
A Randomized Controlled Pilot Study of the Effectiveness of Occupational Therapy for Children With Sensory Modulation Disorder

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KEY WORDS

- effectiveness
- occupational therapy
- pediatric
- sensory integration
- sensory modulation disorder (SMD)
- sensory processing

OBJECTIVE. A pilot randomized controlled trial (RCT) of the effectiveness of occupational therapy using a sensory integration approach (OT-SI) was conducted with children who had sensory modulation disorders (SMDs). This study evaluated the effectiveness of three treatment groups. In addition, sample size estimates for a large scale, multisite RCT were calculated.

METHOD. Twenty-four children with SMD were randomly assigned to one of three treatment conditions; OT-SI, Activity Protocol, and No Treatment. Pretest and posttest measures of behavior, sensory and adaptive functioning, and physiology were administered.

RESULTS. The OT-SI group, compared to the other two groups, made significant gains on goal attainment scaling and on the Attention subtest and the Cognitive/Social composite of the Leiter International Performance Scale–Revised. Compared to the control groups, OT-SI improvement trends on the Short Sensory Profile, Child Behavior Checklist, and electrodermal reactivity were in the hypothesized direction.

CONCLUSION. Findings suggest that OT-SI may be effective in ameliorating difficulties of children with SMD.

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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, & Ramsey, 2000; Sackett, Richardson, Rosenberg, & Haynes, 1997; Tickle-Degnen, 1999). In occupational therapy, this vital need has been emphasized by the recent surge of scholarly writings appealing for empirical outcomes research (Law & Baum, 1998; Pankiewicz, 1999; Taylor, 2000; Tickle-Degnen, 2000). Although the quality of published studies is improving (Holm, 2000), rigorous effectiveness studies in pediatrics are just beginning to emerge (Case-Smith & Bryan, 1999; Kinnealey, Koenig, & Huecker, 1999; Melchert-McKernan, Deitz, Engel, & White, 2000).

A wealth of non-peer reviewed information is now available on the World Wide Web. In addition, new popular press publications are available (Aron, 2002; Ayres, Erwin, & Mailloux, 2004; Biel & Peske, 2005; Heller, 2002; Kranowitz, 2004, 2005; Miller, 2006; Smith & Gouze, 2004). Access to these sources is creating additional demands for occupational therapy using a sensory integration approach (OT-SI). Given the lack of high-quality empirical data evaluating this approach (Miller, 2003), the widespread use of this intervention, and the surge of new books, rigorous effectiveness studies are essential.

Prevalence of Sensory Processing Disorders

Sensory processing disorders (SPDs) are impairments in detecting, modulating, interpreting, or responding to sensory stimuli. Sensory modulation disorders (SMDs) are impairments in regulating the degree, intensity, and nature of responses to sensory input, resulting in considerable problems with daily roles and routines (Miller, 2006). The most current theoretical taxonomies (Miller, Lane, Cermak, Osten, & Anzalone, 2005; Zero to Three, 2005) supported by growing empirical research hypothesize three subtypes of SMD: Sensory Overresponsivity, Sensory Underresponsivity, and Sensory Seeking.

For people with diagnosed developmental disabilities, the rate of comorbid SMD is estimated to be from 40% to 80% (Baranek et al., 2002), depending on the specific developmental condition. Survey data indicate that the prevalence of SMD in children in the general population is 5% (Ahn, Miller, Milberger, & McIntosh, 2004). In the study, parents of incoming public school kindergartners completed the Short Sensory Profile (McIntosh, Miller, Shyu, & Dunn, 1999), a parent report screening tool of the functional correlates of SMD. Of the 703 participants, a conservative estimate suggested that 5.3% of the sample met screening criteria for SMD.

Use and Cost of the Treatment

Use of the sensory integration treatment approach is widespread in occupational therapy. Of the 50,000 occupational therapists practicing in the United States, 33% rate themselves as primarily practicing in pediatrics (American Occupational Therapy Association [AOTA], 1996). Of these, more than half rate sensory integration treatment to be a primary or secondary focus of their practice (AOTA, 1996). As of December 2006, the Sensory Integration Special Interest Section had about 12,000 members—the second highest number of members of the AOTA specialty sections (C. Foster, personal communication, December 19, 2006).

