Telephone-Based Mental Health Interventions for Child Disruptive Behavior or Anxiety Disorders: Randomized Trials and Overall Analysis

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Objective: Most children with mental health disorders do not receive timely care because of access barriers. These initial trials aimed to determine whether distance interventions provided by nonprofessionals could significantly decrease the proportion of children diagnosed with disruptive behavior or anxiety disorders compared with usual care. **Method:** In three practical randomized controlled trials, 243 children (80 with oppositional-defiant, 72 with attention-deficit/hyperactivity, and 91 with anxiety disorders) were stratified by *DSM-IV* diagnoses and randomized to receive the Strongest Families intervention (treatment) or usual care (control). Assessments were blindly conducted and evaluated at 120, 240, and 365 days after randomization. The intervention consisted of evidence-based participant materials (handbooks and videos) and weekly telephone coach sessions. The main outcome was mental health diagnosis change. **Results:** Intention-to-treat analysis showed that for each diagnosis significant treatment effects were found at 240 and 365 days after randomization. Moreover, in the overall analysis significantly more children were not diagnosed as having disruptive behavior or anxiety disorders in the treatment group than the control group (120 days: $\chi^2_1 = 13.05$, $p < .001$, odds ratio 2.58, 95% confidence interval 1.54–4.33; 240 days: $\chi^2_1 = 20.46$, $p < .001$, odds ratio 3.44, 95% confidence interval 1.99–5.92; 365 days: $\chi^2_1 = 13.94$, $p < .001$, odds ratio 2.75, 95% confidence interval 1.61–4.71). **Conclusions:** Compared with usual care, telephone-based treatments resulted in significant diagnosis decreases among children with disruptive behavior or anxiety. These interventions hold promise to increase access to mental health services. Clinical trial registration information—Strongest Families: Pediatric Disruptive Behaviour Disorder, http://www.clinicaltrials.gov, NCT00267579; Strongest Families: Pediatric Attention-Deficit/Hyperactivity Disorder, http://www.clinicaltrials.gov, NCT00267605; and Strongest Families: Pediatric Anxiety, http://www.clinicaltrials.gov, NCT00267566. J. Am. Acad. Child Adolesc. Psychiatry, 2011;50(11):1162–1172. **Key Words:** child attention-deficit/hyperactivity disorder, child anxiety disorder, tele-mental health, distance treatment, health service access

Approximately 15%[1] to 18%[2] of children have mental health problems that interfere with their daily functioning. However, only approximately 15% to 30% receive timely mental health services.[1] Treatment barriers (e.g., travel, time from work or school, financial burden, and stigma)[3,4] often trigger families to drop out before completing treatment. Services are rarely designed for the challenges (e.g., poverty and maternal depression) that prevent families from benefiting.[5]

Parent training for oppositional-defiant disorder (ODD) and attention-deficit/hyperactivity disorder (ADHD)[6-8] and cognitive behavioral therapy for anxiety[9] are evidence-based treatments that trained nonprofessionals[10] can provide. Media-based behavior-management interventions are effective in children and are strengthened by therapist support.[11] The authors developed a novel system, entitled Strongest Families, to provide mental health services for families with children diagnosed as having ODD,

ADHD, or anxiety disorders. Using the authors' call center, trained, nonprofessional coaches supervised by mental health professionals provided care using a handbook, instructional videos, and weekly telephone contacts without any face-to-face contact.[12] The interventions were family centered rather than health care professional centered[13] and designed to overcome many access barriers: no travel was required, appointments were at times convenient for the family, telephone interventions occurred in the comfort of families' homes, and missed appointments were followed up. The design was informed by advice received from consumers, clinical practitioners, and policymakers.[14] The goal was to determine in these preliminary pragmatic effectiveness trials whether treatment with Strongest Families would result in more children not being diagnosed as having disruptive behavior or anxiety disorders compared with usual care. In addition, these initial trials would establish feasibility and proof of concept of distance pediatric mental health delivery using nonprofessionals.

METHOD

Three single-center randomized trials for ODD, ADHD, and anxiety were conducted from May 2003 through September 2007. These practical effectiveness trials[15] attempted to reflect real-world conditions with outcomes of most clinical interest. Study participants were randomized in a 1:1 ratio to receive the Strongest Families intervention (treatment group) or usual care (control group). Outcomes were collected and scored blinded to group assignment. Protocols were approved by applicable Nova Scotia, Canada ethics review boards.

Participants and Procedures

In total 429 participants were referred (Figure 1) from Nova Scotia primary care sources (99% from family physicians and 1% from nurse practitioners) and completed a checklist of the symptoms of their disorder. Promotional activities included presentations, posters, brochures, and radio and televised announcements.[14] Referring agents were not paid. Participants were reimbursed for assessment time (i.e., Can$25 check or gift certificate).

Informed parental authorization was obtained by telephone. Telephone assent was obtained from children in the anxiety trial. Assent was not required for the ODD and ADHD trials because there was no direct contact between the child and study staff. Once the participant consented, baseline assessments were completed by telephone. If eligible, the participant was randomized into the appropriate trial (ODD, ADHD, or anxiety). After randomization, participants were informed of group placement by letter and telephone. The treatment group began the Strongest Families intervention and completed timed follow-up assessments. The control group completed the timed assessments only. Neither group was restricted from receiving alternative services during the study. Because the intervention approaches were distinctively different for behavior disorder versus anxiety, participants were permitted to participate in more than one trial if diagnostic criteria were met. Only one participant took part in the ODD and anxiety trials and one participant in the anxiety and ADHD trials. In both cases, the interventions occurred 1 year apart.

