

Running head: LESSONS LEARNED FROM A DECADE OF CONDUCTING PILOT
STUDIES ON THE EFFECTIVENESS OF OCCUPATIONAL THERAPY FOR CHILDREN
WITH SENSORY PROCESSING DISORDER

Lessons Learned from a Decade of Conducting Pilot Studies on the
Effectiveness of Occupational Therapy for Children with Sensory Processing Disorder

Lucy Jane Miller, PhD, OTR, FAOTA

Associate Professor in Departments of Rehabilitation Medicine and Pediatrics

University of Colorado at Denver and Health Sciences Center

Joseph R. Coll, PhD

Biostatistician

University of Colorado at Denver and Health Sciences Center

Sarah A. Schoen, PhD, OTR

Clinical Assistant Professor

University of Colorado at Denver and Health Sciences Center

Sensory Therapies And Research (STAR) Center

Judy Benzel

Executive Assistant

KID Foundation

Clare A. Summers, MS, OTR

Occupational Therapist

The Children's Hospital

Cheryl Mock, MS, OTR

Occupational Therapist

Sensory Therapies And Research (STAR) Center

Lee Tarsitano, MA, MS, OTR

Occupational Therapist

Sensory Therapies And Research (STAR) Center

Key Words: Evidenced-based Practice, Outcome Study, Sensory Integration Treatment, Sensory
Processing Disorder

Send correspondence to first author: Lucy Jane Miller, KID Foundation, 1901 West Littleton
Blvd., Littleton, CO 80120. Phone: 303-794-1182; FAX: 303-798-2526;
Miller@KIDFoundation.org

Abstract

This article describes two pilot studies in pediatric OT intervention that used a sensory-based approach with children who had Sensory Processing Disorder (SPD). The first was a single group pilot treatment study that helped define the sample, intervention, outcome measures and power needed for the next pilot study. The second was a randomized controlled pilot study to help determine if group trends were moving in the expected direction and to obtain power estimates for a large scale, multi-site intervention trial.

The findings suggest that a sensory-based approach may be effective in ameliorating difficulties of children with SPD. Gains were made on goal attainment scaling and the attention and cognitive/social composite of the Leiter-R. Lessons learned from both studies relate to four essential criteria for conducting rigorous randomized trials: 1) homogenous and replicable criteria for sample selection, 2) manualized intervention with fidelity to treatment measurement, 3) sensitive and appropriate outcome measures, and 4) rigorous methodology.

Lessons Learned from a Decade of Conducting Pilot Studies on the Effectiveness of Occupational Therapy for Children with Sensory Processing Disorder

The increasing emphasis in medicine on effective outcomes and cost containment highlights the need for evidence-based studies to improve patient care, provide effective use of limited resources, and improve policy making (Geyman, Deyo et al., 2000; Sackett, Richardson et al., 1997; Tickle-Degnen, 1999). In Occupational Therapy (OT), this vital need has been stressed by the recent surge of scholarly writings appealing for empirical research (Law & Baum, 1998; Pankiewicz, 1999; Taylor, 2000; Tickle-Degnen, 2000). While the quality of published studies is improving (Holm, 2000), OT research in pediatrics is a relatively young field, and rigorous effectiveness studies are just beginning to emerge (Case-Smith & Bryan, 1999; Kinnealey, Koenig et al., 1999; Melchert-McKearnan, Deitz et al., 2000).

The effectiveness of a pediatric OT intervention that uses a sensory-based approach with children who have Sensory Processing Disorder (SPD) is specifically needed. Sensory processing is a term that refers to the way the nervous system receives sensory messages and responds. SPD occurs when sensory signals are not organized into appropriate responses resulting in disruption in daily activities. Sensory processing abilities fall on a continuum with wide individual and developmental variations related to an individual's detection, interpretation and/or response to sensory input. The range of disordered sensory processing includes mild as well as severe manifestations of dysfunction. A "disorder" is identified *only* when the behaviors observed are extreme enough to interfere with daily routines and tasks at home, at school or in community life (Miller, Lane et al., 2005a). A disorder in sensory processing is usually manifested as an emotional, social, motor, and/or at times a language or cognitive problem.

Sensory integration therapy, a sensory-based approach, has an almost 50-year clinical history in OT. OT with a sensory-based approach has been tested in numerous published research studies (see Appendix). Controversy regarding the interpretation of these research publications exists. Over 70 studies have been published on this topic (see Appendix). Approximately half of the existing research papers demonstrate some positive treatment effects and the other half demonstrate no significant effect of intervention. Two meta-analyses (Ottenbacher, 1982; Vargas & Camilli, 1999) and four research syntheses are published (Arendt, MacLean et al., 1988; Hoehn & Baumeister, 1994; Polatajko, Kaplan et al., 1992; Schaffer, 1984). One meta-analysis concludes that the treatment has no positive effect (Vargas et al., 1999); however, this meta-analytic study had significant methodological flaws including studies: 1) with small sample sizes (median sample size = 4.5 for 13 studies), 2) that evaluated a variety of diagnoses, 3) that had such general descriptions of treatment that they could not be replicated and 4) with such poor power that an effect is unlikely to have been detected even if present (Type II error). The other meta-analysis, while suggesting that the intervention has positive effects based on a large effect size ($d = .80$), is quite old and did not include studies conducted after 1980 (Ottenbacher, 1982). The four review articles stated that previous studies are not rigorous enough to make valid conclusions, yet each review paper concluded that a sensory-based approach to OT intervention may not be effective.

The cost and complexity of conducting a large-scale randomized trial is immense. Despite numerous applications, to date, no federal agency has been willing to fund this research. Yet OT is criticized both within and outside the profession for not having a rigorous, randomized trials evaluating this approach to intervention.

A wealth of non-peer reviewed information is now also available on the World Wide Web (see for example: www.SPNetwork.org and www.sensorynation.com). In addition, numerous new popular press publications are available (Aron, 2002; Ayres, Erwin et al., 2004; Biel & Peske, 2005; Heller, 2002; Kranowitz, 2004; 2005; Miller, in press; Smith & Gouze, 2004). Access to this literature is spurring parents to demand sensory-based OT services from school systems and clinic-based therapists. Given the lack of agreement in the literature, the wide-spread use of this intervention in OT, and the plethora of related popular new books, rigorous empirical studies are essential to determine if this approach is effective in remediating social, physical, adaptive or other aspects of functioning.

Prevalence of the Sensory Processing Disorder (SPD)

Estimates of the prevalence of SPD range from 5% (Ayres, 1979) to 15% (Wilbarger & Wilbarger, 1991) to 30% (Kranowitz, 1998) in children. For individuals with developmental disabilities the rate of co-morbid SPD is estimated to be 40% - 80% (Baranek, Chin et al., 2002), depending on the specific developmental diagnosis.

A recent empirical pilot study systematically estimated rates of SPD using survey data (Ahn, Miller et al., 2004). Parents of incoming kindergartners from one suburban U.S. public school district were surveyed using the Short Sensory Profile, a parent-report screening tool that evaluates parents' perceptions of functional correlates of SPD (McIntosh, Miller et al., 1999a). Of the 703 children surveyed, a conservative prevalence estimate of children with symptoms of SPD suggested that 5.3% of the sample met screening criteria for SPD. This translates into 300,000 to 1.5 million individuals in the U.S. who potentially may be affected with the disorder (Ahn et al., 2004).

Prevalence and Cost of the Treatment

Of the 50,000 Occupational Therapists practicing in the United States, 33% rate themselves as primarily practicing in pediatrics (American Occupational Therapy Member (AOTA) Survey, 1998). Of the pediatric therapists, over half rate “Sensory Integration Treatment” to be a primary or secondary focus of their practice (AOTA, 1998). Of the five “Specialty Sections” in AOTA, the 5,500 members of the Sensory Integration Section constitute the highest number.

The cost to society of this intervention approach is large. Sensory-based OT evaluations usually cost over \$500 and may cost over \$1000; intervention sessions often cost \$80–\$160 for a 45 to 60 minute session¹. Direct treatment for children diagnosed with SPD ranges from a few consultation visits to individualized treatment one or more times a week for several months up to several years. Children with SPD are also treated by OTs at school if the child is eligible for services; however the intervention model is educationally-based rather than focused on remediating underlying neurological impairments. In the absence of rigorous effectiveness data, the value of this intervention approach to society and/or to individual parents is frequently questioned.

Previous Studies of the Effectiveness of Sensory-based OT with SPD

The gold standard for outcome studies is a randomized controlled trial (Bury & Mead, 1998) comparing the targeted intervention to either an Alternate Placebo Protocol (AP) and/or to No Treatment (NT). Of the previous studies reviewed in the Appendix, 22 had a treatment vs. NT design, 14 had a treatment vs. AP design; and 10 had a treatment vs. NT and AP design.

Criteria for rigorous randomized trials are well established (Boruch, 1997; Bury et al., 1998) and include four primary standards that the trial must have:

¹ These cost figures are estimated from records at three large pediatric hospitals and from the three largest Sensory Integration private practice settings in the United States in 1999.

1) a sample that is objectively defined and homogeneous with regard to the impairment studied (Bulpitt, 1983);

2) an intervention that is manualized (e.g., described in detail in written form in a manual that others can obtain and replicable the procedures) (Boruch, 1997) and has a method to monitor adherence to, or “fidelity” in, the delivery of treatment (Ottenbacher, 1991);

3) outcomes that are meaningful, appropriate and sensitive to hypothesized changes (Fuhrer, 1997); and

4) rigorous methodology, including: a) random allocation to experimental and control treatment groups, b) blinded outcome assessments, and c) adequate power to evaluate the statistical significance of effects (Jadad, 1998).

The relation of previous studies to these four criteria is briefly summarized below.

1. *Homogenous Sample*: Previous studies include extremely heterogeneous samples such as combinations of children and adults with: mental retardation, learning disabilities, aphasia, and “at risk” diagnoses. No study defined a sample with SPD that was homogenous with regard to subtypes of SPD, although theoretical (Miller, Lane et al., 2005b) and empirical (Schoen, Miller et al., 2005) evidence suggests that SPD subtypes exist. With subtypes such as Sensory Over-responsivity and Sensory Under-responsivity, the need for sample homogeneity is obvious since outcomes might average to an apparent “no significance” if mean scores were analyzed (e.g. over-responsive children would become less responsive with treatment and under-responsive children would become more responsive with treatment). Since new taxonomies suggest that even within SPD, multiple behavioral and physiological manifestations of the disorder occur, crucial is identification of a sample which is homogenous with regard to inclusion criteria for SPD subtype.

2. *Replicable Treatment*: None of the studies have published manuals or procedural manuals that can be acquired from the study authors which detail the elements of the treatment. One study (Polatajko, Law et al., 1991) did use a manual but the manual is not available so replication of the study is not possible. Polatajko et al. (1991) provides an excellent demonstration of the purpose of a manualized approach. The study compared “sensory integration treatment” to “perceptual motor treatment” with both types of intervention provided by OTs. The performance of both groups demonstrated significant changes after treatment on academic and motor measures, but no group differences were significant. Without a clear description of how the two treatments differed, the unique effect of each treatment is not known. One interpretation of the findings is that both treatments worked equally well, although the paper is best known for its statement (taken out of context) and quoted that “neither approach has an effect on academic and motor performance ” (Polatajko et al., 1991) (page 171). In addition to not having a manualized approach, none of the previous studies had a method of coding adherence of therapists to the treatment protocol. Fidelity to treatment is a critical piece of evidence that assures team members who provided treatment adhered closely to the principles of treatment espoused in the treatment manual (Kazdin, 1994).