The potential cost to society of this intervention approach is considerable. Occupational therapy evaluations using a sensory integration frame of reference cost between \$500 and \$1,000; intervention costs between \$80 and \$180 for a 45- to 60-min session. (These cost figures are estimated from records at three large pediatric hospitals and from the three largest OT-SI private practice settings in the United States in 2005.) In the absence of rigorous effectiveness data, the cost-to-benefit ratio of this intervention approach is frequently questioned.

OT-SI has a 50-year history in the field (Ayres, 1954, 1960, 1961), with more than 80 published articles related

to the effectiveness of the approach. Controversy exists regarding the interpretation of the findings of these studies. Four research syntheses are published (Arendt, MacLean, & Baumeister, 1988; Hoehn & Baumeister, 1994; Polatajko, Kaplan, & Wilson, 1992; Schaffer, 1984) as well as two meta-analyses. One meta-analysis suggests that the treatment approach has no positive effect (Vargas & Camilli, 1999); however, this study has significant methodological flaws. The study's flaws include (a) extremely small sample sizes (median sample size = 4.5 participants for 13 studies); (b) heterogeneous samples; (c) only general descriptions of treatment—for example, “replication was impossible”; and (d) such poor power that an effect was unlikely to be detected if present (Type II error). The other meta-analysis suggested that the intervention approach did have a positive effect, but the article is dated (Ottenbacher, 1982).

Previous Studies of the Effectiveness of OT-SI With SMD

The gold standard for outcome studies is randomized controlled trials (RCTs) (Bury & Mead, 1998), comparing the targeted intervention to either an active Alternate Placebo, or to No Treatment—often a wait-list condition—or to both. Criteria for RCTs are well established (Boruch, 1997; Bury & Mead, 1998) and mandate inclusion of the following four primary criteria:

1. An objectively defined homogeneous sample (Bulpitt, 1983)
2. A manualized intervention (i.e., using a written manual to define the intervention) with a detailed manual, which allows treatment to be replicated (Boruch, 1997) with a method to evaluate adherence to treatment methods (Ottenbacher, 1991)
3. Outcomes that are meaningful and sensitive to hypothesized changes (Fuhrer, 1997)
4. Methodology that is rigorous; for example, methodology with random allocation to experimental and control groups, blinded evaluators, and adequate power (Jadad, 1998)

No previously published research study evaluating the outcome of OT-SI meets all four criteria; few meet even one criterion. Thus, the current conclusion from previous studies is that rigorous evidence supporting or denying the effectiveness of this approach does not exist. The reported study, a culmination of 10 years of research, addresses previous studies' limitations by using a homogeneous sample, a manualized treatment, outcome measures sensitive to change from OT-SI, and randomization to treatment groups with blinded evaluators.

Specifically, this study sought to answer the following research question: Does OT-SI better ameliorate attention,

cognitive/social, sensory, or behavioral problems than an active Alternate Placebo treatment (Activity Protocol) or a passive placebo (e.g., No Treatment)?

Method

Participants

The pool of participants consisted of children referred to outpatient occupational therapy at The Children's Hospital of Denver from April 1999 to December 2001. Approximately 150 children per year with SMD symptoms were evaluated by the Occupational Therapy Department. About one-third of that pool ($n = 50$) met inclusion or exclusion criteria per year.

During informed consent, 30 families agreed to participate. Six participants dropped out before the intervention began because of moving, vacations, illness, or the mother's pregnancy. A prospective cohort of 24 children with SMD participated. Five children had a previous diagnosis of attention deficit hyperactivity disorder (ADHD), 3 had diagnoses of learning disabilities, and 1 had notable anxiety symptoms. Fifteen children had no previous diagnosis. Although only 5 children were diagnosed with ADHD, when all children were screened with the Swanson, Nolan, and Pelham (SNAP-IV) questionnaire (Swanson, 1992), 62.5% (15) met criteria for ADHD.

Table 1 displays demographic characteristics for participants. Using Fisher's exact test for categorical variables and a one-way analysis of variance (ANOVA) for age, no significant group differences were found on age, gender, mother's education, or ethnicity.

Inclusion and Exclusion Criteria

Inclusion and exclusion criteria for SMD identified a homogeneous sample, including the following measures:

Table 1. Demographic Characteristics of Children Participating in Randomized Controlled Pilot Study

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

Note. OT = occupational therapy group; AP = activity protocol group; NT = no treatment group.