Study inclusion criteria were child age (3-7 years for ODD, 8-12 years for ADHD, and 6-12 years for anxiety), ability to speak and understand English, telephone access, 6-month symptom duration, a mild or moderate primary diagnosis with impairment in two or more domains determined by a Schedule for Affective Disorders and Schizophrenia—Present and Lifetime Versions (K-SADS-PL)[16] parental interview, and parental commitment to study requirements. Eligible anxiety diagnoses included generalized, separation, and social anxiety disorders and specific phobias. Medication stabilization for 1 month before baseline assessment was required. Table 1 presents demographic information.

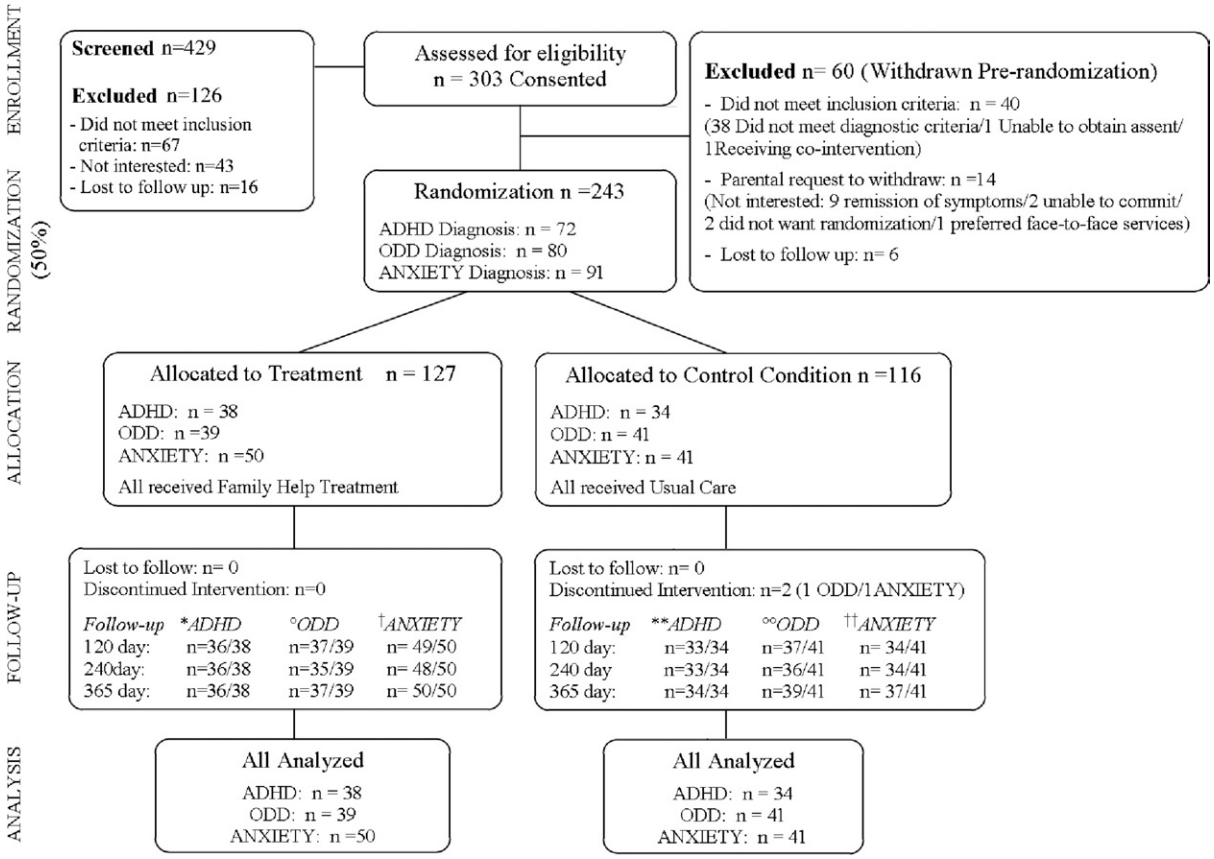
Exclusion criteria were a co-intervention (within 6 months) and disorder severity, including evidence of immediate danger to self or others; involvement with child protection authorities; autism, schizophrenia, or other psychosis; complex comorbidity; and serious cognitive delay. In Figure 1, the Consolidating Standards of Report Trials diagram outlines trial participation.

Randomization and Blinding

The randomization sequence was generated by a qualified delegate (at arm's length) using an equal treatment versus control ratio in blocks of 20 (10 units per condition). After allocating the first block, subsequent blocks were randomly selected from the remaining units until the original 20 blocks were allocated. Allocation assignment was concealed by sealed double envelopes. The investigator and study staff were blinded to allocation and block size. There were no randomization violations.

