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Effect of Vergence/Accommodative Therapy on Attention in Children with Convergence Insufficiency: A Randomized Clinical Trial

CITT-ART Investigator Group

Abstract

Significance.—The results of this study suggest that clinicians providing vergence/accommodative therapy for convergence insufficiency in children should not suggest that such treatment will lead to improvements in attention when compared to placebo treatment.

Purpose.—Compare the effects of 16 weeks of vergence/accommodative therapy and placebo therapy on changes in attention for children in the Convergence Insufficiency Treatment Trial-Attention & Reading Trial (CITT-ART).

Methods.—310 children 9 to 14 years old with CI were assigned to receive treatment with office-based vergence/accommodative therapy or placebo therapy. Attention tests were administered at baseline and after 16 weeks of treatment. The primary measure of attention was the Strengths and Weaknesses of attention deficit hyperactivity disorder (ADHD) Symptoms and Normal Behavior Scale (SWAN). Other measures included the Swanson, Nolan, and Pelham checklist (SNAP-IV); the Homework Problems Checklist (HPC); and the d2 Test of Attention. Within and between-group differences are reported using Cohen's *d* effect sizes.

Results.—For the SWAN, there was no significant difference between the groups for the inattention scale parental-report (d=0.036: 95% Confidence Interval (CI) −0.21 to 0.28) or for the hyperactivity impulsivity scale parental-report (d=−0.003 95% CI −0.24 to 0.24). Similar results were found for teacher reports and the secondary measures (*d* estimates from −0.97 to +0.10). There were, however, large within group changes with $d \geq 1$ in both treatment groups for the SWAN, the HPC, and the d2 Test of Attention.

Conclusions.—These results suggest that vergence/accommodative therapy is no better than placebo therapy in improving attention. Large improvements in inattention, completing homework, and selective and sustained attention were found in each group. However, these improvements cannot be attributed to improvements in vergence and accommodation and are likely due to nonspecific effects of an intensive therapy regimen.

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Convergence insufficiency is a common binocular vision disorder that affects approximately 5% to 15% of school-aged children.[1–5] Compared with children who have normal binocular vision, children with convergence insufficiency report more somatic (e.g., sore eyes and headaches), visual (e.g., blur and double vision), and performance (e.g., loss of concentration, frequent need to reread, and difficulty remembering what is read) problems.[6, 7] In addition, on the Academic Behavior Survey, their parents report a greater than normal frequency of problematic behaviors when these children engage in schoolwork or homework, and they worry more about their children's school performance.[8]

Recent randomized clinical trials have shown that treatment with office-based vergence/accommodative therapy (henceforth referred to as vergence/accommodative therapy) is effective in improving clinical measures of convergence function and reducing somatic-, visual-, and performance-based symptoms in children with symptomatic convergence insufficiency.[9–12] In addition, successful or improved outcomes after treatment were associated with a reduced frequency of adverse academic behaviors and parental concern about reading and school work.[13] Recent studies have also found that improving convergence insufficiency can lead to improvements in attention. An open trial of vergence/accommodative therapy in 44 school-age children with symptomatic convergence insufficiency showed significant improvements in attention as measured by the Conners 3 ADHD (attention deficit hyperactivity disorder) Index and internalizing problems as measured by the Children's Behavior Checklist.[14] Greater improvements were observed for measures of inattention for the Conners 3 ADHD Index and for somatic complaints for the Children's Behavior Checklist. Lee et at al[15] reported that among school-age children with convergence insufficiency and ADHD those who had received 12 weeks of vergence therapy (n=8) showed significant improvements in vergence function and a reduction in attentional problems as measured by the Korea-ADHD Rating Scale compared to a no treatment group (n=8). However, both studies lacked a placebo control group.

The Convergence Insufficiency Attention and Reading Trial (CITT-ART), a multi-center, randomized clinical trial, was designed to determine if vergence/accommodative therapy resulted in improvements in reading and attention in 9- to 14-year-old children with symptomatic convergence insufficiency. Findings for reading comprehension the primary outcome of the overall trial and other reading tests were published elsewhere.[16] Herein we report on the measures of attention which were secondary outcome measures for the CITT-ART

The purpose of this aspect of the study was to compare the effect of 16 weeks of vergence/accommodative versus placebo therapy on measures of attention. The main secondary measures were teacher- and parent-rated attention as measured by the Strengths and Weaknesses of ADHD Symptoms and Normal Behavior (SWAN) rating scale.[17] Additional Secondary measures of attention included the Swanson, Nolan, and Pelham checklist for DSM-IV (SNAP-IV), Homework Problems Checklist (HPC) and the d2 Test of Attention.[18–20]