- A clinical diagnosis of SMD by the referring occupational therapist after comprehensive evaluation, including the Sensory Integration and Praxis Tests (Ayres, 1989) for children ages 5 years or older, Miller Assessment for Preschoolers (Miller, 1988), and FirstSTEP (Miller, 1993) for children ages 5 years or younger. Clinical diagnosis was based on global impression of SMD after a comprehensive occupational therapy evaluation that included standardized and clinical testing (low test scores were not essential, but behavior during testing had to indicate SMD). Each child met the criteria: 25% of items endorsed as ≥ 2 on SMD Behavior Observations during testing (see Appendix).

- Hyperreactive electrodermal activity (EDR) to stimuli in ≥ 2 sensory domains on the Sensory Challenge Protocol (Miller et al., 1999) (average magnitude per trial $\geq .05$ mmhos or average number of peaks ≥ 2 per stimuli). In the Sensory Challenge Protocol, children watched the movie *Apollo 13* while electrodes were attached to their hands "like real astronauts." A series of 50 sensory stimuli were administered, 10 in each of five sensory domains, as data were continuously recorded. Children with SMD have higher amplitude EDR than children who are typically developing (McIntosh, Miller, Shyu, & Hagerman, 1999; Miller et al., 1999).

- Short Sensory Profile (SSP; McIntosh, Miller, Shyu, & Dunn, 1999) total *z* score of ≥ -3 standard deviations (SD) below the mean, > -2.5 SD on two or more subtests, or > -4 SD on one subtest.

- Clinical confirmation of SMD by the first author after the parent interview.

Exclusion criteria for SMD were any of the following measures:

- *Other conditions:* Other *DSM-IV* or *ICD-9* diagnoses except ADHD, learning disabilities, or anxiety symptoms; for example, pervasive developmental disorders; genetic, orthopedic, and neurologic disorders; and psychiatric disorders (e.g., mood disorder, bipolar disorder)

- *Age:* Younger than 3.0 or older than 11.6 years (3 years is the youngest age to obtain reliable EDR; 11.6 is prepubertal)

- *IQ:* < 85 , based on the short form of the Wechsler Intelligence Scale for Children (3rd ed.) (WISC-III; Wechsler, 1991) (block designs and vocabulary)

- *Previous occupational therapy treatment:* Direct individual occupational therapy (not including occupational therapy at school)

- *Serious confounding life events:* Death of parent, abuse or neglect, residence in a foster home, and so forth

- *Special education:* Enrollment with an IEP (individualized education program) resulting in pull-out services

Instrumentation

Based on previous research, the following measures were selected:

- *Leiter International Performance Scale–Revised: Parent Rating Scale* (Leiter–R; Roid & Miller, 1997). The Leiter–R is a standardized parent rating scale of Attention and Cognitive/Social composite (the other subtests were not used) with excellent national standardization, reliability, and validity.
- *Short Sensory Profile* (SSP; McIntosh, Miller, Shyu, & Dunn, 1999). The SSP is a parent report that screens functional behaviors related to sensory responsiveness. Norms were obtained from the Sensory Profile (Ermer & Dunn, 1998) and standardized on 1,200 children. Reliability of the SSP = .90, and discriminant validity is > 95% (McIntosh, Miller, Shyu, & Hagerman, 1999).
- *Vineland Adaptive Behavior Scales* (Sparrow, Balla, & Cicchetti, 1984). The Vineland scale is a well-validated parent interview that focuses on the child's functional skills (only the socialization subtest was used). A widely used adaptive scale (Stinnett, Havey, & Oehler-Stinnett, 1994; Wodrich & Barry, 1991), it discriminates atypical performance on daily living skills (Altman & Mills, 1990; Douhitt, 1992; Rosenbaum, Saigal, Szatmari, & Hoult, 1995).
- *Child Behavior Checklist* (CBCL; Achenbach, 1991). The CBCL measures social and emotional behaviors based on parent report, reflected in two composite scores: Internalizing and Externalizing. The CBCL is substantiated for wide use in research (Elliott & Busse, 1992; Mooney, 1984).
- *Goal attainment scaling* (GAS; Kiresuk, Smith, & Cardillo, 1994). The GAS evaluates individual differences related to families' priorities for change. Parents, with the assistance of the interviewer, determine and rank-order five goals that identify changes deemed achievable over the 20-session duration of the study (Clark & Caudrey, 1986; Rockwood, Joyce, & Stolee, 1997). The rank weights each goal. A trained therapist wrote the GAS items, defining five increments of observable change for each item. Although individual goals are written for each participant, the scores are standardized by having response options that are equally spaced (e.g., the same level of difficulty to achieve). Thus, the extent to which the goals are met can be mathematically calculated (Kiresuk & Sherman, 1968; Kiresuk, Smith, & Cardillo, 1994).
- *Electrodermal reactivity* (EDR). EDR is a marker of sympathetic nervous system activity, measured by changes in the electrical conductance of the skin associated with activation of eccrine sweat glands. The Sensory Challenge Protocol, described previously, was used to collect EDR (Mangeot et al., 2001; McIntosh, Miller, Shyu, & Hagerman, 1999; Miller et al., 1999).