3. *Sensitive and Meaningful Outcomes*: Although a few previous studies included appropriate outcome measures. In general, the existing studies evaluated either outcomes that were not reliable or did not measure the types of changes that parents report are their hopes for outcomes of treatment (Cohn, Miller et al., 2000). Changes measured included: motor or reflex performance, academic performance (i.e., reading, math), language abilities and some pathological behaviors. In contrast to what has previously been utilized, recent research suggests that the outcomes that are of importance to parents of children with SPD are three: increased

social participation, increased self-regulation, and increased perceived competence (Cohn, 1999). None of the previous studies evaluated these constructs. The sensitivity of outcome measures used in previous studies has not been evaluated for specific sensitivity to the sample researched nor have they been shown to have small enough increments of change to document expected differences from intervention in children with SPD.

4. *Rigorous Methodology*: Rigorous methodology includes having a randomized assignment to treatment groups: *experimental* (OT); *active placebo* (tutoring, special education, or play time); and *passive placebo* (no treatment such as a wait-list condition). In addition, the assignment must be made using a method where the assignment is random, without any persons making a qualitative decision about which child is included in a specific group. Other requirements for rigor include having evaluators who are blinded to the treatment group of the children, having appropriate research designs, and having adequate power to show an effect. Very few previously published research studies incorporate elements of rigorous methods.

No previous study meets all four criteria above and most do not even meet one criterion. Continued research into the effectiveness of OT with a sensory-based approach, correcting as many of these limitations to internal and external validity, is crucial.

Pilot Studies on the Effectiveness of OT with Children who have SPD

The research design and methods for two pilot studies are reported. The first is a single group pilot treatment study using one group that helped to define the sample, intervention, outcome measures and power needed for the next pilot study. The second study is a pilot randomized controlled trial to help determine if group trends were moving in the expected direction and obtain power estimates for a large scale, multi-site intervention trial. The lessons learned from both pilot studies are described.

Pilot Study One: Single Group Pilot Study

Research Questions

The following research questions were addressed in Study One:

1. What criteria can be used to identify a homogenous group of children with SPD?
2. What are the essential components of treatment and how can a fidelity procedure be implemented to assure compliance to a treatment protocol?
3. What outcome measures seem sensitive to changes over a 20 session time period (twice a week for 10 weeks)?
4. What procedures can be implemented to assure rigor in research design and methodology?

Method

Study One was a pragmatic trial (Jadad, 1998) to evaluate possible challenges to implementing a clinical trial in a hospital setting.

Participants

The participants were referred by occupational therapy master clinicians at The Children's Hospital of Denver after completion of a comprehensive evaluation including the *Sensory Integration and Praxis Test* (Ayres, 1989) and related clinical observations (Blanche, 2002). The inclusion criteria were: developmental and medical history as well as atypical behaviors consistent with a diagnosis of SPD (Miller et al., 2005a). Exclusion criteria were IQ < 85, and children with any other developmental, psychiatric, neurological, or orthopedic diagnosis except Attention Deficit Disorder, Learning Disorders and mild Tourette's syndrome. The sample demonstrated a combination of sensory modulation (over-responsive, under-responsive, and/or sensory seeking), sensory discrimination, and sensory-based motor disorders (postural

difficulties and/or dyspraxia) noted by evaluating therapist. The sample demographic characteristics are displayed in Table 1.

Insert Table 1 about here

The Experimental Treatment – OT with a sensory-based approach

The intervention, OT with a sensory-based approach (Ayres, 1972; Koomar & Bundy, 2002; Parham & Mailloux, 2001) was administered twice a week for 10 weeks. Occasionally, a session was missed due to illness of therapist or child, but sessions were “made up” within two weeks.

The intervention was based on principles defined as OT with a sensory integration approach (Ayres, 1972) and emphasized use of a clinical reasoning process to attain occupational goals. A more specific description of this intervention is presented in Sensory Integration Theory and Practice (Miller, Wilbarger et al., 2002). In summary, the therapist engages in a reflective process to understand for each child, what sensory stimuli causes the child to respond atypically (over, under or seek sensation) and whether there are sensory stimuli that can be used to counteract the effects of the problem stimuli. Then the therapist observes whether the child’s **A**ttention, **S**ensory responses, or **E**motional reactivity is primarily affected. The therapist next explores the influence of demands of the child’s **C**ulture, requirements for the child to **R**elate to others, complexity of the child’s **E**nvironment and what the **T**ask entails. One acronym used to teach parents and others this technique is “**A SECRET**” (Miller, in press). Thus, the therapist uses and then teaches the parent and child (if possible) the OT “secrets” that regulate the specific child, increase his social participation and self-confidence/esteem, and then address other specific occupational goals of the family.

Using subtle cues the therapist engages in one-to-one interactions with the child in a large OT room that is equipped with sensory activities and toys. The child's imagination is engaged to help create a pretend situation (e.g., captain of a ship, prima ballerina) where the child can interact with the sensory materials in a meaningful and fun manner. The abilities of the child are challenged but with scaffolding the child is always successful. Gradually, the child's motor competency, responses to sensory input, behaviors and ability to participate in occupations which are age appropriate improve. Guided by parent's priorities for their child, the therapist is a role model, educator and coach for parents who participate in the sessions.

During the study the elements of intervention were specified and a draft of a fidelity measure was constructed in bi-monthly meetings of the six participating therapists who reviewed tapes of each another providing intervention. This fidelity measure was greatly expanded and researched further by a national team of master clinicians during a National Institutes of Health grant and is still under study (Parham, Cohn et al., 2005).

Instrumentation

The literature on SPD suggests that many domains can be problematic and previous effectiveness research has shown changes in a wide variety of areas. Therefore, it was not possible to pinpoint outcome measures that had a history of proven utility. In Study One we tested a wide variety of measures to determine which were most suitable for future studies. The following domains were evaluated with the specific outcome measures noted below.

Sensory Functioning

Over a four-year period, a reliable and valid parent-rating scale of functional sensory behaviors was developed. Beginning with items from the Sensory Profile (SP) (Dunn, 1999), with permission of the author, content analysis, item analysis and factor analysis were evaluated

to create a research tool, the Short Sensory Profile (SSP) (McIntosh et al., 1999a). The SP has 125 items that fall into 8 subtests and 9 factor domains (51% of the items do not factor). The final scale, the Short Sensory Profile (SSP) includes 38 items targeting only sensory behaviors. It has a stable factor structure that corresponds to several sensory constructs hypothesized to be affected in SPD (McIntosh et al., 1999a). Internal reliability is .96 and the scale discriminates children with SPD from typically developing children on total test score and on all subtests ($p < .01$).

Attention, Impulsivity and Activity Level

To evaluate attention, the ADD-H Comprehensive Teacher's Rating Scale (ACTeRS) (Ullmann, Sleator et al., 1991) was selected because it has been shown to be effective in discriminating children with and without attention disorders (Ullmann & Sleator, 1985; 1986; Ullmann, Sleator et al., 1984). The Leiter-R Parent Rating (Roid & Miller, 1997) was also evaluated because it has an excellent national standardization, and impressive reliability and validity characteristics and three subtests that specifically target attentional functioning mapped onto criteria for Attention Deficit Disorder in the Diagnostic and Statistical Manual-IV (American Psychiatric Association, 2000).

Anxiety

The Multi-dimensional Anxiety Scale for Children (MASC) (March, 1997) was selected because it separates pathological anxiety from fears that are a natural part of development (March, 1995; Silverman, LaGreca et al., 1995). It is valid in separating children with and without anxiety disorders (overall classification accuracy, 87%) (March, 1997; March, Parker et al., 1997; Parker & March, 1997) above age 8. The Revised Children's Manifest Anxiety Scale was used for younger children.

Activities of Daily Living

The most widely used adaptive scale was selected, the Vineland Adaptive Behavior Scale (Stinnett, Havey et al., 1994; Wodrich & Barry, 1991). It is validated by many studies for accurate discrimination of abnormal daily living skills (Altman & Mills, 1990; Douhitt, 1992; Rosenbaum, Saigal et al., 1995; Voelker, Shore et al., 1990).

Social and Emotional Behaviors

The Child Behavior Checklist (CBCL) (Achenbach, 1991) measures social and emotional behaviors based on parent and teacher reports. It was selected to evaluate this domain because numerous critiques substantiate its wide use in research (Elliott & Busse, 1992; Mooney, 1984). The construct, content, and criterion validity of the CBCL for discriminating social and behavioral issues is well established (Chen, Faraone et al., 1994; Jensen, Wantanabe et al., 1996; Macmann, Barnett et al., 1992).

Physiologic Measures

Methods for physiologically evaluating sensory reactivity are well-defined elsewhere (Mangeot, Miller et al., 2001; McIntosh, Miller et al., 1999b; Miller, McIntosh et al., 1999; Miller, Reisman et al., 2001a). The primary physiological outcome measure in Study One was electrodermal reactivity (EDR), a phasic measure of electrodermal activity. EDR was recorded continuously during the Sensory Challenge Protocol, a 15-20 minute protocol in which 50 sensory stimuli are administered (10 stimuli in each of five sensory systems). EDR measures changes in the electrical conductance of the skin associated with sympathetic activation of eccrine sweat glands. EDR is a marker of the activity of the sympathetic nervous system as it responds to stimulation both in the environment and internally within the nervous system.

Changes in Natural Settings

The children were videotaped before and after intervention in two settings: playtime and dinnertime. The videotapes were ~ 30 minutes for each session. Working with the graduate faculty and students of Thomas Jefferson University, OT Department, we next prepared transcripts describing the activities observed in each episode on the videotapes. Using the transcript as a guide, we developed a coding scheme following the procedures outlined in Lofland and Lofland (1995). Behavior codes were: verbal interactions, non-verbal socialization, self-initiation, challenges encountered/success in resolution, and type of sensory input. Five minute segments were randomly selected from five 30-minute tapes, which two investigators coded them independently. The total number of behaviors in each category were summed before and after intervention (inter-rater reliability = .90) (Schaaf, Miller et al., 2001).

Individualized Measure of Parent Perceived Priorities for Change

None of the previous studies evaluating the effectiveness of OT with children with SPD used a contextually relevant measure of change. Therefore, Goal Attainment Scaling (GAS) was explored as an outcome. GAS examines individual priorities for change that are not represented by items in standardized scales. GAS is gaining recognition as a valid outcome of individualized change over time (Kiresuk, Smith et al., 1994). Researchers in a wide variety of fields have discussed advantages in evaluating idiographic treatment outcomes that are patient-centered and meaningful to each participant in a study (Abikoff, 2001; Rockwood, Stadnyk et al., 2000). Although the goals are different for each participant, the score is standardized by writing goals which have responses that are theoretically spaced the same distance apart (e.g., the same level of difficulty to achieve) (Forbes, 1998). Thus, a mathematical method of calculating the extent to which the goals are met can be derived (Kiresuk & Sherman, 1968).