METHODS

The CITT-ART was supported through a cooperative agreement with the National Eye Institute (NEI) of the National Institutes of Health and conducted according to the tenets of the Declaration of Helsinki at 9 clinical sites (see Acknowledgements). The respective institutional review boards approved the protocol and Health Insurance Portability and Accountability Act (HIPAA) Authorization-compliant informed consent and assent forms. The parent or legal guardian of each participant gave written informed consent and written assent was obtained from each child. Study oversight was provided by an NEI-appointed independent data and safety monitoring committee (see Acknowledgements). The study is registered at www.clinicaltrials.gov (CITT-ART: NCT02207517, accessed 3.25.2020). The CITT-ART Manual of Procedures is available at https://u.osu.edu/citt/.

Participants

Children 9 to 14 years of age with symptomatic convergence insufficiency were recruited at participating clinical sites (See Table 1 for a comprehensive list of inclusion and exclusion criteria). The diagnosis of convergence insufficiency was made by a comprehensive eye examination and was consistent with our previous trials (Table 1).[6, 9,10,21,22]

Testing & Treatment Regimens

Children were randomized into the study within two weeks of determining their eligibility, at which time assessments of reading and attention were completed. It was required that school be in session for a minimum of 2 weeks prior to enrollment and that school still be in session at the time of the 16-week outcome visit (2-week window allowed at outcome). The study outcome measures asked about the child's current school performance from both the parent and the teacher. Certified CITT-ART investigators conducted the testing and were masked to participants' assigned treatment. Procedures for the CITT-ART have been described in detail elsewhere so the following description focuses on the assessments of attention.[12,16]

Enrolled children were randomly assigned, using a permuted block (3, 6, and 9) design stratified by site and balanced by parental report of ADHD (yes/no), in a 2:1 ratio to vergence/accommodative or placebo therapy using the REDCap (Research Electronic Data Capture)[23] system at the Ohio State University (Figure 1). Subjects were masked to treatment assignment. Both treatment regimens consisted of weekly, hour-long in-office therapy sessions for 16 weeks and assigned home reinforcement activities to be completed 15 minutes per day for 5 days per week as described in the CITT-ART Manual of Procedures.Vergence/accommodation therapy procedures have been described previously.[9,10] The placebo therapy was designed to appear similar to vision therapy procedures except that vergence or accommodation were not stimulated beyond that resulting from typical near viewing distances.[24,25] Placebo procedures included typical vergence therapy techniques that were altered to be performed monocularly rather than binocularly or had zero vergence demand. To simulate vergence/accommodative therapy, filter glasses were often worn and participants were told the glasses were to help the eyes work together as a team. There were protocolized objectives and goals that were conveyed to the participants; and therapists provided encouragement, feedback, and positive

reinforcement for motivational purposes. The placebo therapy is described in more detail in previous papers. It was not possible to mask the therapists but they were instructed on providing the therapy in a similar manner to each group.

Outcome Measures

For the overall CITT-ART, reading comprehension was the primary outcome measure and tests of attention were secondary outcome measures. However, among the four measures of attention, the key measure of interest was the SWAN Rating Scale. Thus, for purposes of this paper on attention, the SWAN is considered the primary outcome measure of attention, and the SNAP-IV, HPC and the d2 Test of Attention are secondary outcome measures of attention.

Primary Outcome Measure: SWAN Rating Scale

The SWAN rating scale for the assessment of attention deficit hyperactivity disorder symptoms was the primary measure of attention since our target population was selected for the presence of convergence insufficiency, not ADHD.[17, 26, 27] The SWAN assesses a person's ability to focus attention, control activity, and inhibit impulses based on an observer's responses to questions.(Table 2) It has 18-items that are scored using a balanced 7-point Likert scale (−3 = far above average, −2 = above average, −1 = slightly above average, 0= average, 1= slightly below average, 2 = below average, 3 = far below average). The SWAN allows attention to be assessed on a complete range from highly normal to highly abnormal for inattention and hyperactive/impulsivity types of ADHD.[17] In contrast to other ADHD rating scales where the questions are stated in terms of pathology (Often has difficulty sustaining attention in tasks or play activities), the SWAN states an ability (sustain attention on tasks or play activities) and asks the rater to decide if the child is above or below average. This approach allows for a wider range of scores and a more normal distribution. Research has found high internal consistency, with a mean Cronbach alpha score of 0.88.[26] In addition, reliability ranged from 0.72 to 0.90 in a group of school-aged children with a mean age of 75.7 months.[26] Raters are instructed to compare the subject to children of the same age who are from the same school and family settings.