Treatment Conditions

Experimental Treatment: OT-SI

OT-SI (Ayres, 1972; Koomar & Bundy, 2002; Parham & Mailloux, 2001) was administered twice a week for 10 weeks. Occasional missed sessions were made up within 2 weeks. The manualized intervention (Miller, Wilbarger, Stackhouse, & Trunnell, 2002) was based on principles proposed by Ayres (1972) emphasizing clinical reasoning (Mattingly & Fleming, 1994) to attain occupational goals. Key to this approach is asking questions moment-by-moment rather than using prescribed activities (Miller, 2006).

The therapist and child interact in a large occupational therapy room equipped with sensory activities and toys. The child's imagination creates a pretend situation (e.g., captain of a ship) where the child interacts with the sensory materials in an active, meaningful, and fun manner. The child is challenged but with scaffolding is always successful. Guided by the parents' priorities for their child, the goal is improving the child's sensory responsiveness, social behavior, motor competence, and participation in meaningful occupations. The occupational therapist serves as coach, educator, and role model for the parents, who participate actively in the sessions.

A draft fidelity-to-treatment measure was constructed in bimonthly meetings of the six participating therapists during the pilot project and used during this study. This measure has been expanded and is undergoing further study (Parham et al., 2007).

Alternate Placebo Treatment: Activity Protocol

The Alternate Treatment, an active placebo, was called the Activity Protocol, designed to control for therapeutic alliance and attention to the child. Activity Partners, non-occupational therapy staff members or graduate students, participated to the extent that the child indicated in each session. Activity Protocol included a variety of engaging tabletop play activities (e.g., arts and crafts, puzzles, blocks, reading stories, interactive games). Activity Partners had education or psychology degrees and experience with young children. The same opportunity existed in the Activity Protocol and occupational therapy for appropriate, fun activities supported by adult attention, in the same-size room.

The differences between Activity Protocol and occupational therapy were the type of activities, the process of challenge and support that occurred, and parent education or coaching. In Activity Protocol, parents were not educated about the disorder and no intervention related to problems occurred.

No Treatment

The No Treatment condition was a passive control: a 10-week wait list for OT-SI.

Procedures

Occupational therapists at The Children's Hospital of Denver recruited families. Evaluating occupational therapists referred children who met inclusion criteria to research staff. After informed consent, parents rated the SSP and SNAP-IV. An intake interview was then conducted, including Vineland, a detailed history, review of presenting difficulties, and parents' goals. Third, physiological testing was completed and the child took a WISC-III (short form). Fourth, the parents completed the Leiter-R and the CBCL.

Twenty-four eligible children were randomized to one of three intervention groups: OT-SI (Group A), Activity Protocol (Group B), and No Treatment (Group C). After 10 weeks, children in groups B and C received 10 weeks of occupational therapy at no cost. Figure 1 displays the design of the study and number of participants in each group.

Fidelity to the two treatment protocols was maintained via review of videotaped sessions 1, 7, 14, and 20, as occupational therapists and Activity Partners watched and discussed each other treating children bimonthly. Therapists were supervised by the team leader of the Sensory Integration Program at The Children's Hospital, and Activity Partners were supervised by the research project director. Queries at initiation of treatment determined that no participants had obtained services elsewhere while waiting for occupational therapy to begin.