Recent studies have demonstrated the utility of GAS in outcome studies for individuals with a wide variety of disabilities: lower extremity amputations (Rushton & Miller, 2002); traumatic brain injury (Joyce, Rockwood et al., 1994; Malec, 2001); cognitive rehabilitation (Rockwood, Joyce et al., 1997); motor delays in infants (Palisano, 1993), and geriatrics (Stolee, Rockwood et al., 1992). In some studies, GAS has been found to be more responsive to intervention than norm-referenced standardized measures (Rushton et al., 2002). Inter-rater reliability has been found to be moderate to excellent (.67, Rushton et al., 2002), (.67, Joyce et al., 1994).

GAS provides information on meaningful individual differences that relate to families' values. In this study, parents, with assistance of the trained interviewer, noted four to six goals which identified achievable changes during the 20-session duration of the study such as: play more with other children, have increased self confidence, and control temper tantrums. Parents rank ordered goals based on their global impression of the importance and difficulty of the change for their child (Clark & Caudrey, 1986; Rockwood et al., 1997). The global rank was used as a weight for each goal. A trained therapist completed the final writing of the GAS (see sample item in Table 2) which defined observable and objective behaviors, in five increments of change.

Insert Table 2 about here

Procedures

During the single group pretest-posttest study, 30 children ages 3 years 9 months to 11 years who met inclusion/exclusion criteria s received sensory-based occupational therapy (OT) twice a week for 10 weeks. Recruitment was completed by participating OTs who conducted a 2-4 hour evaluation of each child referred to the OT department of The Children's Hospital of

Denver from October, 1996 to December, 1998. If in their expert opinion the child met inclusion and exclusion criteria, the parents were referred to research staff. After researchers completed informed consent, interested parents rated the parent report scales, completed the Vineland Interview Scale and answered questions in a private, one-hour, semi-structured interview using The Family-Centered Interview Scale (Miller & Summers, 2001b) to elicit developmental and medical history, current functioning and priority areas and/or goals. In addition, the child participated in a “space ship lab” to obtain physiological measures of EDR (Miller et al., 1999). Goals for the GAS were obtained during parent interview and scaling for the goals was completed by an OT trained in GAS procedures who viewed a video tape of the parent interview.

Results

The following were evaluated: 1) each subtest in the standardized scales noted in *Instrumentation*; 2) changes in behavior codes for videotaped natural settings; 3) physiological variables reflecting sensory reactivity; and 4) goal attainment scaling. Paired t-test statistics were used and the findings are summarized in Table 3 for each measure that was significant or showed a trend in the expected direction.

Insert Table 3 about here

The mean change over the ten session period is displayed (pre-test to post-test score).

Significance ranged from $p = .20 - < .001$ and effect sizes ranged from .06 to 2.40. These

measures warranted further study in the next pilot study. Other dependent measures were determined not to be sensitive enough to detect changes over a 10 week period. Knowledge gained from Study One permitted Study Two to be conducted.

Pilot Study Two: Randomized Controlled Pilot Study

Research Questions

Comment [LM1]: Joe to check effect sizes.

The following research questions were addressed in Study Two:

1. Does Occupational Therapy with a sensory-based approach better ameliorate attentional, cognitive/social, sensory, and/or behavioral problems more than an active placebo (an alternative treatment) and/or a passive placebo (no treatment)?
2. Does OT reduce abnormal physiological reactivity more than the other two treatment conditions?
3. Does OT change individualized goals selected by parents more than the other two treatment conditions?

Method

Participants

Having studied the issue of inclusion/exclusion criteria in Study One, and due to work categorizing SPD into subtypes (Miller et al., 2005b), the inclusion/exclusion criteria for Study Two were defined more narrowly than for Study One. Rather than including all children with SPD and symptoms of sensory modulation dysfunction, quantitative criteria were established. Only children with Sensory Modulation Disorder were included as documented by: the Short Sensory Profile, 2) atypical EDR, and 3) expert clinical opinion. Children were entered into the study from April, 1999 to December, 2001.

Approximately 150 children per year, who have disorders that include difficulty modulating sensory information, are evaluated by the OT Department. Half of the 150 children had symptoms of SPD, of whom about one third (55) met strict inclusion/exclusion criteria for sensory modulation disorder. Children could have other difficulties as well such as ADHD, but were required to have significant Sensory Modulation Dysfunction to be included in Study Two. The sample was selected from all children referred to the Department of Rehabilitation for

outpatient OT during the period of the clinical trial. When the research project was explained to families, over half (30) agreed to participate. Six subjects dropped out before the intervention began for various reasons (moving, vacations, illnesses, and mother's pregnancy). A prospective cohort of 24 children who had Sensory Modulation Disorder was enrolled in the study. Five children had a previous diagnosis of Attention Deficit Hyperactive Disorder (ADHD), three had diagnoses of Learning Disabilities (LD) with ADHD, and one had Generalized Anxiety Disorder (GAD). Fifteen children were referred with no previous diagnosis. Children with diagnoses other than ADHD, LD and GAD were not considered for the study. When evaluated with the SNAP-IV (Swanson, Nolan et al., 1987), a total of fifteen children met criteria for ADHD on the SNAP-IV.

Demographic variables for participants in Study Two are displayed in Table 4. The groups were compared using Fisher's exact test for categorical variables and by a one-way analyses of variance (ANOVA) for age. No significant group differences were found on any demographic variables including: age, gender, mother's education and ethnicity.

Insert Table 4 about here

Inclusion Criteria

Diagnosis of Sensory Modulation Disorder with all of the following:

1. Electrodermal Reactivity (EDR) scores demonstrating hyper-reactive or hypo-reactivity reactions to sensory stimuli in two or more sensory domains. See Miller et al. (1999) for description of specific criteria for abnormal reactivity.
2. Short Sensory Profile (SSP) *z-scores* that were < -3 standard deviations (SD) below the mean for the total score and/or < -2.5 SD on two or more subtests and/or < -4 SD on one subtest.
3. Clinical confirmation of SMD by master OT who evaluated the child.

Exclusion Criteria

1. Other Diagnoses: Children with other DSM-IV or ICD-9 diagnoses were excluded except ADHD, Learning Disabilities, or Generalized Anxiety Disorder. Exclusion categories included: Pervasive Developmental Disorders (e.g., Autism), Genetic Disorders (e.g., Fragile X Syndrome, Down syndrome), Orthopedic Disorders (e.g., amputation), Neurological Conditions (e.g., Cerebral Palsy, Epilepsy) and other Psychiatric Disorders (e.g., Mood Disorders; Bipolar Disorder);

2. Age: Children less than three years or more than 11 years 6 months of age were excluded. Three was the youngest age at which a reliable result on dependent variables could be obtained; 11 years 5 months was the last pre-pubertal age group;

3. IQ < 85 based on WISC-III short form (block designs and vocabulary);

4. Previous Treatment: Children who had received direct individual OT (not including OT at school previously);

5. Serious Confounding Life Events: Children who had experienced death of a parent, abuse, neglect, foster placement, drug or alcohol exposure or other severe deleterious life events;

6. Special Education: Children who were or had been enrolled in special education (received a formal IEP through the school system that resulted in pull-out services in an educational setting), even if they did not have a specific diagnosis.

Instrumentation

The scales and physiological measures that showed a significant effect or a trend towards significance in the hypothesized direction were selected for the randomized trial. These are all discussed in Study One and included: The Leiter-R Parent Rating Scale (Attention Cognitive/social composite score); the Short Sensory Profile; the Vineland Socialization Subtest;

the Child Behavior Checklist (Internalizing and Externalizing compiled scores); and Goal Attainment Scaling. The dependent measures are detailed in Study One.

Alternative Treatment

The active alternative treatment, called the Activity Protocol (AP), controlled for therapeutic alliance and attention to the child, two of the basic elements of the occupational therapy that might account for changes from treatment. The sessions were guided by an Activity Partner, a non-OT staff member or graduate student. Activity Partners had education or psychology degrees and were experienced working with young children. The same opportunity existed in AP, as in OT, for developmentally appropriate activities supported by adult attention. The room for AP was identical in size to the OT room and held a wide variety of play opportunities. The difference between AP and OT was the type of activities in which the adult/child pair engaged. Instead of sensory- motor equipment, a variety of engaging tabletop play opportunities were offered in AP. The child chose an activity (arts and crafts, puzzles, building with blocks, reading stories, interactive games, outdoor playground etc.) and played with the adult (they could also choose to play alone). No attempt was made to teach the parent or to focus on arousal, sensory-motor, or functional problems. The active alternative treatment, like OT, occurred in a playful, safe, and fun environment, however the child was never challenged and his/her difficulties were not remediated directly. The Activity Partner focused on the relationship with the child and having fun.

Procedures

Recruitment was completed by participating OTs who conducted a 2-4 hour evaluation of each child referred to the OT department of The Children's Hospital of Denver. If in their expert opinion the child had a Sensory Modulation Disorder, the family was referred to research staff.

After researchers completed informed consent, interested parents rated the Short Sensory Profile, and the SNAP-IV. Next, a two-hour intake interview was conducted with one or both parents that included developmental and medical history, presenting difficulties, and goals for intervention. The Vineland Scale was also administered through interview at this time. Next, physiological testing was completed administering the Sensory Challenge Protocol described in Study One and elsewhere (Miller et al., 1999) and the child completed with WISC-short form. Concurrently, the parents completed the remaining dependent measures and a trained experimenter developed the Goal Attainment Scale. If the child met all criteria and did not have any exclusionary criteria, she or he was randomly assigned to one of three intervention groups using a random numbers table. Twenty-four children met criteria for the study during the allotted time period before funding was depleted.

The randomized study was initiated with three arms: 1) occupational therapy (OT) with a sensory-based approach as described under Study One; 2) an active alternate control treatment called the Activity Protocol; and 3) a passive control, No-Treatment (being placed on a wait-list). Hence, the study compared 10 weeks of OT (Group A) to 10 weeks of an active control (Activity Protocol, Group B) and 10 weeks of a passive control (No-Treatment, Group C). After 10 weeks, children randomized to the alternate and no-treatment groups received 10 weeks of OT at no cost (this article reviews data from the first 10 week block only). Figure 1 displays the design of the study and number in each group.

Insert Figure 1 about here

Fidelity to the two treatment protocols was assessed via evaluation of videotaped session at approximately sessions 1, 7, 14 and 20. Therapists administering the experimental treatment, Occupational Therapy with a sensory based approach, were supervised by the OT Director of the

Sensory Integration Program, watched video tapes of one another treating children bi-monthly, and discussed the approach so that fidelity to the treatment could be maintained. Activity partners administering the active control treatment, the Activity Protocol, were supervised by the project director and reviewed video tapes of treatment bi-monthly so that fidelity to the active control treatment could be maintained.