In the present study, parents completed the SWAN rating scale at baseline and after 4, 8, 12, and 16 (primary outcome) weeks of therapy; teachers were asked to complete the SWAN at baseline and after the 16-week outcome visit. The parent was also asked if the child had a current diagnosis of ADHD and whether the child was on medications at the baseline, 4, 8, 12, and 16 week visits.

Secondary Attention Outcomes Measure: SNAP-IV, HPC, and d2 Test of Attention

The SNAP-IV is a widely used parent- and teacher-rated norm-referenced checklist rating scale that measures symptoms of ADHD.[20] Each of the 18 items is scored on a 0 to 3 scale (0 = not at all, 1 = just a little, 2 = pretty much, 3 = very much). This instrument has been used in previous treatment studies of ADHD. Using the SNAP-IV allowed us to compare our results to studies that used a four-point scale for assessing ADHD behaviors only in the abnormal range.[17, 28, 29] Parent completed the SNAP-IV at baseline and the 16-week outcome visit.

The Homework Problems Checklist (HPC) is a commonly used parent-report instrument for assessing a variety of behaviors integral to the successful completion of a child's homework.[18] Parents rate the frequency of 20 different homework completion behaviors on a 4-point Likert scale (0=never; 1=at times; 2=often; and 3=very often). The HPC measures two distinct aspects of homework performance, inattention/avoidance of homework and poor productivity/nonadherence with homework rules.[30] The instrument has excellent internal consistency, with Cronbach alpha coefficients ranging from 0.90 to 0.92.[18] The HPC was completed by the parents at the baseline and the 16-week outcome visits.

The d2 Test of Attention is a timed paper-pencil cancellation test of visual attention and text scanning. The test consists of 14 rows of 47 "d" or "p" letters where some letters have one or two hash marks either above or below them.[19] Children were instructed to cross out any letter "d" that had two hash marks above or below it (target) and were given 20 seconds to complete each row. The grader determines the total numbers of letters attempted (TN) by counting the number of letters from the beginning of the first line to the last letter marked. The number of omission and commission errors are subtracted from the TN score to determine the total number correctly marked (TC). Finally, the number of correctly crossed out d2s minus commission errors yields a continuous performance measure. The d2 Test of Attention was administered to each participant at baseline and at the 16-week outcome visit.

Data Analysis

All data analyses were performed using the SAS 9.3 software system (SAS Inc, Cary, NC) Descriptive statistics (means, standard deviations, frequency counts) for demographic characteristics, visual function findings, and baseline reading scores of participants were compared, by visual inspection, to assess the effectiveness of randomization in balancing the treatment arms. Factors that appeared to show a clinically meaningful between-group difference were identified as potential confounders in the subsequent analyses.

An intent-to-treat analysis that included all participants who completed the 16-week outcome was performed using an α-level of 0.05 to assess statistical significance. Hierarchical linear modeling techniques with a random effect for enrollment site were used. Multivariate models were constructed using forward selection (most significant in next) methodology. Variables were retained in the final model if they were significantly associated with the outcome or were determined a priori to be important for inclusion (e.g., baseline value of the outcome). Akaike's Information Criterion (AIC) was used to select the most appropriate parameterization of parent-reported ADHD (previous diagnosis or use of ADHD medications) to be retained in the final model. Any potential differential effect of ADHD status on group response was investigated by including an interaction term of group and ADHD status (i.e. moderator analysis) in the multivariable model. Additionally, treatment group interactions with all significant covariates were assessed for inclusion in the model. Cohen's *d* effect sizes (between-group difference divided by residual error from linear model) were calculated to quantify treatment effect. Between-group differences were determined such that positive values indicate greater improvement in the vergence/accommodative therapy group. Using Cohen's taxonomy, an effect size greater than 0.80 represents a large treatment effect, values between 0.50 and 0.80 a moderate effect, and

those less than 0.50 a small effect. Additional hierarchical linear modeling was used to compare the change in scales related to hyperactivity/impulsivity and inattention.