Results

All participants with baseline and 10-week data were included in analyses. For the outcome variables, distributions were inspected for normality. Skewed distributions (e.g., EDR) were log transformed. Some scales were not usable (i.e., incomplete data, missing score sheets), and thus

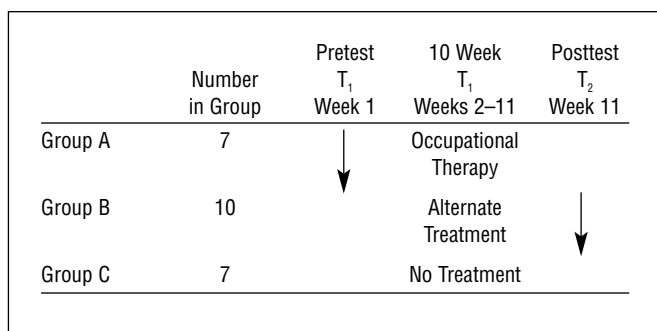


Figure 1. Design of randomized controlled pilot study.

the number of participants differs slightly in the tables accompanying this article. Differences among the treatments were evaluated with one-way ANOVA. The group means and standard deviations for changes from pretreatment to posttreatment on standardized scales are noted in Table 2.

The children in Group A, the OT-SI group, made gains that were significantly greater than the children in the other two groups on GAS ($p < .001$ compared to No Treatment and Activity Protocol). Children in the OT-SI group also increased significantly more than the other groups on Attention ($p = .03$ compared to No Treatment; $p = .07$ compared to Activity Protocol [trend toward significance]) and on the Cognitive/Social Composite of the Leiter-R ($p = .02$ compared to Activity Protocol). For both the SSP Total Score and the CBCL Internalizing Composite, change scores were greater in the hypothesized direction for the OT-SI group, but not significant. The children in Group B, the Activity Protocol group, made greater but nonsignificant gains compared to the other two groups on Socialization (Vineland). Children in Group C (No Treatment) made greater but nonsignificant gains on the CBCL Externalizing Composite. Findings are displayed numerically in Table 2 and graphically in Figure 2. Effect sizes were Leiter-R, Attention and Cognitive/Social scores (0.29), SSP Total (.08), Vineland Socialization (.14), CBCL Externalizing (.10) and Internalizing (.07), and GAS (1.62). No significant changes on other subtests of the Vineland or Leiter-R were noted.

Physiologically, even with a very small sample, the OT-SI group showed greater reduction in amplitudes of EDR compared to the Activity Protocol and No Treatment groups (OT-SI, $n = 4$; Activity Protocol, $n = 3$; No Treatment, $n = 4$) as seen in Figure 3. This result must be interpreted with caution because 54% of the data were unusable (either pretest or posttest data were not of good enough quality to use on 13 children). Although not significant, a trend was observed for the OT-SI group to improve in the hypothesized direction (reduced hyperreactivity).

Discussion

The findings suggest that OT-SI may be effective in ameliorating difficulties of children with SMD. Children in the OT-SI group made significant changes compared to the Alternate Treatment and the No Treatment groups on GAS and on Attention and Cognitive/Social composite (Leiter-R Parent Rating). In addition, trends occurred toward greater improvement in the OT-SI group on Internalizing (CBCL) and the SSP Total Score. However, the small sample size and lack of statistical power mandate caution in interpretation of results.

Table 2. Mean and SD of Posttreatment Changes in Randomized Controlled Pilot Study

Measure	OT Group Changes			AP Group Changes			NT Group Changes			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	0.42
Vineland										
Socialization	3	4.67	5.13	5	6.20	13.97	5	-1.60	7.92	0.49
CBCL										
Externalizing ^c	7	2.14	4.14	10	1.10	5.30	6	4.83	4.58	0.34
Internalizing ^{b,c}	7	6.00	7.28	10	2.30	4.92	6	3.83	5.46	0.45
GAS ^a	7	37.37	9.10	9	13.59	13.02	7	7.10	6.57	< 0.001

Note. OT= occupational therapy; AP = Activity Protocol; NT = No Treatment; SD = standard deviation; Leiter-R = Leiter International Performance Scale-Revised (Roid & Miller, 1997); SSP = Short Sensory Profile (McIntosh, Miller, Shyu, & Dunn, 1999); Vineland = Vineland Adaptive Behavior Scales (Sparrow, Balla, & Cicchetti, 1984); CBCL = Child Behavior Checklist (Achenbach, 1991); GAS = goal attainment scaling.