Results

All analyses were performed on the “intention to treat” sample and included all randomized participants regardless of their compliance to the study. For the outcome variables, distributions were inspected for approximate normality. Although no child withdrew from the study, some scales were not usable (incomplete data, missing score sheets) and thus the number of participants for each scale in the table below differs slightly. Skewed distributions (e.g., electrodermal reactivity) were log transformed. Differences among the treatments were evaluated with one way ANOVAs. The group means and standard deviations for the change in the pre-treatment to post-treatment behavioral outcomes are noted in Table 5.

Insert Table 5 about here

The children in group A, OT Group, made gains which were significantly greater than children in the other two groups on Goal Attainment Scaling. Children in the OT group also increased more than the other groups on Attention ($p < .03$ compared to No Treatment; $p < .07$ compared to Activity Protocol) and on Cognitive/Social Composite of Leiter-R ($p < .02$ compared to Activity Protocol). The children in Group B, the active placebo treatment made gains on the socialization subtest of the Vineland. Socialization subtest scores were greater than but non-significant compared to the other two groups. The children in Group C, the No Treatment Group, made larger, but non-significant gains compared to the other two groups on

the CBCL Externalizing composite score. These findings are displayed numerically in Table 5 and graphically in Figure 2. Physiologically, the OT group showed larger improvements than the AP and WL group as seen in Figure 3.

Insert Figure 2 about here

Insert Figure 3 about here

Discussion

The implementation of a rigorous effectiveness study to evaluate occupational therapy with a sensory-based approach is a complex process requiring years of pilot work. Previous studies have contributed to the knowledge base in this area, but none have included all criteria required so that a reasonably valid conclusion can be made about the efficacy of this intervention. All are lacking in one or more of the following four essentials: homogenous and replicable criteria for sample selection, manualized intervention with fidelity to treatment measurement, sensitive and appropriate outcome measures and rigorous methodology.

To prepare to conduct a rigorous randomized controlled trial, research was undertaken 1996-2005 (Ahn et al., 2004; Cohn et al., 2000; Mangeot et al., 2001; McIntosh et al., 1999a; McIntosh, 1999 #915; Miller et al., 1999; Miller et al., 2001a; Miller, Robinson et al., 2004; Miller et al., 2001b; Miller et al., 2002; Schaaf & Miller, 2005), including a wide variety of studies related to defining a homogenous sample, developing a manualized intervention and fidelity evaluation, determining reliable and valid outcomes and piloting rigorous treatment trial research designs and procedures. The two pilot projects are among these studies.

The findings of Study One and Study Two suggest that OT with a sensory-based approach may be effective in ameliorating difficulties of children with Sensory Processing Disorder. However, no causal inferences can be drawn from either of these pilot studies. Both

were useful in 1) developing a standard system for participant inclusion, assessment, treatment, and outcomes measurement; 2) piloting a manualized treatment procedure and fidelity measure; 3) implementing the necessary administrative policies to conduct trials; and 4) identifying the threats to validity (e.g., effects of attention, therapeutic alliance, statistical regression, maturation, history, testing, and instrumentation (Cook & Campbell, 1979) so these threats could be controlled in the next study. However, a large randomized controlled trial is necessary before a more definitive conclusion can be offered with reasonable assurance that results are not attributable to chance and that external and internal sources of invalidity have been controlled.

This has been an informative decade as the groundwork was laid for a large randomized trial. The lessons learned from these studies were accomplished by systematically building upon the pilot studies using the four criteria for rigorous randomized trials presented in the introduction (Boruch, 1997; Bury et al., 1998). Pilot Study One followed a broad-based design while Pilot Study Two was more specifically focused, a process which required ten years of work. The insights gained will inform other practitioners who wish to conduct randomized controlled trials of occupational therapy with a sensory-based approach in children with SPD.

1. Selecting a homogenous and objectively defined sample

Numerous methods of identifying a sample were piloted. Progress has been made although some questions remain. In the process of attempting to quantify selection criteria so that the sample could be replicated by others we learned many new things. For example, we learned that SPD is a heterogeneous condition. While this has been speculated in the literature previously and documented in factor analytic studies, we now have empirical data which allowed us to suggest a nosology with three primary divisions and subtypes within each division. A simple graph depicting this taxonomy appears in Figure 4 (Miller et al., 2005a).

Insert Figure 4 about here

In particular, found was that sensory over-responsivity, sensory under-responsivity and sensory seeking almost always occur in combination in the same child, often within different sensory systems. One quantitative method of documenting atypical sensory reactivity is electrodermal reactivity. Although this research focused on active measures of responding, future work should include passive levels of arousal which mark sympathetic nervous system activity. Clear is the tenet that individuals with SPD can be either over- or under-reactive to sensory stimulation. Critical is identifying a sample that is homogenous in physiological as well as behavioral functioning.

Other fruitful areas for further exploration are the relation of active to passive electrodermal activity as well the relation of sympathetic to parasympathetic activity. Finally, we have learned that the most informative method of identifying individuals with SPD includes three collaborative evaluations that isolate the subtype of SPD being demonstrated: a parent-report measure, a recommendation of an expert clinician, and a performance measure administered directly to the client. Pilot work is ongoing to develop a system of evaluating all three classic patterns and their hypothesized subtypes (Schoen et al., 2005).

Finally, the issue of comorbidity must be explored. Many children with other diagnoses have SPD as well. Comorbidity and SPD is an area that has barely been researched quantitatively. Much remains to be done.

2. Developing a manual to administer the intervention and a method to evaluate adherence to the intervention delivery models

In 2001, a National Institutes of Health grant was obtained by the first author that permitted a national group of experts to get together and collaborate on this difficult issue.

Researchers in OT may not recognize the critical need for a manual detailing intervention procedures and a fidelity evaluation to evaluate adherence to an intervention model. Though few examples of this appear in the OT literature, other professions have extensive examples to reference (Kazdin, 1994). Our field must address this issue; difficult as it is, due to the holistic nature of our intervention, the need to individualize treatment plans and the multidimensional aspects of person, environment and task to which attention is paid. Until such time as OT is manualized, and a method to monitor fidelity exists, rigorous effectiveness trials can not be conducted because the research procedures are not replicable.

3. Identifying meaningful, appropriate and sensitive outcomes

The outcome measures used in these two studies may not have been sensitive enough to detect the full range of changes hypothesized by therapists to occur after OT with children who have SPD. Critical is the exploration of other outcome measures. The importance of a sound theoretical basis for both selecting dependent measures must become a high priority for the field. Use of subjective measures (parent-report) should be supplemented by more objective measures (e.g., EDR). Multiple outcome measures that are appropriate for the child's age, but not targeted to the child's hypothesized changes from intervention, should not be perpetuated. Researchers should be cautious unless numerous instruments are used in pilot studies for hypothesis generation, not for forming conclusions. The alpha level should always be adjusted to account for the testing of multiple outcomes.

4. Establishing rigorous methodology

Finally, research design and statistics must be improved in the effectiveness studies in OT. Few previous studies evaluating OT with a sensory-based approach used random group

allocation, which is the cornerstone of randomized controlled trials. Even if other areas must be compromised, without randomization no causal conclusions can be drawn.

Also needed are studies where therapists are blinded to the child's status when doing outcome evaluations. The powerful effect of expectations on outcomes has been demonstrated in research not only with humans, but with animals as well. If the evaluator performing the post-intervention assessments is privy to the group membership of the participant, the validity of the findings of the entire research study will be questioned. Of course, substantial difficulties exist in putting this principle into practice (small offices, team discussions, unwitting unblinding by secondary persons), still an effort must be made to incorporate blinded assessment into post-intervention evaluation procedures.

Other rigorous research designs and methods must be utilized. As we learned from Study Two, cross-over designs should not be used when OT is the intervention since the effects of OT do not wash out and, therefore, only the first period of data can be used. Pilot data should be used to estimate power so that appropriate samples and sensitive "enough" outcome measures can be chosen. Too often, OT research is plagued by Type II errors (not enough power to show an effect even if one is present). Measures must have documented reliability and validity for the sample selected to study. Therapists must be creative in using a combination of qualitative and quantitative methods, but an effectiveness study should *never* be conducted with scales or methods that have not been field tested. Rarely is pilot testing reported in OT, thus researchers are left to unknowingly replicate each other's work and are relegated to staying in the domain of pilot research rather than moving forward with research that truly has the potential to document the effectiveness of practice. Findings that are "negative" should also be published, not to prove whether an intervention "works or doesn't work" but rather to inform the field about outcomes

that may not be useful in documenting effects. If effects are seen for a holistic intervention the need may exist to test specific components of the intervention (such as the effect of parent training, the time/intensity of intervention).

Conclusion

This article elucidates some of the conceptual and methodological problems of effectiveness trials in OT with children who have SPD. Over ten years of insights have been gained. Multiple pilot studies assist researchers in describing and defining the design of future rigorous intervention studies. OTs can therefore become more competitive in their pursuit of federal funding by designing more rigorous studies. Without adequate funding, large scale effectiveness trials are not possible. Until such time as a rigorous, randomized controlled trial that adheres to the four principles noted above is implemented, other professionals, parents and third party payers will keep asking, “Does OT really work? How do we know?”

Acknowledgements

The authors thank the children and adults participating in this study and the therapists located at The Children's Hospital of Denver who implemented the OT: Julie Butler, Becky Greer, Julie Wilbarger, Tracy Stackhouse, Nicki Pine, Sharon Trunnel, and Robin Seger. The authors also wish to thank the KID Foundation and STAR Center staff who worked tirelessly over 10 years to complete this project. Primary funding for this work was provided by an NIH Mentored Research Scientist Development Award (1K01HD001183-01A1), the Wallace Research Foundation, and the American Occupational Therapy Foundation. Additional support was provided by an R21 NIH One-Year Planning grant (#1 R21 HD41614-01), the General Clinical Research Centers Program at The Children's Hospital (#M01 RR00069), The Children's Hospital Research Institute Scholar Award, and the Coleman Institute for Cognitive Disabilities research fellowship.

References

- Abikoff, H. (2001). Tailored psychosocial treatments for ADHD: The search for a good fit. *Journal of Clinical Child Psychology, 30*(1), 122-125.
- Achenbach, T.M. (1991). *Manual for the Child Behavior Checklist/4-18 and 1991 Profile*. Burlington, VT: University of Vermont, Department of Psychiatry.
- Ahn, R.R., Miller, L.J., Milberger, S., & McIntosh, D.N. (2004). Prevalence of parents' perceptions of sensory processing disorders among kindergarten children. *American Journal of Occupational Therapy, 58*(3), 287-302.
- Altman, J.S., & Mills, B.C. (1990). Caregiver behaviors and adaptive behavior in home care and daycare. *Early Child Development and Care, 62*, 87-96.
- American Psychiatric Association. (2000). *Diagnostic and statistical manual of mental disorders* (DSM-IV-R ed.). Washington, DC: American Psychiatric Association.
- Arendt, R.E., MacLean, W.E., & Baumeister, A.A. (1988). Critique of sensory integration therapy and its application in mental retardation. *American Journal on Mental Retardation, 92*, 401-411.
- Aron, E.N. (2002). *The highly sensitive child: Helping our children thrive when the world overwhelms them*. New York: Broadway Books.
- Ayres, A.J. (1972). *Sensory integration and learning disorders*. Los Angeles: Western Psychological Services.
- Ayres, A.J. (1979). *Sensory integration and the child*. Los Angeles: Western Psychological Services.
- Ayres, A.J. (1989). *Sensory Integration and Praxis Tests*. Los Angeles: Western Psychological Services.