Due to previous studies finding large within group improvements in measures of attention following placebo treatments, we investigated whether children in the vergence/accommodative therapy and the placebo therapy groups made significant gains on the attention measures from baseline to the 16-week outcome visit.[31, 32] Group gains or improvements in variables of interest from baseline to outcome are indicated by within-group changes greater than zero. For each measure, the estimated residual error from the hierarchical linear model was used to determine significance of the mean within-group change and to calculate 95% confidence intervals (CI). The magnitude of mean within-group change was characterized by an effect size and associated 95% CIs using the estimated residual error and methodology that controls for the inherent correlation between two measures obtained from the same individual.[33]

Sample Size/Power Analysis

Although attention was not the primary outcome measure for the CITT-ART trial, sample size estimates were also completed for between-group comparisons for each SWAN subscale. To our knowledge, there are no published statistics (specifically an estimate of variability after treatment) for the SWAN subscales obtained from children with convergence insufficiency. Due to the limited amount of data on variability and/or clinically relevant between-group differences, sample size determination was performed to obtain a detectable effect size. While hierarchical linear modeling (HLM) was used to investigate the significance of a between-group difference, sample size calculations were performed using a two-sample t-test. Such a calculation results in a conservative estimate of the required sample size since the more sophisticated HLM will result in a more accurate estimate of effect (i.e., reduce estimate of standard error).

The desired magnitude of the effect size was determined from a study reported by Abikoff et al.[27] In that study, they reported an effect size of 0.43 using the parent-reported SWAN score and 0.34 using the teacher-reported SWAN score. Assuming a two-sided hypothesis and desired effect size of 0.35, a total sample size of 291 children (97 placebo therapy: 194 vergence/accommodative therapy) was required to achieve 80% power. The final sample size for the CITT-ART (n = 324) was based on the maximum number of participants required to address all study aims (comparison of reading and attention measures). Ranging from 293 to 296, the number of valid observations for SWAN parent-report, SNAP, HPC, and d2 Test of Attention are more than large enough to detect the 0.35 effect size. Due to a larger than expected missing data rate on the SWAN for teacher-reported ADHD behavior, the number of valid observations (203) increases the detectable between-group effect size to 0.41 (80% power).

RESULTS

Enrollment

Between September 2014 and March 2017, 311 participants were randomized at 9 clinical sites. The IRB excluded data from one participant determined ineligible after randomization, leaving 310 participants for analysis; of these 206 were assigned to vergence/accommodative therapy and 104 to placebo therapy (Figure 1). The mean (±SD) age of participants was 10.8 (±1.5 years) and 55% were female; 57.1% were white, 26.5% were African American, and 37.1% were Hispanic (Table 3). There were no clinically meaningful between-group differences in demographic and clinical measures at baseline (Table 3). The parents of 59 participants (19%) reported a previous diagnosis of ADHD: 21 were assigned to placebo therapy, constituting 20% of that group, and 38 were assigned to vergence/accommodative therapy, constituting 18% of that group (P=.71)

ADHD-related medications were defined as any FDA-approved stimulant, atomoxetine, or alpha-2 agonist. Among participants with parent-reported ADHD, 44% reported use of ADHD medications (42% among those assigned to vergence/accommodative therapy and 48% assigned to placebo therapy). Of the 86 (28%) children reported by their parents as taking medications during the study (54 vergence/accommodative therapy and 32 placebo therapy), CNS stimulants were reported most often. Among those with reported medication usage, 17 (31%) participants assigned to vergence/accommodative therapy and 11 (34%) assigned to placebo therapy group reported use of CNS stimulants. Within the medicated group, the parents of two participants reported use of ADHD medication but no previous diagnosis of such.

Study Visit Completion

Of the 310 participants, 303 (98%) completed the 16-week outcome examination (Figure 1). All 7 drop-outs occurred in the vergence/accommodative therapy group. Only 159 out of 4,921 (3.2%) scheduled therapy visits were missed, 3.1% in the vergence/accommodative therapy group and 3.4% of placebo therapy participants.

Completion of Attention Measures

In the vergence/accommodative group the parent-report survey completion rates ranged from 98% (202 of 206; SWAN Inattention subscale) to 100% (SNAP Inattention subscale). Similar results were observed in the placebo group, at baseline with response rates ranging from 97% (101 of 104; SWAN Inattention subscale) to 100% (SWAN Hyperactivity subscale and HPC score/subscales). These findings were also replicated at the Week 16 visit with 195 of 199 of the vergence/accommodative therapy group and 103 of 104 in the placebo therapy group completing the SWAN.