^aSignificant difference in outcome scores with occupational therapy demonstrating most improvement.

^bTrend for OT-SI to be most improved in the hypothesized direction: Attention ($p = .03$ compared to NT; $p = .07$ compared to AP); Cognitive/Social ($p = .02$ compared to AP); SSP Total and CBCL Internalizing Composite.

^cScores 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).

The study was useful in developing a standard system for participant inclusion, treatment, and outcome measurement and testing controls to validity threats. The inclusion criteria were objectively defined by a combination of behavioral and physiological criteria. The treatment used a manualized procedure, and development of a fidelity to treatment measure was initiated. The outcomes retested assessments that previously appeared sensitive to change in a pilot study (Schoen, Miller, & Green, 2007). Threats to validity were identified and controlled for (attention, therapeutic alliance, statistical regression, maturation, history, testing, and instrumentation) (Cook & Campbell, 1979), and protocols were established to control these threats in future studies.

A larger RCT is required before a more definitive conclusion related to the effectiveness of OT-SI can be offered with reasonable assurance that results are not attributable

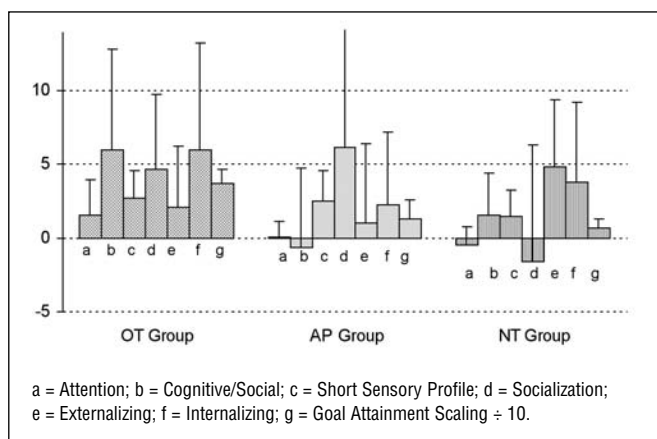


Figure 2. Findings of randomized controlled pilot study. OT = occupational therapy; AP = Activity Protocol; NT = No Treatment.

to chance and that external and internal sources of invalidity have been fully controlled. The insights gained from this study will inform future RCTs of OT-SI in children with SMD.

Selecting a Homogeneous and Objectively Defined Sample

This study identified useful measures for selecting a homogeneous sample based on physiology and behavior. Participants met behavioral criteria (SSP), physiological criteria (EDR), and global diagnostic impression by clinicians. We

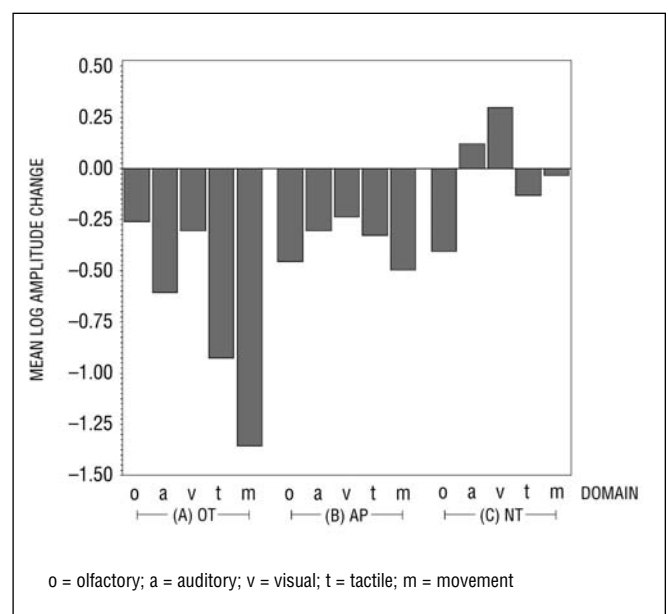


Figure 3. Improvement in electrodermal activity (log amplitude) after occupational therapy (OT), Activity Protocol (AP), and No Treatment (NT).

learned that even these stringent criteria result in a heterogeneous sample; for example, behavioral and physiological overresponsivity combines with sensory underresponsivity and/or sensory seeking in various sensory domains. A performance assessment for different SMD subtypes will further sample homogeneity (Schoen et al., 2007).

