.8 | 40.8 17.4 | 25.5 | <0.000 | 0.732 | 1<2,3,4 2<3,4 3<4 |
| Vineland Socialization | 42.6 21.2 | 51.3 22.9 | 58.1 28.0 | 75.5 31.1 | 27.3 | <0.000 | 0.745 | 1<2,3,4 2<3,4 3<4 |
| Vineland Daily Living Skills | 39.9 23.5 | 47.4 24.9 | 58.8 33.9 | 76.4 40.2 | 23.6 | <0.000 | 0.716 | 1<2,3,4 2<3,4 3<4 |

**Table 2:** Repeated measures ANOVA results for pre-/post-treatment (6-months), 12 month and 24 month follow-up.

participants with less than full fidelity. Level of fidelity was seen to have the most direct and significant effect on improving abnormal touch.

## Effects of pre-treatment severity of tactile impairment on outcomes

Children with varying levels of tactile abnormality at pre-treatment made significant improvements in touch, severity of autism, as well as autistic behaviors, as seen in Table 3. Pre-treatment groups based on severity of abnormal tactile response were created by simply splitting the sample in half based on tactile abnormality score. The

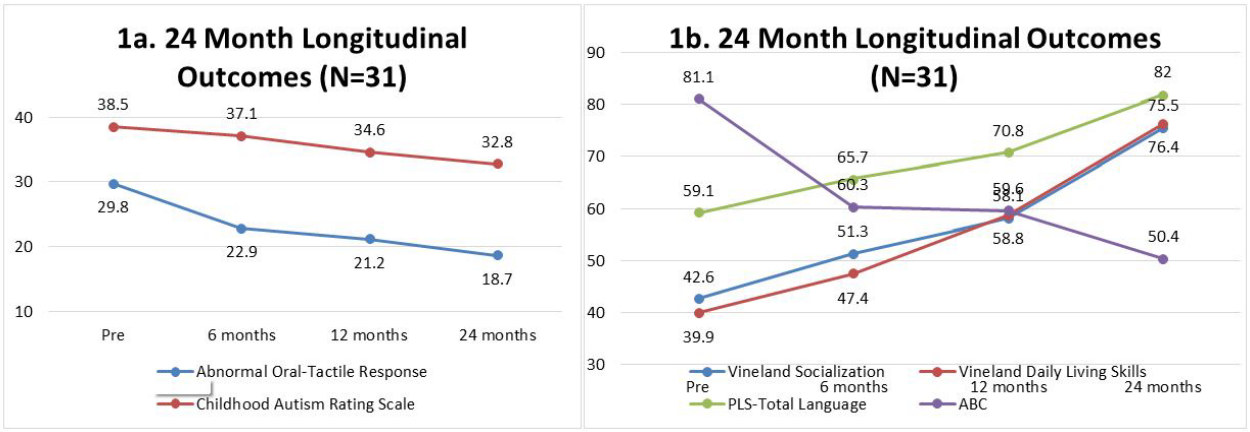


**Figure 1:** Overall changes in treatment outcomes for 24 month cohort.

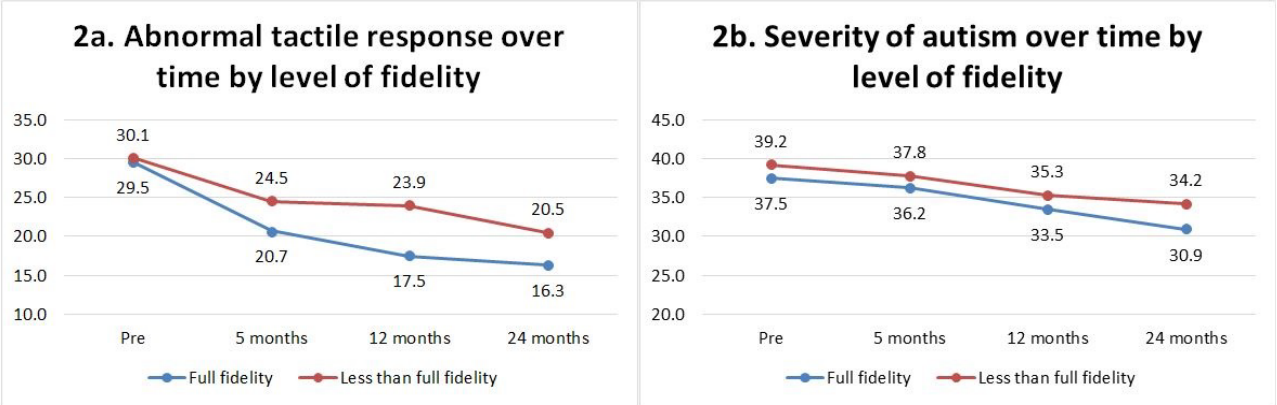


**Figure 2:** Changes in treatment outcomes for 24 month cohort by level of treatment fidelity.

absolute magnitude of improvement in touch was larger in the more severe group while children with less severe touch experienced larger decreases in severity of autism and autistic behaviors. Severity of tactile abnormalities differentiated severity of autism and autistic behaviors prior to treatment. These differences were maintained over time.

As can be seen in Figure 3, the observed differences in scores were significant at each assessment period for abnormal tactile response, autistic behavior and language development on independent samples t-tests. Scores for severity of autism differed significantly post treatment and at 24 months using the same tests.

At 24 months the differences are pronounced between children with severe tactile abnormalities prior to treatment and those with milder tactile abnormalities. Mean abnormal tactile response decreased from 23.5 to 14.4 with milder tactile abnormalities and from 35.1 to 22.3 with more severe tactile abnormalities. On average this represents a 100% change to normalization with half the children reaching normalized touch for those starting with milder tactile issues and a 62% normalization and 17.6% of the children reaching normalized touch for those with more severe tactile issues.

