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Participant Satisfaction in a Study of Stimulant, Parent Training, and Risperidone in Children with Severe Physical Aggression

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Abstract

Objective: The purpose of this study was to examine the satisfaction of families who participated in the Treatment of Severe Childhood Aggression (TOSCA) study.

Methods: TOSCA was a randomized clinical trial of psychostimulant plus parent training plus placebo (basic treatment) versus psychostimulant plus parent training plus risperidone (augmented treatment) for children with severe physical aggression, disruptive behavior disorder, and attention-deficit/hyperactivity disorder. Parents completed a standardized Parent Satisfaction Questionnaire (PSQ).

Results: Of the 168 families randomized, 150 (89.3%) provided consumer satisfaction data. When they were asked if they would join the study again if they had the option to repeat, 136 (91%) said ''yes,'' 11 (7%) said ''maybe,'' and one (< 1%) said ''no.'' When asked if they would recommend the study to other parents with children having similar problems, 147 (98%) said ''yes'' and 3 (2%) said ''maybe.'' Between 71% (rating one aspect of the Parent Training) and 96% (regarding the diagnostic interview) endorsed study procedures using the most positive response option. Asked if there were certain aspects of the study that they especially liked, 64 (43%) spontaneously reported parent training. Treatment assignment (basic vs. augmented) and responder status were not associated with reported satisfaction. However, responder status was strongly associated with parent confidence in managing present ($p < 0.001$) and future ($p < 0.005$) problem behaviors.

Conclusions: These findings indicate high levels of satisfaction with TOSCA study involvement and, taken together with previous pediatric psychopharmacology social validity studies, suggest high levels of support for the research experience. These findings may inform research bioethics and may have implications for deliberations of institutional review boards.

Trial Registry: Treatment of Severe Childhood Aggression (The TOSCA Study), NCT00796302, clinicaltrials.gov.

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Introduction

Assessing self-reported participant opinion regarding the research experience is a valuable, yet largely unexplored, area in clinical psychopharmacological studies. In the studies to date, treatment procedures are usually assessed solely for acceptability, whereas outcomes are assessed for their social importance (e.g., Does the degree of client change represent an important improvement for the client?) (Foster and Mash 1999).The earliest published discussions of the importance of social validity can be traced back to Baer et al. (1968). In the early 1970s, behavior analysts started to stress the importance of social validity (i.e., the perceived social importance and acceptability of treatment goals, procedures, and outcomes) (Kazdin 1977, Wolf 1978). In 1991, Schwartz and Baer outlined two tenets: First, they noted the need to show the degree of acceptance of an intervention and its viability, once implemented. Second, they charged clinical researchers to document ''social importance'' by generating meaningful changes and outcomes in each client's life.

In their 1995 review of 68 drug studies (in the mental retardation literature published between 1987 and 1993), Poling and LeSage found that not one provided any parent, other primary caregiver, or patient satisfaction (social validity) data. They remarked on the minimal additional cost most pharmacological trials would incur, the minor effort such data collection would entail, and the fact that such information would enable society to place findings in a ''broader, socially significant, context.'' Although several studies between 1993 and 2003 did include parent satisfaction data (stimulant medication delivery-type studies), few included questions regarding the research experience and its acceptability, as exemplified in Johnston and Fine (1993), Pelham et al. (2001), Wolraich et al. (2001), Biederman et al. (2002), Dirksen et al. (2002), Wan and Bukstein (2003), and Wilens et al. (2003).

The first pediatric psychopharmacological study including social validity data (Aman and Wolford 1995) reported a high level of satisfaction among parents whose children with intellectual disability and attention-deficit/hyperactivity disorder (ADHD) participated in two crossover trials involving methylphenidate and fenfluramine. Eighty-eight percent of participants indicated that they would choose to take part in the studies again if re-presented with the choice. The National Institute of Mental Health Multimodal Treatment Study of Children with ADHD (MTA) reported that parent and teacher satisfaction ratings were significantly higher with intensive multicomponent behavioral treatment alone compared with those for medication management alone (Pelham 1998). These same raters, however, scored ADHD symptom severity significantly lower for those taking medication alone, therefore indicating a discrepancy between treatment outcome and satisfaction with that treatment.