In addition, this study demonstrated the usefulness of EDR to assist in selecting a homogeneous sample. This study focused on one variable, magnitude of response; however, other electrodermal variables may help define more homogeneous samples. Future work should include tonic measures of electrodermal activity (e.g., skin conductance level).

Finally, this study highlighted the complex issue of comorbidities in conditions that must be carefully explored in future studies. Many children in this sample had evidence of ADHD symptoms (62.5%). The potential confound of comorbidities such as ADHD and Generalized Anxiety Disorder on treatment effectiveness should be further explored.

Developing a Manualized Approach to Intervention

This study successfully used a published, manualized approach to intervention (Miller et al., 2002) and a videotape-and-discussion methodology to assess fidelity to treatment. Supervision and bimonthly meetings to discuss videotaped treatment sessions helped ascertain adherence to treatment principles. Few examples of manualized treatment protocols exist in occupational therapy because the individualized nature of occupational therapy makes this approach difficult; however, manualization is crucial to rigorous outcome studies. Until interventions are manualized and fidelity to treatment can be measured, rigorous large-scale effectiveness trials cannot be conducted because treatment protocols cannot be replicated. In 2001, a National Institutes of Health grant permitted a national group of experts to further develop a manualized treatment approach and a fidelity to treatment measure (ongoing; see Parham et al., 2007).

Identifying Meaningful, Appropriate, and Sensitive Outcomes

GAS was the most meaningful and sensitive outcome measure in this study. Additionally, change was observed in magnitude of EDR. These results support future exploration of GAS and physiological measures as outcomes to supplement more subjective parent rating scales. Some subtests in each of the three behavioral measures show promise.

A crucial issue for future effectiveness studies is exploring other outcome measures that are sensitive to and conceptually matched to expected changes. Content validity of

outcome measures is critical; that is, rather than measures that simply fit a child's age, outcomes must target hypothesized intervention changes. Both a sound theoretical and psychometric basis for selecting dependent measures is imperative. Use of subjective measures (e.g., caretaker, teacher, examiner report) should be supplemented by more objective measures (e.g., physiological data). However, use of too many outcome measures—as is typical of previous research in OT-SI—is deleterious because of an increased likelihood of Type I errors with multiple measures. Researchers should use only hypothesis-driven outcome measurements.

Establishing Rigorous Methodology

Finally, this study addressed the use of random allocation to treatment conditions. Few previous studies evaluating OT-SI used randomization to treatment group, the cornerstone of rigorous effectiveness study research designs. Even if other aspects of the study must be compromised, randomization to treatment group must occur for causal conclusions to be drawn.

If the posttreatment evaluator knows the group membership of the participants, the validity of the findings of the entire study is questionable. The current study attempted to “blind” parents' expectations by conveying that the treatment group the child was randomized to was the “best” group. If randomized to Group B, the Alternate Placebo Treatment, parents were told, “You are lucky, you get both treatments”; if randomized to Group C, the No Treatment group, parents were told, “You are lucky, you get to have an OT [occupational therapist] especially selected to match the personality of your child.” However, the effect of this approach is not known. Although physiological experimenters were blind to treatment group assignment, given the small team some information may have been disclosed. Substantial difficulty exists putting blinded evaluations into practice because of small offices, team discussions, or unwitting unblinding by secondary people; thus, future studies should develop careful strategies to assure blind post-intervention assessments.

This study demonstrated the usefulness of pilot studies before randomized trials. A post hoc power analysis deemed that, in the future, studies designed to detect changes in outcomes after 20 sessions could detect changes as small as 0.50 SD if 64 children were included in each group (80% power with a Type I error rate of 5%). If larger differences are suggested by pilot studies (i.e., more than 1.0 SD between group differences, e.g., GAS), then 17 children per group would provide 80% power. Pilot data should inform selection of outcome measures so that appropriate sample sizes are chosen. Previous occupational therapy research in

the area of effectiveness of OT-SI has been plagued by Type II errors (not enough power to show an effect even if one is present). Urgently needed are studies with adequate power to evaluate the statistical significance of effects.