Although the manager, study staff, and study participants were not blinded to group assignment after randomization, assessment staff remained blinded. Outcome data were scored by a blinded psychologist not involved with the trial. Seven unblinding instances occurred (three in participants with ADHD, one in a participants with ODD, and three in participants with anxiety) at the beginning of assessment calls. When unblinding occurred, a different blinded assistant was assigned.

FIGURE 1 Strongest Families randomized clinical trial participant flow diagram: screening to completion (intention-to-treat analysis). Note: *Attention-deficit/hyperactivity disorder (ADHD) treatment: two participants missed the 120-day follow-up but completed the 240- and 365-day follow-ups; two participants refused the 240- and 365-day follow-ups but had completed the 120-day follow-up (reasons: not interested in continuing). **ADHD control: One participant missed assessments in the 120- and 240-day periods but completed the final assessment. °Oppositional-defiant disorder (ODD) treatment: one participant missed the 120-day but completed the 240- and 365-day follow-ups; one missed the 120- and 240-day follow-ups but completed the 365-day follow-up; one refused the 240- and 365-day follow-ups but had completed the 120-day follow-up (reasons: not interested in continuing); two missed the 240-day but completed the 120- and 365-day follow-ups; one missed the 365-day but completed the 120- and 240-day follow-ups. °°ODD control: One withdrew/discontinued intervention and did not complete the 120-, 240-, and 365-day follow-ups (reason: not interested in continuing); the remaining missed were different participants per period. †Anxiety treatment: one participant missed the 120-day but completed the 240- and 365-day follow-ups; two missed the 240-day but completed the 120- and 365-day follow-ups. ††Anxiety control: One withdrew/discontinued intervention and did not complete the 120-, 240-, and 365-day follow-ups (reason: not interested in continuing); two missed the 120- and 365-day follow-ups but completed the 240-day follow-up; three missed the 120- and 240-day follow-ups but completed the 365-day follow-up; one missed the 120-day but completed the 240- and 365-day follow-ups; one refused the 240- and 365-day follow-ups but completed the 120-day follow-up (reasons: not interested in continuing); two missed the 240-day but completed the 120- and 365-day follow-ups.



Treatment Group

The Strongest Families intervention was provided through handbooks, videos, and weekly protocol-defined telephone sessions from a coach. The intervention materials and video content were based on evidence and skill-focused learning. The telephone coach sessions included skill material review, skill modeling using role-playing and verbal examples, and problem-solving around the presenting issues, and focused on skill implementation. The anxiety program consisted of 11 sessions and the behavior programs had 12 sessions (Table 2). All programs had two follow-up booster calls at 2 and 4 months after treatment completion. The weekly coach session calls were on average 40 minutes. Calls were scheduled at the family's convenience. Participants could discontinue coaching

TABLE 1 Baseline Characteristics of Randomized Participants in Each Trial and Combined Sample