Severity of autism scores for children with milder tactile issues normalized by 72.8%, with 42.9% of children reaching neurotypical development. Scores for children with more severe tactile issues normalized by 27% with 17.6% of children reaching neurotypical development. Changes in autistic behavior scores followed a similar pattern. Scores for children with milder tactile issues normalized by 64.5%, with 21.4% of children reaching normalized behavior. Scores for children with more severe tactile issues normalized by 39.7% with 5.9% of children reaching normalized behavior.

Changes in overall language development also followed this pattern. Scores for children with milder tactile issues normalized by 54.8%, with 50.0% of children reaching normalized language. Scores for children with more severe tactile issues normalized by 23.6% with 5.9% of children reaching normalized language.

## Parents' perception of a change in children's affective and affiliative responses to touch

Parents' narrative responses to the following questions were analyzed:

1) Do you see any differences in your relationship with your child, compared to a year ago? and,

2) What differences, if any, did you notice about your child's development during the last year? Parents reported an increase in child-initiated touch and bonding more frequently than any other

| Pre-post-12 month-24 month Outcomes | Pre Mean (SD) | Post Mean (SD) | 12 months Mean (SD) | 24 months Mean (SD) | F (3,14) F (3,11) | p | $\eta^2$ | Tukey's HSD |
|---|---|---|---|---|---|---|---|---|
| Abnormal Oral-Tactile Response: More severe | 35.1 (4.1) | 27.7 (7.9) | 26.2 (9.0) | 22.3 (7.7) | 15.0 | <0.000 | 0.762 | 1>2,3,4 2>4 |
| Abnormal Oral-Tactile Response : Less Severe | 23.5 (6.7) | 17.1 (7.1) | 15.2 (9.1) | 14.4 (8.4) | 4.3 | 0.031 | 0.540 | 1>2,3,4 |
| Behavior: More severe | 92.4 (23.5) | 77.0 (28.1) | 74.0 (28.1) | 62.8 (29.1) | 4.1 | 0.027 | 0.470 | 1>4 |
| Behavior: Less Severe | 67.3 (28.3) | 40.0 (22.2) | 42.0 (27.6) | 35.4 (22.0) | 9.3 | 0.002 | 0.717 | 1>2,3,4 |
| Severity of Autism: More Severe | 40.7 (9.1) | 39.2 (8.7) | 37.7 (9.4) | 36.6 (9.3) | 3.5 | 0.044 | 0.429 | 1>4 |
| Severity of Autism: Less Severe | 35.8 (6.0) | 34.5 (6.0) | 30.8 (6.4) | 28.3 (6.7) | 10.1 | 0.002 | 0.734 | 1>3,4 2>4 3>4 |
| Language (PLS): More Severe | 47.9 (22.4) | 53.7 (23.6) | 56.2 (28.8) | 66.1 (29.2) | 11.5 | <0.000 | 0.711 | 1<2,3,4 2<4 3<4 |
| Language (PLS): Less Severe | 72.8 (30.6) | 80.4 (28.5) | 88.5 (29.4) | 101.4 (31.4) | 24.8 | <0.000 | 0.871 | 1<2,3,4 2<3,4 3<4 |