Tierney et al. (2007) reported satisfaction data obtained during a randomized clinical trial of risperidone in children with autistic disorder plus concomitant severe irritability and disruptive behaviors. At the end of the acute 8 week double-blind risperidone trial, depending on the question, 80–97% of parents indicated satisfaction with their research experience. In all, 93% indicated that they would rejoin the study if they had the decision to make again. No other published reports of parent satisfaction with respect to child psychopharmacological research were located.

In this article, we report parent satisfaction, measured by the Parent Satisfaction Questionnaire (PSQ), in a randomized double-blind placebo-controlled clinical trial in children with ADHD and severe physical aggression (Aman et al. 2014). All parents or primary caregivers also received nine weekly parent training sessions in behavioral management (Community Parent Education Program [COPE]) (Cunningham 1998; see also Farmer et al., 2011). Our primary aims included assessing 1) the overall levels of satisfaction in the study, 2) any satisfaction differences between responders and nonresponders, 3) whether or not treatment assignment (placebo versus risperidone augmentation) made a difference in satisfaction, and 4) relation of study conditions with parental confidence in managing present/future problem behaviors. As in the Tierney et al. (2007) study, we hypothesized that parents would have moderately high satisfaction with the study experience, and that parents of children showing improvement during the trial (responders) would be more satisfied than those whose children did not improve (nonresponders).

Methods

Elsewhere, we have reported on the Treatment of Severe Childhood Aggression (TOSCA) study (Farmer et al. 2011; Aman et al. 2014; Gadow et al. 2014). Briefly, this was a randomized clinical trial comparing parent training in behavior management (PT) plus psychostimulant (STIM) plus placebo (basic treatment) versus PT plus STIM plus risperidone (RIS) (augmented treatment). During weeks 1–3, only PT plus STIM were provided. Thereafter, if there was room for further improvement, placebo (basic treatment) or RIS (augmented) was started (see Farmer et al. 2011; Aman et al. 2014 for details).

Entry criteria: The participants were required to be 6–12 years of age, inclusive, with Disruptive Total (D-Total) scores ≥ 27 (i.e., $\geq$ 90th percentile) on the Nisonger Child Behavior Rating Form–Typical Intelligence Quotient (IQ) version (NCBRF-TIQ) (Aman et al. 2008). The D-Total is a composite of 9 Oppositional subscale items and 14 Conduct Problem subscale items. All participants had to display serious physical aggression as determined by a single item unweighted score ≥ 3 on one or more items of the Overt Aggression Scale (Coccaro et al. 1991) for assaults against other people, objects, or self (see Gadow et al. 2014). Participants were free of other psychotropic drugs for ≤ 2 weeks. Each received blood draws at screening and at the end of the acute trial as safety measures; although not done for this purpose, this also helped preserve the study's double-blind integrity.

Exclusion criteria included intellectual disability (IQ < 71), presence of current *Diagnostic and Statistical Manual of Mental Disorders,* 4th ed. (DSM-IV) defined pervasive developmental disorders, schizophrenia, eating disorders, or major mood disorders (including bipolar disorder or major depressive disorder); active substance use disorders; two or more first-degree relatives with type 2 diabetes; or any indication of significant physical health conditions (American Psychiatric Association 1994).

At the end-point visit (Week 9), or at the last visit if participants terminated earlier, parents completed the Parent Satisfaction Questionnaire (PSQ) (items appear in Table 1). Briefly, the PSQ asks about various features of the study such as number of visits, aspects of PT, general satisfaction with the study, and hypothetical willingness to join it again.

Pearson's χ^2 and Fisher's exact test were used to examine bivariate associations among treatment assignment, child treatment response, and parent satisfaction with study participation. Subsequently, logistical regression was used to examine multivariate models predicting parent satisfaction with study participation and parent confidence in managing their children's aggressive behaviors.