Characteristics	Total Sample (N = 243)		ODD[a,b] (n = 80)		ADHD[a,b] (n = 72)		Anxiety[b] (n = 91)	
	Treatment (n = 127)	Control (n = 116)	Treatment (n = 39)	Control (n = 41)	Treatment (n = 38)	Control (n = 34)	Treatment (n = 50)	Control (n = 41)
Child sex, n (%)								
Male (n = 149, 61.3%)	79 (62.2)	70 (60.3)	34 (87.2)	28 (68.3)	25 (65.8)	29 (85.3)	20 (40.0)	13 (31.7)
Female (n = 94, 38.7%)	48 (37.8)	46 (39.7)	5 (12.8)	13 (31.7)	13 (34.2)	5 (14.7)	30 (60.0)	28 (68.3)
Age of child (y), mean (SD)	7.61 (2.62)	7.33 (2.37)	4.82 (1.50)	5.02 (1.35)	8.87 (2.01)	8.91 (1.83)	8.82 (1.69)	8.32 (1.72)
Comorbid disorder,[c] n (%) (n = 117, 48.1%)	60 (47.2)	57 (49.1)	26 (66.7)	25 (61.0)	20 (52.6)	22 (64.7)	14 (28.0)	10 (24.4)
Prescription medicines, n (%) (n = 42, 17.3%)	22 (17.3)	20 (17.2)	3 (7.7)	2 (4.9)	19 (50.0)	17 (50.0)	0 (0)	1 (2.4)
Sex of primary caregiver, n (%)								
Female (n = 236, 97.1%)	124 (97.6)	112 (96.6)	39 (100)	40 (97.6)	37 (97.4)	34 (100)	48 (96.0)	38 (93)
Male (n = 7, 2.9%)	3 (2.4)	4 (3.4)	0 (0)	1 (2.4)	1 (2.6)	0 (0)	2 (4.0)	3 (7)
Age of primary caregiver (y), n (%)								
19–25 (n = 1, 0.4%)	0 (0)	1 (0.9)	0 (0)	1 (2.4)	0 (0)	0 (0)	0 (0)	0 (0)
26–35 (n = 61, 25.1%)	35 (27.6)	26 (22.4)	21 (53.8)	18 (43.9)	10 (26.3)	6 (17.7)	4 (8.0)	2 (4.9)
36–45 (n = 138, 56.8%)	72 (56.7)	66 (56.9)	18 (46.2)	18 (43.9)	24 (63.2)	20 (58.8)	30 (60.0)	28 (68.3)
>46 (n = 43, 17.7%)	20 (15.7)	23 (19.8)	0 (0)	4 (9.8)	4 (10.5)	8 (23.5)	16 (32.0)	11 (26.8)
Highest education level, n (%)								
Some high school (n = 34, 14.0%)	17 (13.4)	17 (14.7)	9 (23.1)	11 (26.8)	5 (13.2)	6 (17.6)	3 (6.0)	0 (0)
High school diploma (n = 63, 25.9%)	34 (26.8)	29 (25.0)	11 (28.2)	6 (14.6)	15 (39.5)	11 (32.4)	8 (16.0)	12 (29.2)
Vocational school (n = 40, 16.5%)	19 (15.0)	21 (18.1)	5 (12.8)	8 (19.5)	7 (18.4)	4 (11.8)	7 (14.0)	9 (22.0)
Some university (n = 3, 1.2%)	3 (2.3)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	3 (6.0)	0 (0)
University degree (n = 74, 30.5%)	37 (29.1)	37 (31.9)	11 (28.2)	15 (36.6)	10 (26.3)	12 (35.3)	16 (32.0)	10 (24.4)
Professional/graduate (n = 29, 11.9%)	17 (13.4)	12 (10.3)	3 (7.7)	1 (2.5)	1 (2.6)	1 (2.9)	13 (26.0)	10 (24.4)
Marital status, n (%)								
Married/common law (n = 168, 69.1%)	87 (68.5)	81 (69.8)	22 (56.4)	27 (65.9)	27 (71.1)	26 (76.5)	38 (76.0)	28 (68.3)
Single, separated, or divorced (n = 72, 29.7%)	39 (30.7)	33 (28.4)	17 (43.6)	13 (31.7)	11 (28.9)	7 (20.6)	11 (22.0)	13 (31.7)
Widowed (n = 1, 0.4%)	0 (0)	1 (0.9)	0 (0)	1 (2.4)	0 (0)	0 (0)	0 (0)	0 (0)
Refused to answer (n = 2, 0.8%)	1 (0.8)	1 (0.9)	0 (0)	0 (0)	0 (0)	1 (2.9)	1 (2.0)	0 (0)
Annual income, n (%)								
<$25,000 (n = 16, 6.6%)	8 (6.3)	8 (6.9)	2 (5.1)	4 (9.8)	4 (10.5)	1 (2.9)	2 (4.0)	3 (7.3)
$25,000–$45,999 (n = 35, 14.4%)	22 (17.3)	13 (11.2)	9 (23.1)	5 (12.2)	8 (21.1)	3 (8.8)	5 (10.0)	5 (12.2)
$46,000–$55,000 (n = 14, 5.8%)	4 (3.1)	10 (8.6)	2 (5.1)	4 (9.8)	0 (0)	5 (14.7)	2 (4.0)	1 (2.5)
>$55,000 (n = 44, 18.1%)	26 (20.5)	18 (15.5)	8 (20.5)	6 (14.6)	9 (23.7)	6 (17.7)	9 (18.0)	6 (14.6)
Unknown (n = 134, 55.1%)	67 (52.8)	67 (57.8)	18 (46.2)	22 (53.6)	17 (44.7)	19 (55.9)	32 (64.0)	26 (63.4)

Note: [a]*Suggestion of sex imbalance (oppositional defiant disorder (ODD):* $\chi^2 = 4.089$, p = .043).

[b]*Note the following age exceptions granted before randomization per Schedule for Affective Disorders and Schizophrenia—Present and Lifetime versions diagnosis: ODD, two older-age exceptions; attention-deficit/hyperactivity disorder (ADHD), 16 younger-age exceptions; and anxiety, none.*

[c]*Importantly, comorbid disorders were balanced among groups for ODD, ADHD, and anxiety (*$\chi^2 = 0.083$, p = .82; $\chi^2 = 0.279$, p = .64; $\chi^2 = 0.145$, p = .83). *All other comparisons were nonsignificant (*p > .10).

TABLE 2 Contents of the Treatment Programs

Session	Disruptive Behavior (ODD and ADHD) Module: "Parenting the Active Child"	Anxiety Module: "Chase Worries Away"
1	building relationships by noticing good behavior	introduction to anxiety: symptoms of anxiety
2	spreading attention around to more than 1 child (positive relationship building)	understanding anxiety: signs, triggers, avoidance, and escape
3	ignore whining and complaining	muscle tension relaxation
4	transitional warnings and when-then statements	relaxation using belly breathing
5	planning ahead to manage behavior during events in the home	mini-relaxation
6	charts and stickers: positive reward system	using imagination: creating a special place
7	time out	self-talk to control anxiety
8	planning ahead for when others are around	gradual exposure using a Worry List
9	losing points to decrease disruptive behavior patterns (ages 8–12 y)	role-playing and real-life exposure
10	working with the school	living with worry
11	problem solving	relapse prevention
12	put it all together: how to combine skills to deal with behavior as it occurs	NA

Note: ADHD = attention-deficit/hyperactivity disorder; NA = not applicable; ODD = oppositional-defiant disorder.

sessions but continue trial participation (five, two, and nine participants in the ODD, ADHD, and anxiety groups, respectively, discontinued the coach component). Calls were recorded for quality assurance. A subset of staff calls was randomly reviewed by a professional who provided additional training as needed. The focus of the intervention was on the primary diagnosis; comorbid conditions were not specifically targeted.