**Table 3:** Longitudinal outcomes by severity of touch.

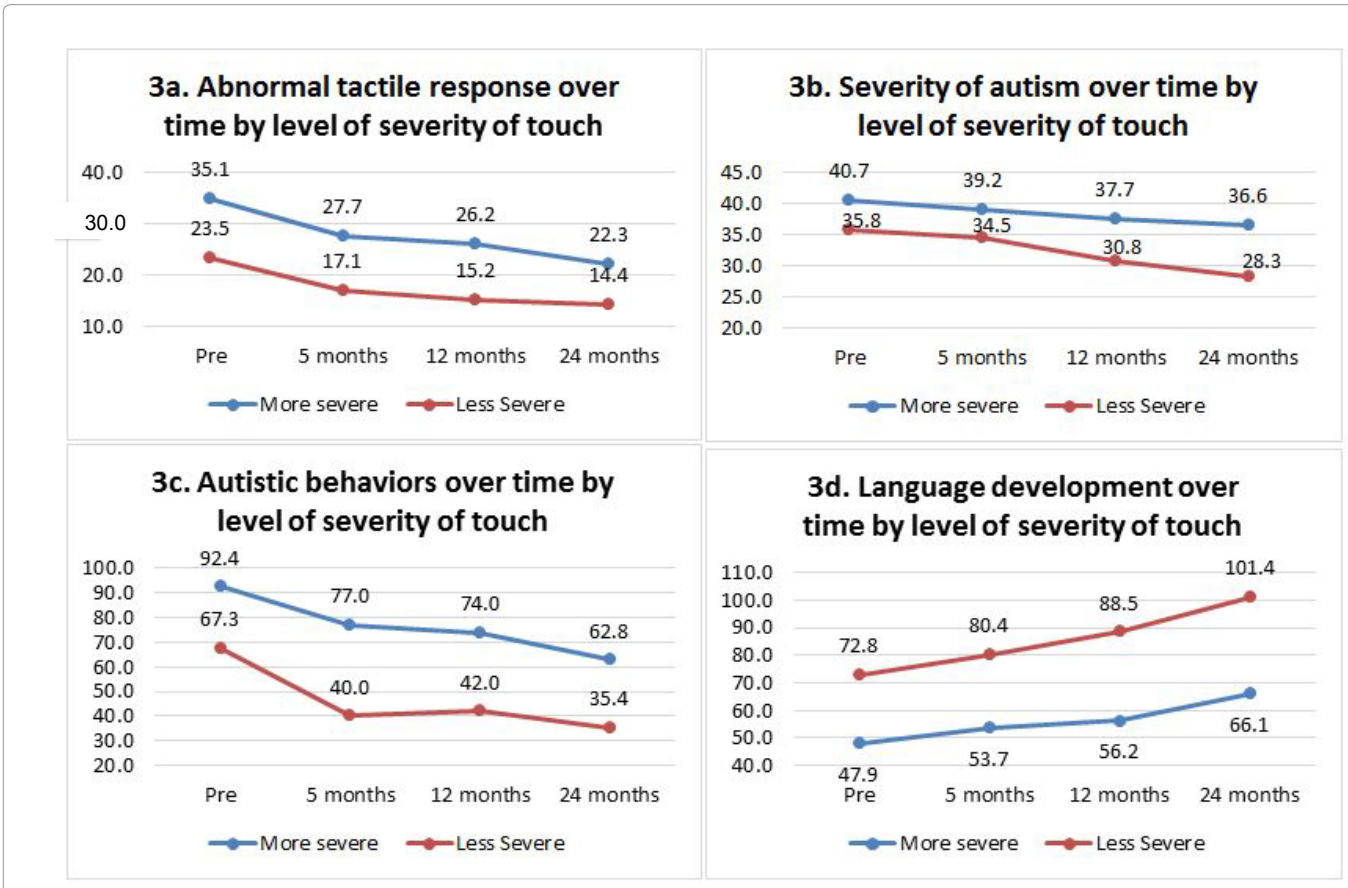


**Figure 3:** Effects of severity of tactile abnormalities over time.

developmental change. One hundred percent of parents reported an increase in bonding with their children at the end of year one. As such, this was by far the most consistent finding in the 1-year parent outcomes data. During year one and year two, nearly three-fourths of parents reported that the child-to-parent bond continued to increase. See Table 4 for examples of parent comments.