- Ayres, A.J., Erwin, P.R., & Mailloux, S. (2004). *Love, Jean: Inspiration for families living with dysfunction of sensory integration*. Santa Rosa, CA: Crestport Press.
- Baranek, G.T., Chin, Y.H., Hess, L.M., Yankee, J.G., Hatton, D.D., & Hooper, S.R. (2002). Sensory processing correlates of occupational performance in children with fragile X syndrome: Preliminary findings. *American Journal of Occupational Therapy*, 56(5), 538-546.
- Biel, L., & Peske, N. (2005). *Raising a sensory smart child: The definitive handbook for helping your child with sensory integration issues*. New York: Penguin Books.
- Blanche, E.I. (2002). Observations based on sensory integration therapy. In. Torrance, CA: Pediatric Therapy Network.
- Boruch, R.F. (1997). *Randomized experiments for planning and evaluation: A practical guide*. Thousand Oaks, CA: SAGE Publications.
- Bulpitt, C.J. (1983). *Randomized controlled clinical trials*. Hingham, MA: Kluwer Boston.
- Bury, T.J., & Mead, J.M. (Eds.). (1998). *Evidence-based healthcare: A practical guide to therapists*. MA: Butterworth-Heinemann.
- Case-Smith, J., & Bryan, T. (1999). The effects of occupational therapy with sensory integration emphasis on preschool-age children with autism. *American Journal of Occupational Therapy*, 53, 489-497.
- Chen, W.J., Faraone, S.V., Biederman, J., & Tsuang, M.T. (1994). Diagnostic accuracy of the Child Behavior Checklist scales for attention-deficit hyperactivity disorder: A receiver-operating characteristic analysis. *Journal of Counseling and Clinical Psychology*, 62(5), 1017-1025.

- Clark, M.S., & Caudrey, D.J. (1986). Evaluation of rehabilitation services: The use of goal attainment scaling. *Int Rehabil Med*, 5, 41-45.
- Cohn, E. (1999). *Parental perception of the effects of occupational therapy using sensory integration approaches for their school-aged children and families*. Unpublished dissertation, Boston University, Sargent College of Allied Health Professions, Boston, MA.
- Cohn, E., Miller, L.J., & Tickle-Degnen, L. (2000). Parental hopes for therapy outcomes: Children with sensory modulation disorders. *American Journal of Occupational Therapy*, 54(1), 36-43.
- Cook, T.D., & Campbell, D.T. (1979). *Quasi-experimentation: Design and analysis issues for field settings*. Boston, MA: Houghton Mifflin Company.
- Douhitt, V.L. (1992). A comparison of adaptive behavior in gifted and non-gifted children. *Roeper Review*, 14, 149-151.
- Dunn, W. (1999). *The sensory profile: Examiner's manual*. San Antonio, TX: The Psychological Corporation.
- Elliott, S.N., & Busse, R.T. (1992). Review of the Child Behavior Checklist. In J. Kramer & J.C. Conoley (Eds.), *Mental measurements yearbook* (Vol. 11, pp. 166-169). Lincoln, NE: Buros Institute of Mental Measurement.
- Forbes, D.A. (1998). Goal Attainment Scaling. A responsive measure of client outcomes. *Journal of Gerontological Nursing*, 24(12), 34-40.
- Fuhrer, M.J. (1997). *Assessing medical rehabilitation practices: The promise of outcomes research*. Baltimore, MD: Paul H. Brookes Publishing Co.

- Geyman, J.P., Deyo, R.A., & Ramsey, S.D. (Eds.). (2000). *Evidence-based clinical practice: Concepts and approaches*. Boston, MA: Butterworth-Heinemann.
- Heller, S. (2002). *Too loud, too bright, too fast, too tight: What to do if you are sensory defensive in an overstimulating world*. New York: Harper Collins.
- Hoehn, T.P., & Baumeister, A.A. (1994). A critique of the application of sensory integration therapy to children with learning disabilities. *Journal of Learning Disabilities, 27*(6), 338-350.
- Holm, M.B. (2000). Our mandate for the new millennium: Evidence-based practice--The 2000 Eleanor Clarke Slagle Lecture. *American Journal of Occupational Therapy, 54*(6), 575-585.
- Jadad, A. (1998). *Randomized controlled trials: A user's guide*. London: BMJ Publishing Group.
- Jensen, P.S., Wantanabe, H.K., Richters, J.E., & Roper, M. (1996). Scales, diagnosis, and child psychopathology: Comparing the CBCL and the DISC against external validators. *Journal of Abnormal Child Psychology, 24*(2), 151-168.
- Joyce, B.M., Rockwood, K.J., & Mate-Kole, C.C. (1994). Use of goal attainment scaling in brain injury in a rehabilitation hospital. *American Journal of Physical Medicine and Rehabilitation, 73*(1), 10-14.
- Kazdin, A.E. (1994). Methodology, design, and evaluation in psychotherapy research. In A.E. Bergin & S.L. Garfield (Eds.), *Handbook of psychotherapy and behavior change* (4th ed., pp. 19-71). New York: John Wiley & Sons, Inc.
- Kinnealey, M., Koenig, K.P., & Huecker, G.E. (1999). Changes in special needs children following intensive short-term intervention. *The Journal of Developmental and Learning Disorders, 3*(1), 85-103.

- Kiresuk, T., & Sherman, R. (1968). Goal attainment scaling: A general method of evaluating comprehensive mental health programs. *Community Mental Health Journal, 4*, 443-453.
- Kiresuk, T.J., Smith, A., & Caudillo, J.E. (1994). *Goal attainment scaling: Applications, theory and measurement*. Hillsdale, NJ: Lawrence Erlbaum Associates.
- Koomar, J.A., & Bundy, A.C. (2002). Creating direct intervention from theory. In A.C. Bundy, S.J. Lane & E.A. Murray (Eds.), *Sensory integration: Theory and practice* (2nd ed., pp. 261-308). Philadelphia, PA: F.A. Davis Company.
- Kranowitz, C.S. (1998). *The out-of-sync child: Recognizing and coping with sensory integration dysfunction*. New York: The Berkley Publishing Company.
- Kranowitz, C.S. (2004). *The Goodenoughs Get In Sync*. New York: The Berkley Publishing Group.
- Kranowitz, C.S. (2005). *The out-of-sync child: Recognizing and coping with sensory processing disorder* (2nd ed.). New York: The Berkley Publishing Group.
- Law, M., & Baum, C. (1998). Evidence-based occupational therapy. *Canadian Journal of Occupational Therapy, 65*, 131-135.
- Lofland, J., & Lofland, L.H. (1995). *Analyzing social settings: A guide to qualitative observation and analysis*. Belmont, CA: Wadsworth Publishing Co.
- Macmann, G.M., Barnett, D.W., Burd, S.A., & Jones, T. (1992). Construct validity of the Child Behavior Checklist: Effects of item overlap on second-order factor structure. *Psychological Assessment, 4*(1), 113-116.
- Malec, J.F. (2001). Impact of comprehensive day treatment on societal participation for persons with acquired brain injury. *Arch Phys Med Rehabil, 82*(7), 885-895.

- Mangeot, S.D., Miller, L.J., McIntosh, D.N., McGrath-Clarke, J., Simon, J., Hagerman, R.J., & Goldson, E. (2001). Sensory modulation dysfunction in children with attention deficit hyperactivity disorder. *Developmental Medicine and Child Neurology*, 43, 399-406.
- March, J. (1995). *Anxiety disorders in children and adolescents*. New York: Guilford Press.
- March, J. (1997). *Multidimensional Anxiety Scale for Children*. New York: Multi-Health Systems, Inc.
- March, J.S., Parker, J.D.A., Sullivan, K., Stallings, P., & Conners, C.K. (1997). The Multidimensional Anxiety Scale for Children (MASC): Factor structure, reliability, and validity. *Journal of American Academy of Child and Adolescent Psychiatry*, 36(4), 554-565.
- McIntosh, D.N., Miller, L.J., Shyu, V., & Dunn, W. (1999a). Overview of the Short Sensory Profile (SSP). In W. Dunn (Ed.), *The sensory profile: Examiner's manual* (pp. 59-73). San Antonio, TX: The Psychological Corporation.
- McIntosh, D.N., Miller, L.J., Shyu, V., & Hagerman, R. (1999b). Sensory-modulation disruption, electrodermal responses, and functional behaviors. *Developmental Medicine and Child Neurology*, 41, 608-615.
- Melchert-McKearnan, K., Deitz, J., Engel, J.M., & White, O. (2000). Children with burn injuries: Purposeful activity versus rote exercise. *American Journal of Occupational Therapy*, 54(4), 381-390.
- Miller, L.J. (in press). *Sensational Kids: Help and hope for children with sensory processing disorder*. New York: Putnam.

- Miller, L.J., Lane, S., Cermak, S., Osten, B., & Anzalone, M. (2005a). Evolution of sensory processing disorder: A new terminology for a new decade. Manuscript submitted for publication. *American Journal of Occupational Therapy*.
- Miller, L.J., Lane, S., Cermak, S., Osten, E., & Anzalone, M. (2005b). Section I - Primary diagnosis: Axis I: Regulatory-Sensory Processing Disorders. In S.I. Greenspan & S. Wieder (Eds.), *Diagnostic manual for infancy and early childhood: Mental health, developmental, regulatory-sensory processing and language disorders and learning challenges (ICDL-DMIC)* (pp. 73-112). Bethesda, MD: Interdisciplinary Council on Developmental and Learning Disorders (ICDL).
- Miller, L.J., McIntosh, D.N., McGrath, J., Shyu, V., Lampe, M., Taylor, A.K., Tassone, F., Neitzel, K., Stackhouse, T., & Hagerman, R. (1999). Electrodermal responses to sensory stimuli in individuals with fragile X syndrome: A preliminary report. *American Journal of Medical Genetics*, 83(4), 268-279.
- Miller, L.J., Reisman, J.E., McIntosh, D.N., & Simon, J. (2001a). An ecological model of sensory modulation: Performance of children with Fragile X Syndrome, Autism, Attention-Deficit/Hyperactivity Disorder, and Sensory Modulation Dysfunction. In S.S. Roley, E.I. Blanche & R.C. Schaaf (Eds.), *Understanding the nature of sensory integration with diverse populations* (pp. 57-88). San Antonio, TX: Therapy Skill Builders.
- Miller, L.J., Robinson, J., & Moulton, D. (2004). Sensory modulation dysfunction: Identification in early childhood. In R. DelCarmen-Wiggins & A. Carter (Eds.), *Handbook of infant, toddler and preschool mental health assessment* (pp. 247-270). New York: Oxford University Press.