The Parenting the Active Child intervention (for families with children with ODD and ADHD) was based on the Community Parent Education Program parent training approach developed by Cunningham et al.[6,17] for large groups. Positive parenting strategies included Noticing the Good, Reward Systems, Time-out, and Problem-solving (Table 2). The Chase Worries Away intervention (for families with children with anxiety) was a cognitive behavioral approach teaching coping strategies combined with gradual exposure to feared stimuli. Coping skills included Positive Thinking, Belly-breathing, and Gradual Exposure (Table 2). Handbooks had a low reading level.[18] The videos were created by the authors and featured volunteer families (not study participants) of varied backgrounds. Behavior videos portrayed three ineffective parental responses to child behavior (errors) followed by skill demonstration (mastery).[6,17] Anxiety videos demonstrated coping skills, gradual exposure, and role-playing. Program materials may be available on request to Dr. Patrick J. McGrath.

Coaches reinforced the handbook and video content with the parent and/or child, helped the family solve problems, and provided encouragement. Coaches were selected for effective telephone skills, experience with families, and ability to follow protocol. All had undergraduate degrees and no professional training. Coaches were trained using problem-specific readings, telephone interviewing skills, review of audio-recorded sample calls, and role-playing mock sessions. Coaches handled approximately 25 cases at a time. A registered staff psychologist provided ongoing supervision through weekly case review. Issues were reviewed at biweekly group discussions, led by the senior author, a registered psychologist. Eight coaches were involved.

Control Group

Once randomized, the control participants received one call from the coach to review the randomization placement results and to inform the parent that the next contact from study staff would be at the 120-day follow-up time point to collect assessment data only. The control group did not receive any Strongest Families materials, coaching sessions, or intervention-related feedback from study staff. Control participants were contacted by study staff only to complete the follow-up assessments.

Outcome Measurements

The primary outcome was diagnosis based on a structured interview, the K-SADS-PL[16] (primary and comorbid diagnoses), and well-validated supplemental measurements conducted by telephone by a trained research assistant with the primary caregiver. The K-SADS-PL is designed to generate current and previous psychopathologic disorders in

children according to *DSM-III-R* and *DSM-IV* criteria. Diagnoses were used because they are a clinically relevant and stringent outcome criterion. Assessment calls were recorded for quality assurance. Staff obtained narrative examples to substantiate the ratings, which were evaluated by a psychologist who determined diagnoses. Data were verifiable by telephone recording.

Validated scales were used as supplemental measurements to corroborate the K-SADS-PL information. The supplemental data were collectively considered with the K-SADS-PL data by the psychologist and, if an item on the KSADS was equivocal, it was adjusted accordingly. The ODD and ADHD trials included parental reports with the IOWA Connors Rating Scale[19-21] and the Disruptive Behaviour Rating Scale–Revised.[22-24] The anxiety trial used the Multidimensional Anxiety Scale for Children[25-27] as a self-report measurement. These supplemental data were used to inform clinical diagnosis and are incorporated into the primary analysis. Therefore, the results of these measurements are not reported separately.

Assessments were scored by a blinded psychologist in a random sequence before analysis. Scoring was verified by another licensed professional, and discrepancies were dealt with by blindly re-releasing the assessment for psychologist scoring. This process was repeated until any diagnostic discrepancies were resolved.

Program adherence of the intervention group was monitored at each session. Satisfaction with the Strongest Families intervention was evaluated at the end of treatment by the intervention group using a researcher-designed questionnaire. It was administered by telephone by a research assistant who was not otherwise involved with the family. Participants were informed that their coach would not be informed of their responses.

For both conditions, medication and specialist services were recorded at follow-up.

Management and Follow-up

At follow-up, participants were asked questions to screen for possible serious adverse events. No serious adverse events were reported. Participants who deteriorated significantly were referred to the public mental health services but continued in the study.

Data Analysis

The primary analysis plan was determined a priori and conducted by a biostatistician blinded to the treatment assignment. A post hoc overall analysis of the three trials was then conducted. The primary outcome variable was a dichotomous designation of successful (no diagnosis) versus unsuccessful (diagnostic criteria still met).

Sample size estimates were calculated a priori to have 80% power ($\alpha = 0.05$) to detect a statistically significant treatment effect. Derived from previous studies, consideration for typical rates of improvement over time and the proportion of participants expected to be successfully treated were included in the calculations.[28] The expected rate of improvement for the control groups was 20%, and the anticipated successful treatment rates were 50% and 40%, respectively, for the behavior disorders and anxiety trials. The required sample sizes were 60 (for the ODD and ADHD trials) and 128 (for the anxiety trial).

Baseline characteristics were examined to evaluate group differences. Data were arranged into 2 (treatment condition: treatment versus control) × 2 (outcome: successful versus unsuccessful) tables for each time point (120, 240, and 365 days) and evaluated using a χ^2 statistic. The effect sizes are described using odds ratios. These evaluations were conducted separately for each treatment condition per time point. SPSS 16 (SPSS, Inc., Chicago, IL) was used with statistical significance set at $p < .05$ using two-sided tests; however, the exact p values are reported.