Table 1. The Parent Satisfaction Questionnaire and Subject Responses

Question	*Frequency‡*	*Percent*
1. How do you feel about the number and frequency of visits for monitoring of medication effects?		
a. They were just right	134	89.3
b. There were too many	14	9.3
c. There were not enough	2	1.3
2. How do you feel about the diagnostic interview? (This was done on or before the first visit.)		
a. It seemed complete and well worth the wait; I am glad it was done	144	96.0
b. It seemed too long and detailed	6	4.0
c. It seemed too short and incomplete	0	0.0
3. How do you feel about the number of blood tests? (Glucose and cholesterol abnormalities were mentioned in the question.)		
a. They were just right	144	96.0
b. There were too many	3	2.0
c. There were not enough	3	2.0
4. How do you feel about the checklists you completed about your child's behavior at each visit? (These included the NCBRF, CASI, ADHD Checklists that you filled in at each visit.)		
a. They were very important	130	86.7
b. They were somewhat important	20	13.3
c. They were not important	0	0.0
5. How do you feel about the side effects assessments?		
a. They were very important	140	93.3
b. They were somewhat important	10	6.7
c. They were not important	0	0.0
6. Would you recommend this study to other parents who have children with similar problems?		
a. Yes	147	98.0
b. Maybe	3	2.0
c. No	0	0.0
d. Missing	0	0.0
7. If you had it to do all over again, *not knowing how your child would react to the medicines,* would you join the study again?*		
a. Yes	136	90.7
b. Maybe	11	7.3
c. No	2	1.3
d. Missing	1	0.7
8. Were there aspects of the study you did not like?		
a. Yes	28	18.7
b. No	122	81.3
c. Missing	0	0.0
9. Were there aspects of the study that you did especially like or thought were particularly valuable?		
a. Yes	108	72.0
b. No	41	27.3
c. Missing	1	0.7
10. How do you feel about the number of behavioral training sessions?		
a. They were just right	127	84.7
b. There were too many	14	9.3
c. There were not enough	9	6.0
11. How do you feel about the length of the behavior training sessions?		
a. They were just right	128	85.3
b. They were too long	18	12.0
c. They were too short	4	2.7
12. How do you feel about the materials presented by clinicians?		
a. They were just right	140	93.3
b. They were too difficult	0	0.0
c. They were too easy	10	6.7
13. How do you feel about the videotape examples?*		
a. They were very helpful	81	54.0
b. They were somewhat helpful	61	40.7
c. They were not helpful	7	4.7
14. How do you feel about the handouts?		
a. They were just right	142	94.7
b. They were too difficult	1	0.7
c. They were too easy	7	4.7

(*continued*)

Table 1. (Continued)

Question	*Frequency*‡	*Percent*
15. How do you feel about the behavioral strategies?†*		
a. They were very helpful	107	71.3
b. They were somewhat helpful	39	26.0
c. They were not helpful	3	2.0
16. My level of confidence in managing *present* behaviors is:		
a. I am more confident since participating in study	126	84.0
b. I am about the same as when I started program	24	16.0
c. I am less confident than before	0	0.0
17. My level of confidence in managing *future* behaviors is:		
a. I am more confident since participating in study	134	89.3
b. I am about the same as when I started program	15	10.0
c. I am less confident than before	1	0.7
18. Would you recommend the behavioral intervention to other parents who have a child with aggression/ADHD?		
a. Definitely yes	142	94.7
b. Maybe	8	5.3
c. Probably not	0	0.0
d. Missing	0	0.0

*Missing at least one response

†Attending and rewards, planned ignoring, response cost, and time out were listed.

‡Eighteen parents did not complete the Patient Satisfaction Questionnaire (PSQ). This was usually because of early droping out and/or being lost to follow-up.

NCBRF, Nisonger Child Behavior Rating Form; CASI, Child and Adolescent Symptom Inventory; ADHD, attention-deficit/hyperactivity disorder.

Results

Subjects

In all, 168 children (77% male; mean age 8.9 ± 2.0 years) were randomized 1:1 to basic or augmented treatment. Roughly half of the children (53%) were parent-described white and 47% were non-white. There were 22 children (26%) in each condition with conduct disorder (CD) and 62 (74%) with oppositional defiant disorder (ODD). Although household income ranged from low to high, there was a predominance of low-income families in this study: < $20,000, $n = 33$ (39%) within basic and $n = 28$ (33%) within augmented; $20,000–40,000, $n = 16$ (19%) within basic and $n = 19$ (23%) within augmented.