- Miller, L.J., & Summers, C. (2001b). Clinical applications in sensory modulation dysfunction: Assessment and intervention considerations. In S.S. Roley, E.I. Blanche & R.C. Schaaf (Eds.), *Understanding the nature of sensory integration with diverse populations* (pp. 247-274). San Antonio, TX: Therapy Skill Builders.
- Miller, L.J., Wilbarger, J.L., Stackhouse, T.M., & Trunnell, S.L. (2002). Use of clinical reasoning in occupational therapy: The STEP-SI Model of Treatment of Sensory Modulation Dysfunction. In A.C. Bundy, S.J. Lane & E.A. Murray (Eds.), *Sensory integration: Theory and practice* (2nd ed., pp. 435-451). Philadelphia, PA: F.A. Davis Company.
- Mooney, K.C. (1984). Review of the Child Behavior Checklist. In D. Keyser & R. Sweetland (Eds.), *Test critiques* (Vol. 1, pp. 168-184). Kansas City, MO: Westport Publications, Inc.
- Ottensbacher, K. (1982). Sensory integration therapy: Affect or effect. *American Journal of Occupational Therapy*, 36(9), 571-578.
- Ottensbacher, K. (1991). Research in sensory integration: Empirical perceptions and progress. In A.G. Fisher, E.A. Murray & A.C. Bundy (Eds.), *Sensory integration: Theory and practice* (pp. 385-399). Philadelphia: F.A. Davis Company.
- Ottensbacher, K.J., & Cusick, A. (1993). Discriminative versus evaluative assessment: some observations on goal attainment scaling. *American Journal of Occupational Therapy*, 47(4), 349-354.
- Palisano, R.J. (1993). Validity of goal attainment scaling in infants with motor delays. *Physical Therapy*, 73(10), 651-660.
- Pankiewicz, R. (1999). Take action on efficacy studies. *American Journal of Occupational Therapy*, 53(1), 114-115.

- Parham, D., Cohn, E.S., Koomar, J., Spitzer, S., Miller, L.J., Burke, J.P., Brett-Green, B., Mailloux, Z., May-Benson, T.A., Smith Roley, S., Schaaf, R., Schoen, S., & Summers, C.A. (2005). Fidelity in sensory integration intervention research. Manuscript submitted for publication. *American Journal of Occupational Therapy*.
- Parham, L.D., & Mailloux, Z. (2001). Sensory integration. In J. Case-Smith (Ed.), *Occupational therapy for children* (4th ed., pp. 329-381). St. Louis, MO: Mosby, Inc.
- Parker, J.D.A., & March, J.S. (1997). *Structure of the Multidimensional Anxiety Scale for Children (MASC): A confirmatory factor analytic study*. Unpublished manuscript submitted for publication.
- Polatajko, H.J., Kaplan, B.J., & Wilson, B.N. (1992). Sensory integration treatment for children with learning disabilities: Its status 20 years later. *Occupational Therapy Journal of Research, 12*, 323-341.
- Polatajko, H.J., Law, M., Miller, J., Schaffer, R., & Macnab, J. (1991). The effect of a sensory integration program on academic achievement, motor performance, and self-esteem in children identified as learning disabled: Results of a clinical trial. *Occupational Therapy Journal of Research, 11*, 155-176.
- Rockwood, K., Joyce, B., & Stolee, P. (1997). Use of goal attainment scaling in measuring clinically important change in cognitive rehabilitation patients. *J Clin Epidemiol, 50*(5), 581-588.
- Rockwood, K., Stadnyk, K., Carver, D., MacPherson, K.M., Beanlands, H.E., Powell, C., Stolee, P., Thomas, V.S., & Tonks, R.S. (2000). A clinimetric evaluation of specialized geriatric care for rural dwelling, frail older people. *Journal of the American Geriatrics Society, 48*(9), 1080-1085.

- Roid, G.H., & Miller, L.J. (1997). *Leiter International Performance Scale-Revised*. Wood Dale, IL: Stoelting Company.
- Rosenbaum, P., Saigal, S., Szatmari, P., & Hoult, L. (1995). Vineland Adaptive Behavior Scales as a summary of functional outcomes of extremely low birthweight children. *Developmental Medicine and Child Neurology*, 37, 577-586.
- Rushton, P.W., & Miller, W.C. (2002). Goal attainment scaling in the rehabilitation of patients with lower-extremity amputations: A pilot study. *Arch Phys Med Rehabil*, 83(6), 771-775.
- Sackett, D.L., Richardson, W.S., Rosenberg, W., & Haynes, R.B. (1997). *Evidence-based medicine: How to practice and teach EBM*. New York: Churchill Livingstone.
- Schaaf, R.C., & Miller, L.J. (2005). Occupational therapy using a sensory integrative approach for children with developmental disabilities. *Mental Retardation and Developmental Disabilities Research Reviews*, 11(2), 143-148.
- Schaaf, R.C., Miller, L.J., Martello, T., Faulkner, J., Girardi, K., Houtras, A., & Rushanan, S. (2001). *Changes in play behavior during sensory integration intervention. Poster presented at the American Occupational Therapy Association 81st Annual Conference and Exposition*. Philadelphia, PA.
- Schaffer, R. (1984). Sensory integration therapy with learning disabled children: A critical review. *Canadian Journal of Occupational Therapy*, 51, 73-77.
- Schoen, S.A., Miller, L.J., & Green, K.E. (2005). The Sensory Over-Responsivity Assessment and Inventory: Reliability and validity. Manuscript in preparation.
- Silverman, W.K., LaGreca, A.M., & Wasserstein, S. (1995). What do children worry about? Worries and their relation to anxiety. *Child Development*, 66, 671-686.

- Smith, K.A., & Gouze, K.R. (2004). *The sensory-sensitive child: Practical solutions for out-of-bounds behavior*. New York: HarperCollins Publishers.
- Stinnett, T.A., Havey, J.M., & Oehler-Stinnett, J. (1994). Current test usage by practicing school psychologists: A national survey. *Journal of Psychoeducational Assessment, 12*, 331-350.
- Stolee, P., Rockwood, K., Fox, R.A., & Streiner, D.L. (1992). The use of goal attainment scaling in a geriatric care setting. *Journal of the American Geriatric Society, 40*(6), 574-578.
- Swanson, J., Nolan, E., & Pelham, W.E. (1987). SNAP-IV checklist. In *Diagnostic and Statistical Manual of Mental Disorders-Revised* (3rd ed.). Washington, DC: American Psychiatric Association.
- Taylor, M.C. (2000). *Evidence-based practice for occupational therapists*. Oxford: Blackwell Science.
- Tickle-Degnen, L. (1999). Organizing, evaluating, and using evidence in occupational therapy practice. *American Journal of Occupational Therapy, 53*(5), 537-539.
- Tickle-Degnen, L. (2000). What is the best evidence to use in practice? *American Journal of Occupational Therapy, 54*(2), 218-221.
- Ullmann, R.K., & Sleator, E.K. (1985). Attention deficit disorder children with or without hyperactivity. *Clinical Pediatrics, 24*, 547-551.
- Ullmann, R.K., & Sleator, E.K. (1986). Responders, nonresponders, and placebo responders among children with attention deficit disorder: Importance of a blinded placebo evaluation. *Clinical Pediatrics, 25*, 594-599.
- Ullmann, R.K., Sleator, E.K., & Sprague, R.L. (1984). ADD children: Who is referred from the schools? *Psychopharmacology Bulletin, 20*, 308-312.

- Ullmann, R.K., Sleator, E.K., & Sprague, R.L. (1991). *ADD-H Comprehensive Teacher's Rating Scale* (2nd ed.). Champaign, IL: MetriTech, Inc.
- Vargas, S., & Camilli, G. (1999). A meta-analysis of research on sensory integration treatment. *American Journal of Occupational Therapy, 53*(2), 189-198.
- Voelker, S.L., Shore, D.L., & Brown-More, C. (1990). Validity of self-report of adaptive behavior skills by adults with mental retardation. *Mental Retardation, 28*, 305-309.
- Wilbarger, P., & Wilbarger, J.L. (1991). *Sensory defensiveness in children aged 2-12: An intervention guide for parents and other caretakers*. Denver, CO: Avanti Educational Programs.
- Wodrich, D.L., & Barry, C.T. (1991). A survey of school psychologists' practices for identifying mentally retarded students. *Psychology in the Schools, 28*, 165-171.

Table 1

Demographics of Sample in Single Group Pilot Study (n = 30)

	Gender		Ethnicity					Mother's Education				Age
	Female	Male	Cauc	Black	Hisp	Asian	Other	< HS	HS	College	Post	Mean (SD)
	N	6	24	26	1	1	1	1	1	5	22	1
%	20	80	86.7	3.3	3.3	3.3	3.3	3.5	17.2	5.9	3.5	

Table 2

Sample Goal Attainment Scale Item

Priority	Difficulty	-2	-1	0	+1	+2
3	2	Refuse to go near bike	Fearful of bikes. Avoids	Reluctant, needs supervision	Will ride bike with training wheels	Will ride two wheeler

Using Ottenbacher and Cusick's (1993) method first, the expected performance (0) is defined. Then other possible outcomes are established: current level of performance (-1); regression from current level (-2); greater than expected (+1); and much greater than expected (+2). Parents rank goals by priority and difficulty.

Table 3

Results of Single Group Pilot Study

Measure	Pre-test			Post-test			Change			<i>p</i> -value
	N	Mean	SD	N	Mean	SD	N	Mean	SD	
Leiter-R										
Attention	24	5.88	1.94	22	6.32	1.94	21	.43	1.47	0.20
Cognitive/Social	24	76.83	10.59	22	80.32	12.62	21	3.57	7.09	0.03
SSP										
Total Score	30	-3.39	1.92	27	-0.39	1.09	27	3.11	1.92	< 0.001
Vineland										
Socialization	24	79.04	12.66	19	89.47	14.41	19	11.95	14.51	0.002
CBCL										
Externalizing	30	60.93	9.79	21	56.95	11.26	21	-4.19	7.83	0.02
Internalizing	30	61.57	10.51	21	57.48	12.10	21	-3.67	8.61	0.07
GAS	27	30.37	1.17	27	55.68	11.46	27	25.31	11.71	< 0.001

Table 4

Demographic Characteristics of Children Participating in Randomized Controlled Pilot Study

	OT First N = 7	AP First N=10	WL First N = 7	<i>p</i> -value
Gender N (%)				
Female	1 (14.3)	3 (30.0)	2 (28.6)	0.85
Male	6 (85.7)	7 (70.0)	5 (71.4)	
Ethnicity N (%)				
Caucasian	6 (85.7)	9 (90.0)	7 (100.0)	0.84
Hispanic	1 (14.3)			
Other		1 (10.0)		
Mother's Education				
N (%)				
High School	1 (14.3)	3 (30.0)	2 (28.6)	0.85
College	6 (85.7)	7 (70.0)	5 (71.4)	
Age Mean (SD)	6.09 (1.53)	6.88 (1.35)	6.67 (2.31)	0.65