### Comparison of cost and efficacy of QST massage

In Table 5 we compare QST Massage and a widely known intervention for autism, early intensive behavioral intervention (EIBI) [38]. For this comparison, we use hours per week required for implementation as our measure of cost in order to avoid confusion with regional variations in cost. Professional and parent hours per week for implementation, efficacy on core autism symptoms, and areas where efficacy is limited are also compared.

### Adverse effects

There were no adverse effects reported in children.

## Discussion

The intention of this follow-along study was to observe the effects of 12 months and 24 months of treatment with QST massage on tactile abnormalities and measures of autism. With regards to tactile abnormalities, results indicate that longer-term treatment resulted in further improvement of tactile responses up to the point of full normalization in a number of children. Improvement was progressive and encompassed not only decreased pain and numbness, but also increased affectionate/affiliative touch. By 12 months, mean tactile responses had normalized by over one-half, and about one-quarter of children had scores within the normal range. At 24 months, mean tactile responses had normalized by about three-fourths; one-third of children scored in the normal range. This is the first report that full normalization of tactile abnormalities is possible with QST massage treatment. Severity of initial tactile abnormalities did not appear to pose a barrier to recovery, and although milder children recovered faster, a number of more severe children also had normalization of scores.

| Comments from Parents |
|---|
| We are closer. |
| We are much closer now as father and son. |
| She is a lot more cuddly. |
| He is more cuddly and affectionate. |
| He often asks for massage. |
| He wants us to touch him more. |
| He hugs me if he thinks that I am sad. |
| He hugs his sister. |
| He will climb up on my lap and give hugs and kisses. |
| He seeks us for comfort. |
| He has more empathy. He displays spontaneous affection. |

**Table 4:** Changes in affective and affiliative touch.

| | Early Intensive Behavioral Intervention | QST Massage for Autism |
|---|---|---|
| Total # professional hrs/ week | 20-40 hrs/week | 1.5 hrs/week |
| Total # parent hrs/week | Optional | 1.75 hrs/week |
| Expected duration of intervention | 2 years | 1-4 years |
| Efficacy on core autism symptoms | Language delay | Language delay<br>Social delay<br>Sensory abnormalities |
| Limited efficacy in some sub-groups of children | Limited efficacy in 50% of children; efficacy tends to be better in higher-functioning children [34] | Efficacy with both higher and lower-functioning groups |

**Table 5:** Cost-efficacy comparison.

Touch is the most important sense informing early childhood development [39]. Parent/caregiver touch stimulates orientation to face and facilitates learning the nonverbal communication skills upon which verbal communication rests [40]. The rewarding and bonding properties of touch provide the primary positive reinforcement for social engagement [41]. And the engaging and soothing properties of touch are necessary for the development of early self-regulation skills relative to attention and self-soothing [42]. Thus it was not surprising that progressive normalization of tactile responses was associated with progressive improvement of language, social skills, and behavioral self-regulation.

As might be expected, normalization of the individual components of autism was associated with a significant decrease in autism severity overall, as measured by the CARS. By 12 months, the mean severity of autism had decreased by 25% and 12% of children scored within the neurotypical range. By 24 months, the mean severity of autism had decreased by 44% and 25% of children scored within the neurotypical range. Children with less severe autism based on the CARS (a score of under 37) were the first to drop into the normal range for CARS scores with 22.6% of children achieving normalization at the end of 12 months, and 57.1% of children at the end of two years. Initial severity of autism (a score of 37 or greater) was not a complete barrier to more severe children reaching the neurotypical range; 2.9% achieved normalization by 12 months, and 5.6% of children by 24 months. This is the first time that full normalization of CARS scores has been reported in response to treatment with QST massage for autism.