In addition to 14 (basic = 3, augmented = 11) participants who dropped out before the end of week 3 (when RIS or placebo was first added), 3 children randomized to basic did not require the second drug (placebo) and 5 children randomized to augmented did not need the second drug (RIS) because of sufficient response to *initial* treatment. High percentages of both groups were judged as clinical responders (much or very much improved) as rated by blinded clinicians on the Clinical Global Impressions–Improvement scale (CGI-I) at end-point: 70% of participants within the basic condition and 79% of those in augmented (nonsignificant). Conversely, parents rated children in augmented as significantly more improved (effect size = 0.50) than those in basic on the D-Total score (primary outcome) and Social Competence subscale of the NCBRF-TIQ, and on the Reactive Aggression subscale of the Antisocial Behavior Scale (Brown et al. 1996).

In all, 150 participants (89% of the original sample) completed the PSQ: 77 from basic and 73 from augmented (of whom 8 did not receive risperidone because of sufficient response to basic treatment). Of the 18 families (7 in basic and 11 in augmented) who did not complete the PSQ, 15 left the study early. There were no statistically significant associations between failure to complete the PSQ and child diagnosis ($p = 1.0$), treatment assignment ($p = 0.455$), or baseline D-Total score ($p = 0.802$). There were significant differences between PSQ completers and noncompleters in disruptive behavior on scores at the last visit attended (respectively, mean D-Total = 15.51 [SD = 13.92] and 25.83 [SD = 19.45]; $t[19.15] = 2.19$, $p = 0.005$). PSQ noncompleters were also more likely be of minority ethnic status ($\chi^2[1] = 5.14$, $p = 0.023$). Associations between PSQ noncompletion and annual family income, child IQ, parental education, and public versus private schooling were all nonsignificant.

PSQ

Table 1 provides frequencies of parent responses to the 18 PSQ items. Overall, parents were highly satisfied with all aspects of the study, including visit frequency (Q-1): 89% ($n = 134$) rated this item as ''just right;'' and side effect assessments (Q-5): 93% ($n = 14$) rated this item ''just right.'' The majority of parents ($n = 147$, 98%) indicated that they would recommend the study to other families whose children struggled with similar problems (Q-6), and a high percentage ($n = 142$, 95%) endorsed the parent training (Q-18) for other parents of aggressive children. Importantly, 126 out of 150 parents (84%) reported that they felt more confident in managing their children's current aggressive behaviors since participating in the study (Q-16), and 89% indicated that they felt more confident in managing future aggressive behaviors (Q-17). A small number of parents (19%; $n = 28$) reported that there were aspects of the study they did not like (Q-8), but most (72%; $n = 108$) reported elements of the study that they especially did like (Q-9).

Aspects of study disliked by parents

Twenty-six parents wrote in responses to Q-8: ''Were there aspects of the study you did not like?'' (Table 2). The most frequent comments ($n = 9$) related to study burden on parents, as follows: 1) too many rating forms ($n = 3$), 2) visits too frequent ($n = 3$), 3) visits too long ($n = 2$), and 4) preference for longer visit intervals ($n = 1$).

Table 2. Aspects of Study that Parents Disliked

Item description	*Frequency*
Too many rating forms to be completed	3
Visits were too frequent	3
Would prefer different visit times so that child does not miss school	3
Visits too long	2
Long distance to study site/amount of travel	2
Dislike for some aspect of COPE	2
More information about what to expect before visits	1
Found COPE vignettes (video tapes) annoying	1
COPE too short	1
Blood draws	1
Trouble opening risperidone capsules (child unable to swallow pills)	1
Study did not last long enough (''to a conclusion'')	1
Allow more time between visits to witness more change	1
Study should guarantee opportunity to receive risperidone (most sites did)	1
Some questions did not make sense	1
Dissatisfaction with child care while parent interacted with study staff members	1

COPE, Community Parent Education Program.

The second-largest group of comments ($n=4$) related to COPE/PT, as follows: 1) dislike for some aspect of COPE ($n=2$), 2) perception of vignettes as annoying ($n=1$), and 3) sense that COPE was too short ($n=1$). Two families disliked the distance from their homes to the study site or the amount of travel. All other comments were limited to one respondent each and are listed in Table 2.

Aspects of study liked by parents. Table 3 summarizes aspects of the study that 108 parents especially liked. Sixty-four families identified COPE/PT as a part of the study that they valued.