Table 5

Means and Standard Deviations of Post-Treatment Changes in Randomized Controlled Pilot Study

Measure	OT Group			AP Group			WL Group			p-value
	N	Mean	SD	N	Mean	SD	N	Mean	SD	
Leiter-R										
Attention ^b	7	1.57	2.37	10	0.10	1.10	7	-0.43	1.27	0.07
Cognitive/Social ^b	7	6.00	6.88	10	-0.60	5.36	7	1.57	2.88	0.06
SSP										
Total Score ^b	6	2.76	1.84	10	2.60	2.02	7	1.49	1.81	ns
Vineland										
Socialization	3	4.67	5.13	5	6.20	13.97	5	-1.60	7.92	ns
CBCL										
Externalizing ^{d,e}	7	2.14	4.14	10	1.10	5.30	6	4.83	4.58	ns
Internalizing ^{b,d}	7	6.00	7.28	10	2.30	4.92	6	3.83	5.46	ns
GAS ^a	7	37.37	9.10	9	13.59	13.02	7	7.10	6.57	< 0.001

a – Significant difference in outcome scores with OT demonstrating most improvement

b – Trend for OT to be more improved than AP and WL in the hypothesized direction

c – Trend for OT to be more improved in the hypothesized direction than WL group only

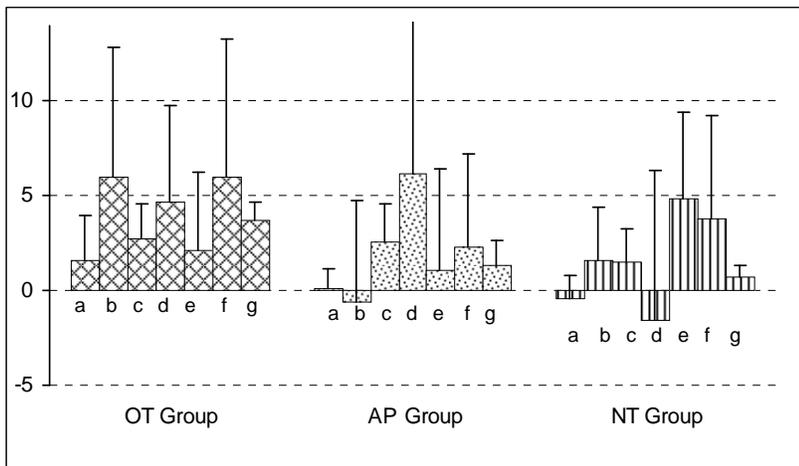
d – Scores on the CBCL have been multiplied by -1 to reflect differences in the same direction as the other scales e.g., a positive number indicates changes in an improved direction

e – Trend for OT to be more improved in the hypothesized direction than AP group only

Figure 1
Design of Randomized Controlled Pilot Study

	Number in Group	Pre-test T ₁ Week 1	10 Week T ₁ Week 2-11	Post-test T ₂ Week 11	10 Week T ₂ Week 12-23
Group A	7	↓	OT		
Group B	10	↓	Alternate Treatment	↓	OT
Group C	7		No-Treatment		OT

Figure 2. Findings of Randomized Controlled Pilot Study



a = Attention

b = Cognitive/Social

c = Short Sensory Profile (SSP)

d = Socialization

e = Externalizing

f = Internalizing

g = Goal Attainment Scaling (GAS)

Figure 3. Changes in Electrodermal Activity after OT, AP and NT

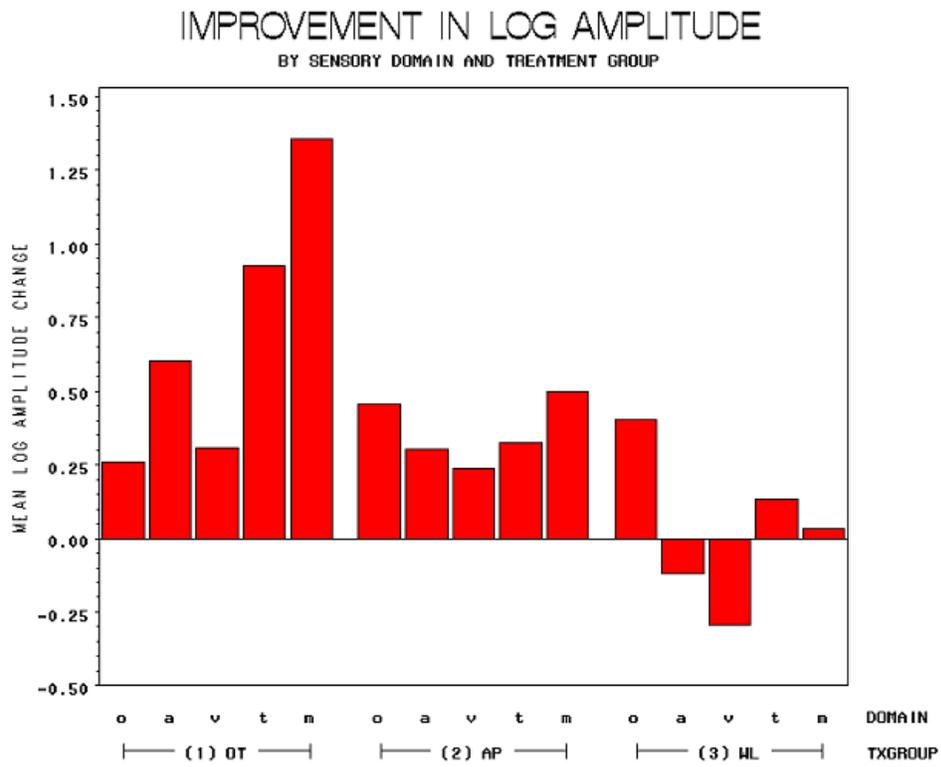
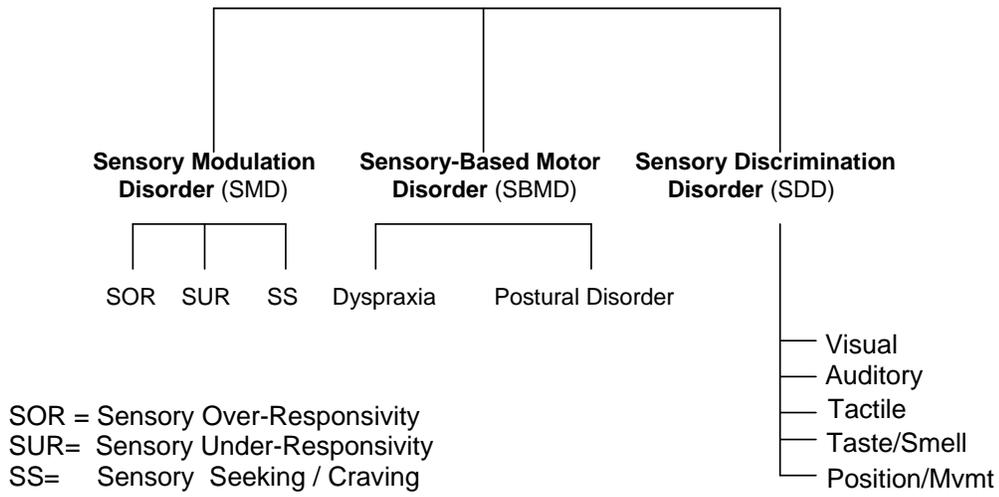


Figure 4. A New Nosology for Identifying SPD



Appendix

Study	Sample Description		Experimental Group	Control Group			Results	
Author	Size/Age	Diagnosis/ Selection Criteria	Treatment Description	Treatment Description	Fidelity Measure (Y/N)	Design	Outcome Measures	If N.S., trend toward hypothesis? (Y/N)
Arnold, et al. (1985)	n=30; aged 5-9 yrs.	ADHD, according to DSM III criteria for ADD with HA; Davids Hyperkinetic Rating Scale; & the hyperkinetic factor on Conners Teacher Rating Scale, & with normal intelligence.	n=30 Vestibular Alone: with 30o forward head tilt, subject spun for 10 one- minute spins - 5 clockwise, 5 counterclockwise. Process repeated with head tilted 90o to right then 90o to left. Vestibular Alone: subject spun under same conditions as above, with eyes occluded.	Tactile: a puff of air is blown across back of subjects hand. Auditory: with eyes occluded, subject listens to optokinetic drum spinning around them. Visual: subject looks through a stereoscopic slide projector.	N	Randomized, split-sample Latin square crossover study. Measures collected at screening, pretest, every 2 weeks during treatment, & at one year follow- up.	Davids Hyperkinetic Rating Scale** (p<.005) Conners Teacher Rating Scale* (p<.05) Bender-Gestalt test	---

			<p>Visual Alone: with head in same three positions as above & the chair still, a surrounding optokinetic drum was spun around subject.</p> <p>Each treatment was 2/wk for 4 weeks, for a total of 12 weeks & 24 sessions.</p>					
Ayres (1978)	n=92; 46 tx; 46 control; 6-10 yrs.; mean=97. 6 mo.	LD	Individual or in pairs; vestibular, proprioceptive, & tactile stimulation plus special education program. Duration: 6 mo; 30 min. 5 days / wk.	Special education only	N		MAC, DC, SCPNT, Dichotic listening, auditory listening, FCTCAA, WRAT, SORT	
Ayres (1972)	n=84; school aged	School-determined learning disorders with low scores on postural-ocular-bilateral integration, praxis, form &	n=30 vestibular, postural, tactile, & proprioceptive stimulation for 25-40 min./day, 5 days/wk, for 6-7 mo (130-150	n=12 No treatment; regular class with individual instruction.	N	Pre-post (> 5m after tx, & > 1y after pretest)	SCSIT; ITPA; WRAT**; SORT	Y

		space perception & auditory-language subtests, & enrolled in Los Angeles area schools.	sessions).					
Ayres (1977)	n=54; aged 8.1-8.4 yrs.	Learning disability with presence of choreoathetosis	n=31 SI treatment, "focused on amelioration of [vestibular system disorder]" for 30 min/day for 6 mo	n=23 No treatment, remain in Special Ed class.	N/A	Pre-post with random control	MAC subtest of SCSIT	Y
Brocklehurst-Woods. (1989)	n=2; 28-33	MR Tactile- Vestibular Behavioral Checklist	50 min/2 days/7 months =56 sessions of tactile/vestibular stimulation.	None	N	Case study	Binomial Chart: Baseline/Treatment Subject A= rate of face/hair rubbing decreased Subject B= rate of head hitting decreased	N
Carte, Morrison, Sublett, et al. (1984)	n=87; 6-11	LD children receiving special education in public school. Clinical	n=46; 45 min/3-4 days/9 mo = 66 sessions with "emphasis on tactile-proprioceptive, vestibular, motor planning & bilateral	n=41; AP = hyponystagmus group	Y	Matched pair design	Postrotary Nystagmus n.s. Underling Test n.s. Target Test n.s. WRAT n.s..	N