Obtaining teacher responses on the SWAN survey was more difficult. Teacher responses were obtained for 85% of participants in the vergence/ accommodative therapy group at both the baseline and Week 16 visits (176 of 206 at baseline; 170 of 199 at Week 16). In the placebo group, responses were obtained for 90 of 104 (87%) of participants at baseline and 88 of 104; (85%) at Week 16. Scores on the d2 Test of Attention were obtained from all

participants at both study visits with the exception of one missing result at baseline in the vergence/accommodation therapy group.

Attention Measures At Baseline

Baseline measures of attention for the SWAN, SNAP-IV, HPC, and the d2 Test of Attention are provided in Table 4. For this cohort of children with symptomatic convergence insufficiency, the scores were higher (i.e., greater symptoms) on the inattentive index compared with the hyperactive/impulsive index for both the SWAN and SNAP-IV parental reports. The teacher report on the SWAN showed a similar trend but had lower scores on each scale. Ratings for the participant group with a parental-report of a diagnosis of ADHD were more severe on the SWAN, SNAP-IV, and HPC compared with the group who did not have a parental-report of ADHD. For the d2 Test of Attention, the overall mean scores for the three measures were close to a standard score of 100, but these scores were worse for the group with the parental report of ADHD.

Changes in Parent- and Teacher-Reported Ratings of Attention Pre- to Post-treatment for the SWAN

The baseline and post-treatment means and 95% CI along with the within- and between-group effect sizes are listed in Table 5 for both therapy groups. The relationship between treatment groups and study visits was not influenced by ADHD status (i.e. no statistically significant interaction). However, presence of parent-reported ADHD was associated with an increase of 0.30 points (p = 0.032) in parent-reported SWAN inattentive index and 0.23 points ($P = 0.01$) in parent-reported SWAN hyperactivity index scores. No such effect of ADHD status was observed for teacher-reported SWAN scores ($P > .35$). When parental report ratings were examined, each group showed at least moderate improvements during the course of treatment with Cohen's d values ranging from 0.55 to 1.04. Moderate to small improvements (0.37 to 0.67) were observed when teacher responses were considered. The largest effect size was for the SWAN inattentive index for parental report for both the vergence/accommodative therapy and placebo therapy groups. However, the difference between groups was not significant.

Secondary Attention Outcomes Pre- to Post-treatment for the SNAP-IV

The baseline and post-treatment means and 95% CI along with the within and between group effect sizes are listed in Table 6 for both treatment groups. The parental-report SNAP-IV scores were similar to the SWAN, with the inattention index yielding higher pre-post effect sizes for both treatment groups. Parent-reported ADHD status was associated with an increase of 0.28 points ($P < 0.001$) on the SNAP-IV inattentive index and 0.17 points ($P = .026$) on the SNAP-IV hyperactivity index scores. Again, there was no significant difference between the groups for either the inattention or hyperactivity/impulsivity indexes.

Pre- to Post-treatment for the HPC

Results for the HPC total and poor productivity/non adherence to homework rules scores are shown by reported ADHD medication use because the initial analyses indicated that the relationship between change in total score and group assignment was affected by reported

use of medications typically prescribed to treat ADHD (i.e. a significant interaction) (Table 6). For children not taking ADHD medications, there were large pre-post effect sizes for the HPC total score for both the vergence/accommodative therapy and placebo therapy groups but there was little difference between the two groups. However, for children taking ADHD medications there was a large effect size for the vergence/accommodative therapy group but not the placebo therapy group with a significant between-group effect size of 0.88 (95% CI: 0.043 to 0.67). A similar trend was seen for the HPC poor productivity/non adherence to homework rules: although the vergence/accommodative group showed a small pre-post effect size (d=0.41) in the children with reported ADHD medication use, the placebo group actually showed worsening for those on ADHD medication, making a significant between-group effect size of 0.97 (95% CI: 0.12 to 1.76). For the HPC inattention/avoidance of homework subscale both groups showed large but similar effect sizes following treatment with an apparent increase of 1.8 points (P = .017) related to ADHD status.