Table 3. Aspects of Study That Parents Liked

Item description	*Frequency*
COPE; parent management training (PT)	64
Appreciation of a particular, named, team member	13
Counseling, added support*	10
Welcoming environment at clinical site; families embraced; respectful	8
Frequency of visits; weekly often mentioned	8
Close monitoring of treatment effects	8
Medications, further undefined	4
My child got much better	3
Access to doctors *beyond* study visits	2
Provision of new information (e.g., ADHD)	2
Everything; ''all areas covered''	2
Side effect assessments	1
Multiple disciplines involved	1
Medication assessment in controlled environment	1
''Tests'' at beginning and end of study	1
Thorough description of what to expect on next visit	1
PowerPoint slides	1
Snacks provided for child participants	1

*These entries suggested a level of counseling and coaching that extended beyond the boundaries of PT.

COPE, Community Parent Education Program; ADHD, attention-deficit/hyperactivity disorder.

Several parents ($n=13$) singled out one or more research staff members whom they especially appreciated. Ten parents referenced additional counseling that presumably extended beyond PT, and eight cited a welcoming/respectful environment at the clinical site. In contrast to the six who commented that visits were too frequent and/or lengthy, eight families mentioned the weekly visits as a positive aspect, and another eight liked the close monitoring of treatment effects. Four respondents made reference to study medications, but it was not clear what it was about the medications that they liked. All other positive features were cited by three or fewer parents.

Associations between child treatment response and parent satisfaction

We examined bivariate associations between child responder status (i.e., clinical responder vs. nonresponder) and three parent satisfaction outcomes: 1) Whether parents would recommend the study to other parents of aggressive children, 2) whether parents would join the study again, and 3) whether parents would recommend the behavioral intervention to other parents of aggressive children. So few parents chose the ''no'' or ''probably not'' response options for these PSQ items that the ''maybe'' and ''no'' responses were combined to enlarge the resulting cells for analysis. However, so few parents selected ''maybe/no'' on Q-6 (''Would you recommend this study to other parents who have children with similar problems?''), that the statistical analysis was not meaningful ($p=0.15$; Fisher exact test). For Q-7 (''Join the study again?''), 6 of 37 (16%) nonresponders might choose not to join the study again, whereas only 7 of 112 responders (6%) gave such a response ($p=0.09$; Fisher's exact test). There was no relationship between response and (Q-18) enthusiasm for behavior intervention ($p=0.63$; Fisher's exact test).

Associations between treatment assignment and parent satisfaction

Bivariate associations revealed no significant relations between assignment to one medication (STIM + placebo; basic) versus combined treatment (STIM + RIS; augmented) and parent satisfaction with the study using the same three outcomes described previously (i.e., Q-6, Q-7, Q-18; all $ps \geq 0.72$).

Associations between child treatment response and parent confidence in managing aggression

We examined bivariate associations between child responder status and parents' level of confidence in managing their children's current (PSQ Q-16) and future aggressive behaviors (PSQ Q-17). Response options were ''more confident since participating in the study,'' ''the same as before,'' and ''less confident than before'' (''same as'' and ''less than'' options were merged to increase cell size). We found significant associations between child responder status and parents' confidence in managing both current aggressive behaviors (χ^2 [1] = 13.38, $p=0.0009$] and future aggressive behaviors (χ^2 [1] = 9.61, $p=0.002$). A greater proportion of parents reported more confidence in managing their children's current aggressive behaviors if their children were treatment responders (90%) than if their children did not respond to treatment (65% of parents). Likewise, the same pattern held for parents' confidence in their ability to manage *future* aggressive behaviors; 94% of parents reported feeling more confident if their children were treatment responders than if they were not (76%).

Table 4. Associations between Child Demographics, Disruptive Behavior Diagnoses, Responder Status, and Parents' Confidence in Managing Current and Future Aggressive Behavior

Outcome: Parents' confidence in managing current aggressive behavior

	Beta	*SE*	*Wald*	p
Responder status	1.679	0.481	12.207	0.000
Diagnosis	−0.649	0.530	1.499	0.221
Child age	0.005	0.120	0.002	0.965
Child gender	−0.014	0.557	0.001	0.980
Child race	0.235	0.500	0.221	0.638

Outcome: Parents' confidence in managing future aggressive behavior

	Beta	*SE*	*Wald*	p
Responder status	1.684	0.568	8.776	0.003
Diagnosis	−0.600	0.632	0.901	0.342
Child age	−0.054	0.142	0.146	0.703
Child gender	0.436	0.711	0.376	0.540
Child race	0.700	0.622	1.265	0.261

Reference categories for both models: Responder status = "non-responder," diagnosis = oppositional defiant disorder (ODD), child gender = male, and child race = white.