Program adherence and intervention satisfaction reports from the intervention group were tallied.

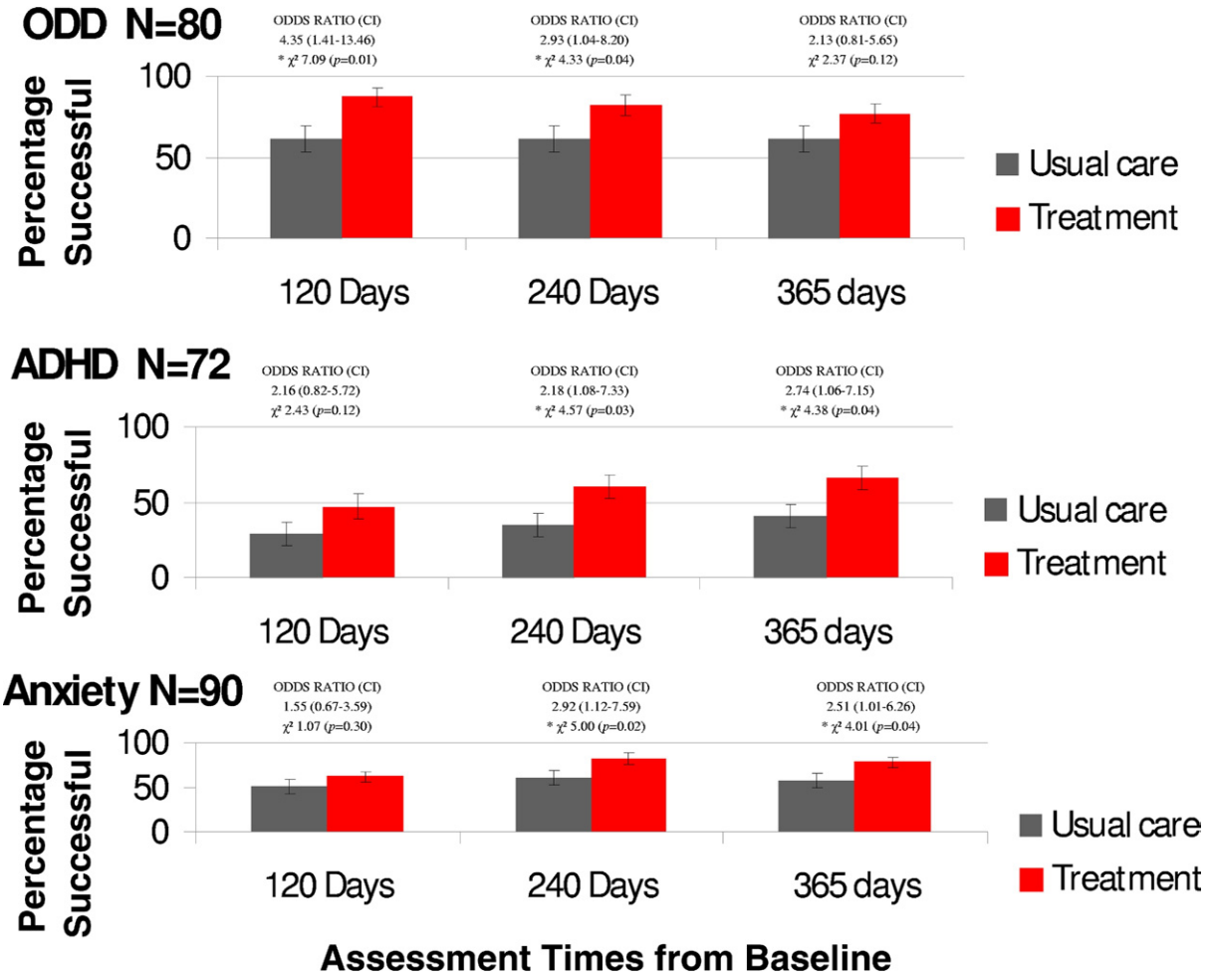
Missing Data

Given the small number and equal distribution of missing data per group in the overall, ODD, and ADHD analyses, there was minimal risk that missing data would influence the treatment effect. Therefore, replacement of all missed data points in each group with the designation "unsuccessful" (0) was deemed an appropriate strategy. However, the anxiety sample had an unequal group allocation of missing data, with more missing data in the control group. The strategy of assigning the value of "unsuccessful" to missing data in this case could favor the treatment group. Thus, an a priori conservative approach suggested by Proschan et al[29] was adopted. Specifically, for the control group, values of successful or unsuccessful were assigned to the missing observations based on the success ratio in the control group, whereas missing data in the treated group were conservatively replaced with unsuccessful scores. Figure 1 presents details on missing data.