Pre- to Post-treatment for the d2 Test of Attention

For the d2 Test of Attention both the vergence/accommodative therapy and placebo therapy groups showed large improvements in scores following treatment, with pre-post effect sizes ranging from 0.89 to 1.79, but no significant between-group differences. The relationship between treatment groups and study visits was not influenced by ADHD status (i.e. no statistically significant interaction). However, presence of ADHD medication usage was associated with an increase in total number attempted (beta = 3.34; P = .023) in number correct (beta = 3.54; p = 0.018) and in concentration performance (beta = 2.63; P = .26).

Pre- to Post-treatment for Clinical Symptoms and Signs of Convergence Insufficiency

The baseline and post-treatment means and 95% CI for symptoms associated with convergence insufficiency (CISS score) and clinical signs of convergence insufficiency are presented in Table 7. As was seen for other measures in this study, both groups showed large but similar improvements in the CISS scores with large effect sizes. In contrast, the pre- to post-treatment improvement in NPC break, PFV break, and accommodative amplitude were significantly greater in vergence/accommodative therapy than in placebo therapy.

Adverse Events

No adverse events were reported.

DISCUSSION

In this multicenter randomized clinical trial, 16 weeks of vergence/accommodative therapy was found to be no more effective than placebo therapy for improving parent- and teacher-ratings of attention as determined by our primary outcome measure of attention, the SWAN rating scale. Similar results were observed for the SNAP, HPC, and d2 Test of Attention. Consistent with the results from our single-arm unmasked trial using the Conners 3 ADHD Index,[14] there were significant improvements in attention following treatment with vergence/accommodative therapy and some of the pre-post effect sizes were large, consistent with placebo responses seen in studies of other novel treatments.[31,32] Indeed, the same magnitude of improvement was found in the placebo treatment group, indicating that the improved

ratings of attention and behavior cannot be attributed to the vergence/accommodative therapy, despite the fact that vergence/accommodative therapy was more effective than placebo in improving convergence insufficiency. Instead, the benefit can be attributed to non-specific effects (placebo expectations, maturation, etc), unintended specific effects of the placebo treatment on convergence insufficiency, or effects on attention that are common to the vergence/accommodative therapy and placebo therapy groups.

There were only previous two studies to our knowledge investigating changes in attention following therapy for children with converence insufficiency. In Borsting et al, we found an effect size of 0.58 on the Conners 3 ADHD Index following office based vergence/accommodative therapy in an open trial.[14] This result is at the lower end of effect sizes observed for the SWAN and SNAP-IV in the current study. In Lee et al, 16 children with convergence insufficiency and ADHD were equally divided into a treatment group of active vision therapy and a no treament group.[15] The treated group had a significantly greater reduction in the Korea Attention Rating Scale compared to the no treatment group. However, no effect size was given for the changes in attention. The current study did not find a greater treatment effect for children who had parent-report of ADHD and convergence insufficiency (i.e. no significant interaction). Both studies lacked a placebo group while the current study has added this component and found that sham treatment yielded similar improvement to office based vergence/accommodative therapy.

The improved attention ratings found after placebo therapy in the present study are consistent with other studies that have shown large positive effects on attention after placebo treatments with multiple office visits for children with ADHD. In a randomized trial evaluating the effects of vestibular stimulation using a novel comprehensive motion apparatus that required 36 treatment visits over 4 months, the researchers reported large improvements by parent ratings (Cohen's $d = 1.75$) and combined parental/teacher ratings ($d = 1.30$), and moderate effect sizes ($d = 0.64$) for teacher ratings on the SNAP-IV.[32] In a pilot, randomized clinical trial of neurofeedback for ADHD consisting of 40 treatment visits in a 3- to 5-month period, the parent-rated effect size was d >1.2 in the placebo group.[31] Thus, treatments for ADHD requiring parental commitment of resources to bring the child for multiple visits per week tend to elicit very strong parent-rated placebo responses.

We also investigated the possible positive impact of placebo therapy on convergence insufficiency as measured by changes in symptoms and clinical signs in a previous publication.[12] Large improvements in symptoms as measured by the CISS were similar between the two groups with pre-post effect sizes of 0.94 for vergence/accommodative therapy and 0.85 for placebo therapy. The placebo group also had large pre-post effect sizes for clinical measures of convergence. However, the effect sizes in the vergence/accommodative group were very large and significantly greater than those found in the placebo group. We cannot rule out that the unintended improvements in vergence and accommodation in the placebo therapy could account for some of the positive response in this treatment condition. Another possibility is that natural improvements in clinical signs and symptoms could have occurred in the placebo therapy group.