Multivariate analyses were conducted to examine predictors of parent confidence in managing current and future aggressive behaviors in their children. In a logistic model using child responder status, disruptive behavior disorder diagnosis (ODD or CD), child age, gender, and race to predict parent confidence in managing their children's current aggressive behaviors, only child responder status emerged as a significant predictor (see Table 4). The child's response was positively associated with parents' confidence in managing aggressive behaviors. Similar results held for parents' confidence in managing children's future aggressive behaviors. Child responder status was the only significant multivariate predictor in the overall model, which was statistically significant ($\chi^2[5] = 11.03$, $p < 0.05$]. Of particular interest, type of disruptive behavior diagnosis (ODD vs. CD) was not a significant predictor of parent confidence in managing current or future aggressive behaviors.

Discussion

To the best of our knowledge, this is the first study of consumer satisfaction in pediatric psychopharmacology that involved typically developing children with severe physical aggression. As was the case in prior studies (Aman and Wolford 1995 [children with intellectual disability]; Tierney et al. 2007 [children with autistic disorder]; McAdam et al. 2002 [children with autism spectrum disorder and intellectual disability]), TOSCA results revealed positive parent appraisal of study procedures for their typically developing children (similar to those reported by parents of children with intellectual and developmental disability [IDD]). Prior studies have not found parent satisfaction linked to a positive clinical response or to randomization to any particular active treatment option. For example, Pelham and the Multi-Modal Treatment of ADHD (MTA) group found that the *highest* satisfaction levels occurred among parents whose typically developing children received behavior therapy, despite the fact that children who received STIM generally had more positive ADHD outcomes. Therefore, the norm appears to be that most parents involved in pediatric pharmacological research have a positive view of the experience. Until demonstrated otherwise, the evidence indicates high social validity in the form of participant approval for pediatric treatment research.

In the TOSCA study, there was no statistically significant relationship between treatment assignment (placebo vs. RIS) and parent satisfaction. It is important to remember that all study families received at least two active treatments, STIM and PT. The lack of significant relationship between treatment assignment and parent satisfaction suggests that other characteristics of the study (i.e., the elements common to basic and to augmented) may have been sufficient to overcome any negative reaction to being assigned to the control group. In any case, this is another parent satisfaction study showing *no difference* in levels of satisfaction between subjects assigned to placebo and augmented treatment conditions; this suggests that study participants are generally willing to accept a more limited treatment assignment possibility in the context of treatment research. Knowledge that they would receive additional treatment, if needed, after completing the controlled phase of the study, may have contributed to this lack of disparity in satisfaction. The finding that participants even in the control condition improved considerably may have also contributed to increased satisfaction.

Parents expressed willingness to join the study again regardless of how their child responded to treatment. This suggests that other characteristics of the study were perceived as helpful to parents regardless of outcome. Understanding which aspects of the treatment protocol were most likely to engage parents (such as detailed assessments, frequent visits with providers, positive relationship with study staff) has relevance to parent commitment in community mental health treatment.

Child responder status was significantly associated with parents' self-reported confidence in managing current and future aggressive behaviors, even when controlling for child demographic variables and diagnosis of ODD or CD (diagnosis was not independently related to parent confidence in managing aggressive behaviors). We do not know which aspects of child response were associated with increases in parent confidence or whether other aspects of the study, such as COPE/PT or positive relationships with study staff interacted with child response to account for these improvements. However, it is clear that most parents (84–89%) experienced increased confidence in managing their children's current and future aggressive behaviors after participating in the study. A future challenge is to identify barriers to and facilitators of parent confidence in behavior management, and to devise teaching strategies to enable them to become better agents of behavior change.