RESULTS

No significant differences were found in the overall analysis sample among groups on any characteristics at baseline. Consistent with other epidemiologic and clinical data, the behavior disorder samples were 76.3% male compared with 63.7% female for the anxiety module. There was a sex imbalance between the ODD groups that was explored using logistic

FIGURE 2 Percentage successful (no diagnosis) with standard errors in the treatment and usual care groups across the three assessment times for the three separate trials (Schedule for Affective Disorders and Schizophrenia—Present and Lifetime plus corroborative data). Note: Attention-deficit/hyperactivity disorder (ADHD), oppositional-defiant disorder (ODD): Missed values were handled by replacement with unsuccessful values, which was considered a conservative approach owing to minimal missed data that presented no advantage to the treatment group. Anxiety: A conservative imputation strategy was used owing to an imbalance of missed data. Treatment indicates unsuccessful; a control value replaced with an imputed value was based on observed success rates in control cases with observed data. *Significant. CI = confidence interval.



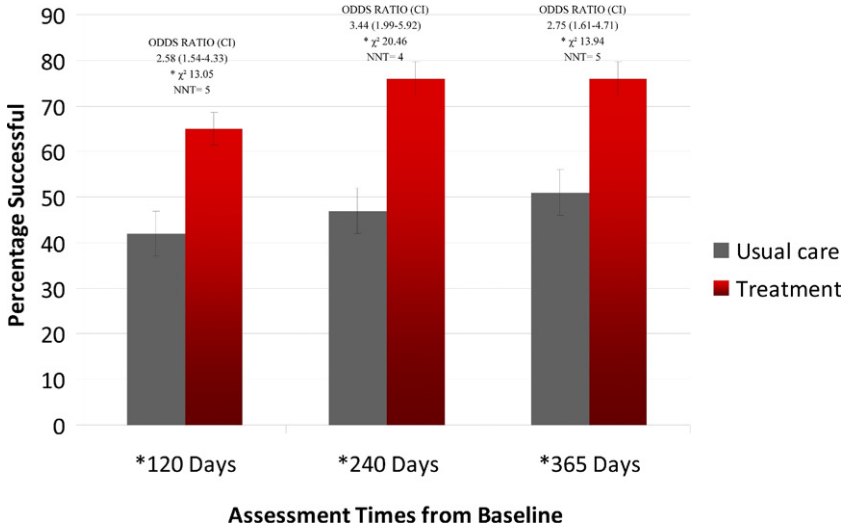
regression to control for sex by adding sex as a covariate before testing the treatment effect. The introduction of sex to the model did not materially change the outcome results, so the unadjusted results are reported. Approximately 50% of children presented with comorbid diagnostic conditions.

Ninety-seven percent of the primary caregivers were female, with 55.7% 36 to 45 years old. The dropout rate after randomization was lower than 10%. Some families missed some assessments (Figure 1). The mean (SD) treatment durations were 172.8 (67.1), 152.6 (50.4), and 152.6 (38.2) days for the ADHD, ODD, and anxiety groups, respectively.

At all time points and in all trials the success rates of the treatment group were higher than the control group (Figure 2), and often these differences reached conventional statistical significance. The combined results of the post hoc overall analysis (Figure 3) provided a secondary evaluation of the effects of the Strongest Families intervention. By combining the separate trial results, the treatment signal is clear.

Based on an intention-to-treat analysis, the results of the trials (Figure 2) are summarized

FIGURE 3 Percentage successful (no diagnosis) with standard errors in the treatment and usual-care groups across the three assessment times for the overall analysis (Schedule for Affective Disorders and Schizophrenia—Present and Lifetime plus corroborative data). *$p < .001$. Note: CI = confidence interval; NNT = number needed to treat; OR = odds ratio.



below, including material adherence of the treatment group:

- ODD: Statistically significant treatment effects were found at 120 and 240 days after randomization. Program adherence rates for the treatment group were 89% for session, 83% for video, and 80% for skill implementation completion.
- ADHD: Statistically significant treatment effects were found at 240 and 365 days after randomization but not at 120 days. Within the 240- to 365-day period (after randomization), there was a continued movement of participants from unsuccessful to successful in the treatment group, with minimal relapse in already successful (diagnosis-free) participants. Program adherence rates for the treatment group were 94% for session, 85% for video, and 81% for skill implementation completion.
- Anxiety: Statistically significant treatment effects were found at 240 and 365 days after randomization but not at 120 days. Similar to ADHD, participants continued to move to successful in the treatment group with minimal relapse. Program adherence rates for the treatment group were 95% for session, 86% for video, and 90% for skill implementation completion.
- End of treatment satisfaction measurements (Table 3) collected from the primary caregivers in the treatment groups were based on a 4-point Likert scale.

Using an intention-to-treat analysis on the combined sample, statistically significant treatment effects were found at all three assessment time points, indicating that children in the treatment group were more than 2.5 times more likely to be diagnosis free than the control group (Figure 3). The diagnosis incident rate was lower for the treatment group than for the control group at follow-up (e.g., combined sample 120-day treatment success, 65% versus 42%; odds ratio 2.58, 95% confidence interval 1.54-4.33, $\chi^2_1 = 13.05$, $p < .001$; number needed to treat = 5; Figure 3). On average, the number needed to treat with the Strongest Families intervention to prevent one additional occurrence of the primary mental health disorder was 5.