Recommendations for Future Research

From this study, we learned that occupational therapists also should consider other research designs in effectiveness studies in addition to homogeneous groups, replicable treatment or fidelity to treatment measures, and sensitive or appropriate outcome measures (previously tested for sensitivity with this population). For example, crossover designs cannot be used with occupational therapy intervention because the effects of occupational therapy do not “wash out.” Additionally, although the profession is advocating the need for outcome studies, effectiveness studies should *never* be conducted with scales or methods that have not been field-tested with a similar sample using similar procedures. Findings that are negative should be published—not to prove whether the intervention works or doesn’t work but rather to inform the field about outcomes that may or may not be useful in documenting effects. Measures must have documented reliability and validity for the sample being studied. One likely reason that many previous studies found no significant changes from OT-SI is that the outcome measures used were not sensitive enough to detect changes. Because previous literature does not present pilot testing of instrumentation, researchers unknowingly replicate each other’s work. Outcomes research in OT-SI, therefore, is continually relegated to pilot research rather than research that moves forward and has the potential to change practice.

Conclusion

This pilot RCT included 24 children randomly assigned to three treatment conditions. Results suggested that on some measures (e.g., GAS, Attention subtest and Cognitive/Social Composite of the Leiter–R parent rating scale), OT-SI was significantly more effective than the two alternate treatment groups: Activity Protocol (an active placebo) and No Treatment (a passive placebo or wait-list condition). On several other outcome measures, OT-SI demonstrated a trend toward greater effectiveness than other groups. However, more power was needed to achieve statistical signifi-

cance (SSP, CBCL Internalizing Composite). On other measures, OT-SI did not demonstrate significantly different results from the control groups in the hypothesized direction (Socialization on the Vineland scale).

This article elucidates the complex conceptual and methodological issues related to implementation of rigorous effectiveness trials in occupational therapy with children who have SPD. Researchers must use selection criteria that will identify a homogeneous sample, likely a combination of physiological and behavioral measures. A manualized protocol for intervention and a fidelity to treatment measure also are needed. Outcome measures that are sensitive enough to detect changes over the specified treatment duration and that target meaningful changes are crucial. Finally, adequate power to detect group differences, if present, must be feasible. This study is a modest beginning; more studies are needed to answer the plethora of questions related to understanding whether OT-SI is an effective intervention, for whom, and under what conditions. The field has matured to a state where these questions can be parsed into meaningful studies and systematically researched. ▲

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Appendix. SMD Behavior Observations During Occupational Therapy Evaluation

1 = Observed, but test reliable without modification
 2 = Observed, with therapist's intervention could continue test reliably
 3 = Observed, had to discontinue testing or felt performance was extremely compromised

<i>Reactions:</i>	<i>Extreme 3</i>	<i>Moderate 2</i>	<i>Mild 1</i>	<i>Normal 0</i>
Response to Sensory Stimuli				
Silliness or giggling during tactile tests				
"Shutting down" during tactile tests				
Withdrawal from or aversive reaction to tactile stimuli				
Bothered by shield touching body				
Bothered by having shield occlude vision				
Complaints of feeling ill during or after PRN or spinning				
Continues to spin on PRN board after test is administered				
Distracted by items in visual field				
Unable to keep eyes closed				
Aversive response to routine noise				
Distracted by outside noise				
Attempts by the Child to Self-Regulate				
Excessive movement (rocking, bouncing in seat, tipping chair)				
Putting things in or around mouth (food/nonfood)				
Heavy or hard poking, pounding, slapping when responding				
Needing more than typical number of breaks during testing				
Behavioral Disorganization				
Restless, fidgety, grabs impulsively				
Unable to stay seated				
Overly talkative				
Impulsive responses to test items				
Poor focus on tasks, needs redirection				
Lack of persistence, needs cues to persist				
Difficulty entering or transitioning into testing room				
Somatic Responses to Testing Situation				
Repeatedly requests to go to the bathroom				
Complains excessively of being thirsty or hungry				
Complains of being tired when reportedly well rested				
Complains that head, stomach, or eyes hurt, or does not feel well				
Yawns				

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