Whereas this type of information may appear in clinical and research journals, it seldom appears in bioethics journals. It should certainly be considered by institutional review boards (IRBs) when deliberating on pharmacological and psychosocial studies such as this. Recommendations for future research might include updating the Poling and LeSage (1995) article to determine the degree to which the collection of social validity has improved in pharmacological studies. Interestingly, despite a similar calling for social validation in the field of applied behavior analysis, the majority of studies published in behavior-analytic journals (e.g., *Journal of Applied Behavior Analysis, Behavior Modification*) still do not regularly include these types of data. Therefore, the lack of social validity data in psychopharmacology mirrors the same problem in applied behavior analysis.

Furthermore, our finding that PSQ noncompleters were more likely to come from ethnic minority backgrounds deserves exploration in future research. There is a substantial literature indicating that people from non-white ethnic backgrounds tend to prefer psychosocial and informal interventions over pharmacological treatments for psychiatric disorders (Ahmed and Bhugra 2007; Cabassa et al. 2007; Shefer et al. 2012). It is important to note, however, that *all* of the participants in this study agreed to receive both medication and psychosocial interventions for their children and that PSQ noncompletion was a result of study attrition rather than refusal to complete the measure. Whereas the literature on minority treatment preferences refers mainly to treatment initiation, the question in this study relates to treatment continuation. To our knowledge, no social validity studies have been conducted that focus on minority families' perceptions of participation in randomized controlled trials that provide both pharmacological and psychosocial interventions.

Limitations

This satisfaction study had several limitations. First, all treatments were free and participants were given stipends to offset the costs of travel and lost time at work. This made it easier for the families to participate fully in a multitherapeutic trial that might otherwise have been too expensive or time consuming for many participants. Although it is common research practice, this possibly influenced participant satisfaction. Second, for scientific reasons, the investigative sites had a vested interest in maintaining active and cordial contact with participants to a degree that may be incompatible with community-based care, which may have positively influenced parental ratings. However, that does not detract from the satisfaction with the research experience, it merely suggests an explanation. Third, and perhaps most importantly, the families in greatest difficulty tended to exit the trial early and were often lost to follow-up; the small minority (18 of 168) who did not contribute satisfaction ratings may well have had lower satisfaction than completers. We did attempt to determine if there were subject features associated with noncompletion of the PSQ. Noncompleters had higher total disruptive behavior scores than completers, and they included more minority participants. However, there was no association with family income, participant age or IQ, parents' educational level, or type of school attended. Nevertheless, the levels of satisfaction reported here were remarkably high and are the first on record from a notoriously difficult patient population. The results speak to the positive participant response when involved in a trial whose therapeutic components may well have exceeded those available in most communities.

Finally, with the exception of the MTA study (Pelham 1998), previous social validity studies have been conducted with children having developmental disabilities, many of whom were nonverbal. In this study, we did not seek input from the children themselves. This was an unfortunate oversight and a limitation, but also an important opportunity for future research.

Conclusions and Clinical Significance

Generalizing this study's findings to real-world settings offers some guidance to clinical practice and treatment implementation. The majority of participants were not only highly satisfied with the experience, but also indicated that they would enroll again if offered the choice. This exemplifies both the willingness of families to engage in pediatric psychopharmacological research and their ability to comply with the rigors of such studies. As noted by Aman and Farmer (2008), the available social validity studies suggest that pediatric psychopharmacological studies are *not* aversive to the children or their participating families. That remained true for this investigation, despite some onerous study demands, such as parent training sessions typically lasting 1–1.5 hours each, and the clinical and medical interviews consuming ∼1 hour weekly. Therefore, regardless of whether the venue was a research or an outpatient clinical setting, parents seeking assistance for their children's emotional and behavioral needs were generally satisfied with care that they considered to be of high quality.

In addition, parents of children with persistent symptoms in this study regarded themselves as less confident in their use of behavior management skills (from PT), as opposed to deeming the particular medication treatment to be suboptimal. Assessing the need for behavior management skills training and reinforcement as part of the treatment regimen for an aggressive child is therefore an important observation, especially when considering the disparity of services available to impoverished families (Zito et al. 2008), whose children are more likely to receive monotherapy with psychotropic medications and, historically, more numerous concomitant prescriptions (Raghavan et al. 2005; Fontanella et al. 2014). Finally, parents were clearly willing to invest the necessary but substantial time to avail themselves of the array of clinical services provided in this study.

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