Prescription medication for the primary disorder was infrequent (except 50% of participants with ADHD were medicated at baseline) and equally distributed among groups at baseline (Table 1). Although use of alternative treatments was infrequent during the study, there was a tendency for the ADHD and ODD control participants to receive help from a mental health specialist or behavioral treatment more frequently than the treatment group (this effect was statistically significant at 120 and 240 days in the ADD group and at 365 days in the ODD group,

TABLE 3 Satisfaction Measurement Results (Score, Mean [SD])

Item Evaluated	Anxiety (n = 40)	ADHD (n = 32)	ODD (n = 32)
Coach was polite and helpful	4 (0)	4 (0)	4 (0)
Called you on time	4 (0)	3.94 (0.25)	4 (0)
Called you back quickly	3.75 (0.59)	3.84 (0.45)	3.91 (0.39)
Happy with the service	4 (0)	3.88 (0.34)	3.94 (0.25)
Parent handbook helpful	3.88 (0.33)	3.78 (0.49)	3.72 (0.52)
Child handbook helpful	3.85 (0.43)	NA	NA
Videotape helpful	3.32 (0.92)	3.38 (0.94)	3.59 (0.56)
Anxiety diary helpful	3.60 (0.59)	NA	NA
Relaxation videos helpful	3.32 (0.94)	NA	NA
Relaxation audio CD/cassette helpful	3.10 (0.93)	NA	NA
Behavior chart	NA	3.22 (0.94)	3.41 (0.80)

Note: ADHD = attention-deficit/hyperactivity disorder; NA = not applicable; ODD = oppositional defiant disorder.

$p < .05$). Participants with anxiety were unlikely to receive medication or alternative services. Supplemental treatments were not associated with success.

DISCUSSION

Strongest Families was effective in treating mild to moderate pediatric mental health disorders from a distance, with no face-to-face contact, and using nonprofessionals. The results suggest that the Strongest Families intervention is generally more effective than usual care and the benefits were sustained for 1 year.

Unlike the ODD trial in which treatment effects were strongest in the early follow-up phases, the ADHD and anxiety trial treatment effects were strongest at 240 days and continued to be found at the 1-year mark. Improvements were seen in the intention-to-treat analysis for the ADHD and anxiety treatment groups at 240 and 365 days after randomization, with the strongest effect at 240 days. Statistical significance was not achieved at 120 days in both trials, but the results are consistent with a positive treatment effect. Odds ratios indicated that the treatment groups were more than twice as likely to be successful as the control group at 120 days. The results in the ODD group indicated a strong, immediate treatment effect that weakened over time. Although the 365-day results did not reach conventional levels of significance, the ODD treatment group was more than twice as likely to be diagnosis free as the usual care control group at 1 year. The overall analysis showed statistically significant and strong positive treatment effects at all time points.

In the present power analysis, rates of 20% were expected for the control groups. Instead, the observed rates of improvement were higher than 50%, indicating an underestimation of the predicted spontaneous improvement rate. In addition, the anxiety study was somewhat disadvantaged because the final sample sizes (Figure 1) were smaller than the planned target enrollment numbers of 64 per group. Therefore, the significant effects and positive trends achieved in these trials are noteworthy.

A possible explanation for the nonsignificant findings for the ADHD and anxiety groups at 120 days is the average length of treatment that exceeded the assessment by 1 month. Treatment was delayed because of a flexibility in responding to family needs (e.g., holidays and sickness). The skills corresponding with 120 days were "losing points" (ADHD) and "gradual exposure" (anxiety), which are expected to elicit symptom escalation. Unlike the ADHD program, the "losing points" session was not applicable for the younger children with ODD.

The trials had a rigorously conducted randomized trial design, which included staff protocol adherence resulting in low treatment attrition rates and persistent treatment effects. Follow-up adherence may be related to the convenience of distance telephone intervention, convenient appointment times, and flexibility in scheduling. The limitations include that the study was conducted in a single center, and thus generalization to other regions should

be done cautiously. Diagnoses were made based on parental report (as is usually the case) that was obtained using a structured telephone interview, which is common in epidemiologic studies[30] and likely valid for clinical studies. Children in this trial met criteria for a clinical disorder but were not severely impaired. The control group probably did not engender the same expectations for improvement as did the treatment condition, given the attention provided to the intervention group. The usual-care control group represents a realistic comparison group at this early stage of the development of this alternate delivery system. However, a standardized attention control group would allow firmer conclusions about the effectiveness of the delivery system beyond attention. For this stage of research, the present delivery method with detailed treatment protocols showed improvement compared with usual-care services. Continued research will be conducted to establish effectiveness of this delivery model.

As important as positive treatment effects, families reported high satisfaction with the treatment. Most families were particularly positive about their telephone coach, quality of service, and program materials, and they would recommend Strongest Families to others. Similar findings were reported in an adjunct pilot study designed to explore the feasibility of a Web-based Strongest Families ODD intervention[31] and a subset of the present trial participants who took part in an adjunct student project exploring distance therapeutic alliance.[32-34] In the adjunct studies parents and children reported a strong therapeutic alliance with their telephone coach, which further validates the high level of customer satisfaction and acceptance of distance services.

In conclusion, the Strongest Families system of care decreased the proportion of children with diagnosed disruptive behavior or anxiety disorders, and this effect appeared to last for up to 1 year. Few children dropped out of the study, and the program was highly valued and widely accepted by families. Primary care–focused systems provided at a distance may be a promising solution for mental health care access issues. &

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