Although the vergence/accommodative therapy and placebo therapy regimens did not include procedures specifically directed at improving visual attention, it is possible that they shared some common elements that may have improved visual attention. Children in both groups were instructed repeatedly to keep targets clear and single during extended viewing periods. This may require the child to isolate a specific visual feature of the target of regard and attempt to sustain near viewing for a period of time, which may have provided practice in paying attention. These tasks were common to both therapy regimens, and required selective and sustained visual attention, which may have contributed to the large improvements that both groups demonstrated on the d2 Test of Attention after 16 weeks of treatment. It is possible that both the vergence/accommodative therapy and placebo therapy have an impact on improving selective and sustained attention as measured by the d2 Test of Attention. While short-term practice effects (1 week between measures) have been shown for the d2 Test of Attention, we could not find studies looking at practice effects over a longer term.[34] Therefore, we cannot rule out that the improvements on the d2 Test of Attention are due to a practice effect.

On on the SWAN, SNAP-IV, and d2 measures there was no interaction between the parental-report of ADHD or the use of ADHD medications and treatment effects. However, the changes in treatments were larger in vergence/accommodative therapy and placebo therapy for children with parent report of ADHD or use of ADHD medications. There was an exception to this trend, for the HPC where we did find an interaction between reported use of ADHD medications and responsiveness to vergence/accommodative and placebo therapies. For these children, vergence/accommodative therapy may have a greater treatment impact than placebo therapy. However, given the small number of children in this group and the problem of multiple tests, we should view this result with caution.

Particular strengths of our study design included a large sample size, randomization to treatment, a placebo-control group, masking of examiners and participants, and both parent and teacher ratings of attention and homework performance. The ineffectiveness of vergence/accommodative therapy in improving attention measures more than placebo therapy did not appear to be because of poor adherence with therapy or ineffectiveness of treatment for the target symptoms of convergence insufficiency. There were very few missed therapy visits and participant retention was excellent for both treatment arms, with no significant difference between active and placebo treatment groups. Limitations for the focus of this report included the lack of a rigorous research diagnosis of ADHD and limited number of teacher observations as compared to parental reports on the SWAN.

Clinical Implications

The results of this study suggest that clinicians providing vergence/accommodative therapy for the treatment of convergence insufficiency in children would find moderate to large improvements in measures of inattention (SWAN), completing homework (HPC), and selective and sustained attention (d2 Test of Attention). However, these improvements cannot be attributed to improvements in vergence and accommodation.

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The Convergence Insufficiency Treatment Trial – Attention & Reading Trial Investigator Group Clinical Sites

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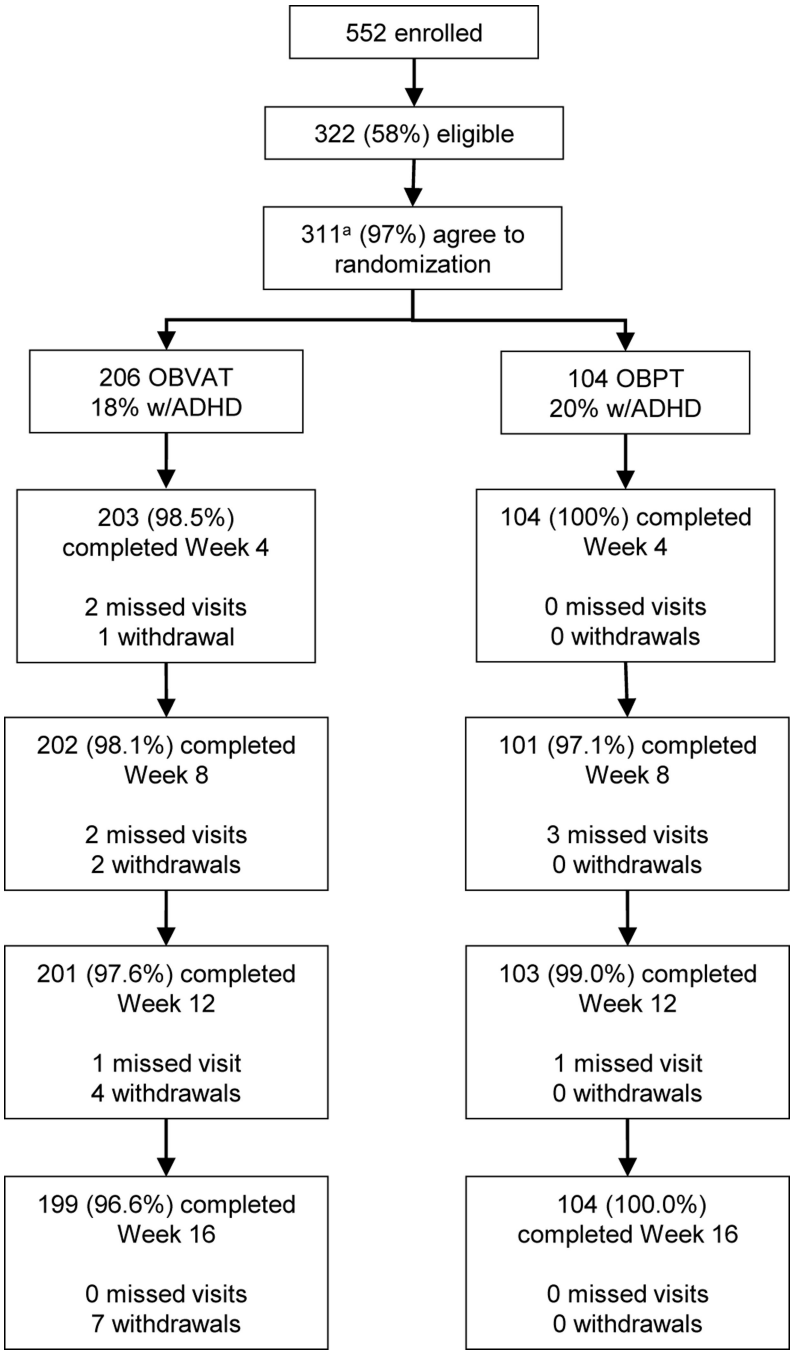