		Assessment SCSIT SCPNT WISC-R WRAT Gates-McGinitie Reading Test levels R-D	coordination".				Gates-McGinitie Reading Test n.s.	
Chee, Kreutzberg, Clark (1978)	n=12; 2-6	CP Screened children had to be in good physical health & with history of no recurrent seizures	1 day/1 mo = 16 sessions of horizontal & vertical semicircular canal stimulation.	n=6; AP = control handled n=5; PP = Control non handled	N	Assigned in equated groups	Motor Skills Test: T/AP**, T/PP***, T*** Reflex Test: T/AP***, T/PP***, T***	Y
Close, Carpenter, Cibiri (1986)	n=6; adults, mean=25. 3 yrs.	Profound retardation Basic life skills scale	Description of available sensory equip., tried to use all sensory equip. Duration: 5 days / wk. for 1 yr.	No treatment; residential care.	N		Outcome at 6 mo. & 1 yr.; OT sensory motor assessment; p < .01.	Y
DePauw (1978)	n=24; aged 3-4 yrs.	Aphasia classified by formal assessment	n=11 "sensorimotor experiences from activities suggested	AP: n=6 remedial P.E.	N	Pre-post	SCSIT subtests: Imitate postures**; cross midline**;	Y

		according to CA Educational Code	by Ayres & Kuzienga" for 20min/day, 5 days/week, for 7 mo (150 sessions)	PP: n=7 no treatment			bilateral motor coordination*; R/L discrimination; standing balance	
Dura, Mulick, Hammer. (1988)	n=1; 15	Non-ambulatory Profound MR Clinical Observations	20 min./3 weeks= 20 sessions of swinging.	AP=attention control of 20 minutes play	N	Case study	rate of self-injury /minute during tx*	N
Humphries, et al. (1990)	n=30; aged 6-8 yrs.	Learning disability & SI dysfunction as determined by >1S.D. discrepancy between WISC-R & WRAT scores, a cluster of deviant SCSIT scores in specific categories with consistency with clinical observations.	n=10 SI therapy based on Ayres theory, with clearly delineated activities, 60 min/week for 24 weeks.	AP: n=10 Perceptual motor training for same time period. PP: n=10 No treatment.	N	Randomized pretest-posttest.	BOTMP-GMC** (p=.02) " " -FMC " " -BC* (p=.05) SCSIT - MAC** (p<.01) " " - Space Visualization (p=.06) " " - Design Copy PRN Beery VMI Clinical Observation WISC-R WRAT-R	Y

							TOLD-SLQ	
Humphries, Wright, Snider, et al. (1992)	n=103; 4.8-8.9	LD & SI dysfunction Typical, clumsy, awkward Significant difference between IQ & achievement. Any score < -1 on SCSIT. Clinical Observations WISC-R WPPSI WRAT SCSIT No primary sensory impairments or physical handicaps.	n=35; 60 min/3 days/8 mo=72 sessions of "therapeutic application of selected activities incorporating the use of suspended equipment that provided tactile, vestibular & proprioceptive input" using individualized tx plans.	n=35; AP=Perceptual Motor n= 33; PP=NT	Y	Randomly assigned to treatment groups	SCSIT* Design Copy PM>SI, NT (1/5 tests) SCPRNT n.s BOTMP** Battery, GM PM>SI, NT (3/6 tests) VMI n.s. Clinical Observations: Motor Planning** SI>PM, NT Clinical Observations: Vestibular Functioning n.s. TVPS n.s K-ABC n.s WRAT n.s. ITPA n.s CELF n.s DARD n.s. CPT n.s. MFFT n.s.	N

							NYSCB n.s.	
Montgomery & Richter (1977)	n=62; aged 5-12 yrs.	Classification of trainable mentally retarded by intelligence tests, without physical or emotional dysfunction, & enrolled in one of two MN schools.	n=23 Sensorimotor program with developmentally sequenced activities for 30 min/day, 3 days/wk, for 16 wks (48 sessions).	AP: n=20 Developmental P.E. with motor & social skill emphasis PP: n=19 P.E. program of randomly selected gross motor activities.	N	Pre-post; age-matched random asgmt	118 test items: 60 gross motor items** (p<.03) 35 fine motor items (p=.27) 6 items from Frostig Movement Skills Test Battery 17-item reflex test by Fiorentino & Ayres*** (p<.001)	---
Polatajko, Law, Miller, et al. (1991)	n=67; 6-8.11	LD children with SI Dysfunction SCSIT Normal IQ Academic delay of 6 months in reading, mathematics, written language for 6 year olds & 1	n=35, n=33 at 6 mon, n=32 at 9 mo.; 60 min/1 day/ 6 months /3 month break "using sensory modalities & graded activities" following a treatment manual.	n=32, n=27 at 6 mo., n=26 at 9 mo.; AP=PM following a treatment manual.	N	Blind Randomization	WJPEB* mathematics BOTMP n.s. BASE PIC n.s	N

		<p>year delay for 7-8 yr. olds measured by WJPE & 1sd discrepancy between potential IQ & performance of academic skill.</p> <p>No sensory, neurological, ED, previous therapy, medical contraindications.</p>						
<p>Reilly, Nelson, Bundy. (1983)</p>	<p>n=18; 5.7-13</p>	<p>Autism DSM III classification expressive language below 3.5 years scores of 67 or higher on ASIEP</p>	<p>30 min. = 4 sessions 2 of which provided SI & 2 tabletop activities.</p>	<p>AP=tabletop activities</p>	<p>N</p>	<p>Randomization</p>	<p>Variety* function articulation average length** autistic speech* total language age raw score rate of vocalizations</p>	<p>N</p>
<p>Werry, Scaletti, &</p>	<p>n=74; aged 4-9</p>	<p>Teacher perceived learning difficulties</p>	<p>n=39; Standard SI treatment given in New</p>	<p>n=35 No treatment</p>	<p>N/A</p>	<p>Pre-post with randomized</p>	<p>SCSIT; Peabody; Burtwood Reading</p>	<p>Y</p>

Mills (1990)	yrs.	with "significant SI problems" determined by Ayres method of clinical observation, & enrolled in local New Zealand schools.	Zealand, based on Ayres, for 1 hr/week for 13 weeks (13 sessions)			control & matching for age, gender, degree of SI disability	Test; Bankson Language Screen; Bruininks SF; Conners Teacher Questionnaire; 3pt. Clinical Observations	
White (1979)	n=21; 5.2-6.9	Children identified as failing readers Satz Battery SCSIT	n=9; 30 min/2 days/6 months = 48 sessions of individualized tx.	n=10; AP = regular classes	N	Random selection	IOTA Word Test 6 mo. St Lucia Graded Word Reading Test 1 yr.* Teacher Rating Scale 1 yr. Neale Analysis of Reading Ability Accuracy & Comprehension scales & St. Lucia 2 years. Neale Analysis 3yrs.* St. Lucia 3 yrs.*	Y
Wilson, Kaplan,	n=29; 5.2-8.6	Problems with motor coordination,	n=14; 50 minutes/ 2 days/12 mo = 75 sessions	n=15; AP=tutoring program	N	Randomly assigned &	WJPETB n.s. at 6/12 months but over time	N

<p>Fellowes, et al. (1992)</p>		<p>vestibular, proprioceptive areas interfering with school performance. SI dysfunction based on interpretation on SCSIT Hyporesponsivity on SCPNT Average Intelligence on WISC-R, WPPSI Below expected performance for age on 3 vestibular / proprioceptive activities based on Clinical Observations Below average</p>	<p>focusing on "provision of tactile, vestibular & proprioceptive input within a meaningful self-directed activity in order to elicit an adaptive response."</p>			<p>stratification based on age, sex, amount of special education & speech therapy, degree of motor & academic problems.</p>	<p>*** Bruininks n.s. at 6/12 months but FM improved over time ***, GM/Upper Limb Coordination * Clinical Observations of Motor & Postural Control n.s. at 6/12 months but over time * MAT n.s. at 6/12 months but over time * VMI n.s. at 6/12 months but over time *** Handwriting Scale n.s. DC of SCSIT n.s. at 6/12 months but over time *** SCPNT n.s. at 6/12 months but improved over time ***</p>	
--------------------------------	--	--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------	----------------------------------------------------------------------------------------------------------------------------------------------------------------------	--	--	-------------------------------------------------------------------------------------------------------------------------------------	----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------	--

		<p>performance on Woodstock Johnson Psychoeducational Test Battery</p> <p>Below average on 1/3 visual motor test (DC, MAT-R, VMI)</p> <p>Below average scores on 1/3 Bruininks (FM, GM, Upper limb coordination)</p>					<p>Hyperactivity Level n.s. at 6/12 months but</p> <p>Hyperactivity Index improved over time **</p> <p>Pictorial Scale of Perceived Competence & Social Acceptance of Young Children n.s.</p> <p>Abbreviated Symptom Questionnaire n.s at 6/12 month but over time ***</p> <p>Behavioral Observations forms of MAP n.s. except over time *</p>	
<p>Ziviani, Poulsen, O'Brien. (1982)</p>	<p>n=18; 5.7-13</p>	<p>LD</p> <p>Matched on age, IQ, motor proficiency, academic ability,</p>	<p>n=8; 90 min/1 day / 3.1mo= 19.5 sessions based on NDT/SI.Tx based on scores from SCSIT/SCPNT.</p>	<p>n=8; AP=Remedial teacher</p>	<p>N</p>	<p>Randomly assigned to groups after being matched on age, IQ, performance on</p>	<p>BOTMP**</p> <p>Hull B Word Recognition Test n.s.</p> <p>Schonell n.s.</p>	<p>Y</p>

		remedial class involvement randomly assigned to groups.				test of motor proficiency, academic ability, & remedial class involvement.		
--	--	------------------------------------------------------------------	--	--	--	-------------------------------------------------------------------------------------------	--	--

* $p < .05$

** $p < .01$

*** $p < .001$

PP, Passive Placebo

AP, Active Placebo

PM, Perceptual Motor

SI, Sensory Integration

ASIEP, Autism Screening Instrument for Education Planning

WJPETB, Woodstock Johnson Psychoeducational Test Battery

WRAT, Wide Range Achievement Test

SCSIT, Southern California Sensory Integration Test

SCPRNT, Southern California Postrotary Nystagmus Test

BOTMP, Bruininks-Oseretsky Test of Motor Proficiency

VMI, Test of Visual Motor Integration

WISC-R, Weschler Intelligence Scale for Children-Revised

WPSSI, Weschler Preschool and Primary Scale of Intelligence

TVPS, Test of Visual Perceptual Skills

K-ABC, Kaufman Assessment Battery for Children

BSSI, Basic School Skills Inventory

ITPA, Illinois Test of Psycholinguistic Abilities

CELF, Clinical Evaluation of Language Function

DARD, Durrell Analysis of Reading Difficulty

Rosner, Rosner Test of Auditory Analysis

Connors, Connors Parent and Teacher Questionnaire

MFFT, Matching Familiar Figures Test

NYSCS, North York Self-Concept Scale

MAT-R, Motor Accuracy Test-Revised

DC, Design Copy of SCSIT

Schonell, SI Graded Word Spelling Test

BASE, Coopersmith Behavioral Assessment of Self-Esteem

PIC-R, Personality Inventory for Children-Revised