The analysis of treatment outcomes by severity of tactile abnormalities indicates that initial severity of tactile abnormalities was a good predictor of whether children reached the normal range for language skills. At 24 months, 50% of less severe children scored in the neurotypical range for language in contrast with 6% for the group with more severe tactile abnormalities. The finding can be explained on the basis of the importance of touch to the development of nonverbal communication skills, and the impact of a barrier to touch on development of these skills. It is noteworthy that to date there has been no consistently accurate early predictor of which children will eventually acquire language [43,44]. Initial severity of tactile abnormalities also predicted comparable differences in outcome on severity of autism as measured by the CARS and the ABC. Thus, if we define higher functioning autism as relatively more language, less autistic behavior, and less severity on CARS scores, then initial severity of tactile impairment would appear to have predicted the emergence of higher versus lower functioning groups in this study. During this follow-along study, fidelity was influenced by frequency of therapist visits. As therapist support visits decreased from weekly, to monthly, to none at all, fidelity also fell. And when fidelity diminished, treatment effects did also. Interestingly, Figure 2 illuminate what is essentially a dose-response curve in treatment outcomes with the lesser dose of treatment resulting in a lesser treatment effect on touch and severity of autism. Treatment outcomes were considerably better in children who received full fidelity, the full "dose" of treatment. Practically speaking, the ongoing therapist visit was a gentle reminder to parents to keep the home program going, although not all parents required ongoing therapist visits for full fidelity.

How then to take the results of this follow-along study into

consideration and design a parent support program to optimize outcomes? The results indicate that the goal of treatment can be established as full normalization of tactile responses. Fidelity with treatment can be monitored with a daily parent log. Response to treatment can be monitored with biannual testing of tactile responses with the SSC. Regular therapist visits are recommended until treatment goals are met, with flexibility to increase frequency of visits if fidelity falls. In more severe children, we estimate therapist visits once or twice a month for the remainder of the first year will protect fidelity. In less severe children, we estimate monthly visits will be sufficient. In the second year, we suggest monthly therapist visits for both groups.

## Limitations of the Study

The main limitation of this study is that it was an observational study rather than an experimental study. A true control group would have provided experimental evidence that longer-term treatment resulted in additional improvement. However, a true control group would have required that treatment be deferred for two years. This was ethically problematic because it is best practice in pediatrics to treat sensory loss as early as possible in order to protect developmental outcomes, and there is now strong experimental evidence that QST massage effectively treats tactile abnormalities and substantially improves developmental outcomes. Two factors strengthened the validity of the observational evidence in this study:

1) The magnitude and direction of results across the multiple measures were consistent with results reported in the experimental studies; and

2) The dose-response relationship in the fidelity data argued against confounding variables. As noted earlier, the natural history of autism in childhood is one of stability of autism severity, and does not account for a 44% decrease in severity of autism, or 1 in four children coming off the spectrum after two years.

## Conclusions

These longer-term observational results lend support to the recommendations made in the preceding randomized controlled trial: that QST massage is an effective treatment for tactile abnormalities in children with autism; that treatment results in decreased severity of behavioral, social, and language components of autism as well as a autism severity overall; and that treatment of tactile abnormalities should be recommended at the time of autism diagnosis in order to enhance developmental outcomes [21]. Longer-term treatment resulted in continued improvement up to the point of full normalization of tactile and CARS scores in some children. Initial severity of tactile impairment was a good predictor of which children ended in the higher and lower functioning groups. Finally, this study provided useful information for structuring the parent support program to optimize treatment outcomes.

## Directions for Future Research

A five-year study to identify the point of maximum benefit from the intervention is planned in preschool children under conditions optimizing parent fidelity with daily treatment. Measures of autism as well as measures of classroom success will be evaluated. Further exploration of the nature of tactile abnormalities in autism is underway, and biopsies for a case-control comparing C-tactile fiber counts in autistic and neurotypical children have been taken. A clinical study evaluating skin biopsies before and after treatment is also planned.

### Acknowledgements

This study was supported by Grant R40 MC 24945 from the Maternal and Child Health Research Program, Maternal and Child Health Bureau, Health Resources and Services Administration, and Department of Health and Human Services. We wish to thank the project's QST therapists and blind-to-group assessors for the time and effort they put into this study.

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