Figure 1.

Convergence Insufficiency Treatment Trial-Attention and Reading Flowchart.

aOne participant was randomized in error (determined to be eligible after randomization). Site's IRB insisted that no data collected beyond the baseline visit could be used.

Table 1

CITT-ART eligibility crite

Eligibility Criteria
1. Age 9 to 14 years
2. Grades 3 through 8
3. Convergence Insufficiency Symptoms Score (CISS) score ≥ 16
4. Exophoria at near at least 4Δ greater than at far
5. Receded near point of convergence (NPC) of ≥ 6 cm break
6. Insufficient positive fusional vergence (PFV) at near (i.e., failing Sheard's criterion or PFV ≤15Δ base-out break)
7. Best-corrected distance and near visual acuity of 20/25 or better in each eye
8. Random dot stereopsis appreciation of 500 s of arc or better
9. Willing to wear refractive correction for any of the following uncorrected, refractive errors (based on cycloplegic refraction within prior 6 months; correction must be worn for at least 2 weeks): Myopia > −0.75D spherical equivalent in either eye Hyperopia > +2.00D spherical equivalent in either eye Anisometropia > 0.75D spherical equivalent Astigmatism > 1.00D in either eye Refractive error corrections adhered to the following guidelines: full hyperopic sphere power or symmetrically reduced by no more than 1.50D, spherical equivalent myopia and spherical equivalent anisometropia within 0.75D of full correction, and astigmatism within 0.75D of full correction and axis within 6° for magnitudes of ≥ 1.00D
10. Not wearing BI prism or plus add at near for 2 weeks prior to study and for duration of study
11. The timing of enrollment must allow a participant to be attending school at both the baseline and the 16-wk outcome examination.
12. English is primary language spoken at home or child proficient in English as determined by the school
13. Parental permission to contact the child's teacher(s) for study purposes
14. Parent and child understand protocol and are willing to accept randomization
15. Parent does not expect child to start any new ADHD medicine or change the dose of any currently taken ADHD medicine while child is being treated in the study
Exclusion Criteria
1. Constant strabismus at distance or near
2. Esophoria of ≥ 2Δ at distance
3. Vertical heterophoria ≥ 2Δ at distance or near
4. ≥ 2 line interocular difference in best-corrected visual acuity
5. Monocular near point of accommodation >20 cm (accommodative amplitude <5D) as measured by push-up method
6. Manifest or latent nystagmus
7. Single-word decoding difficulties (associated with phonological-based reading disability or dyslexia) based on the Wide Range Achievement Test Word Reading subtest score < 80.
8. Kaufman Brief Intelligence Test (KBIT-2) Matrices subtest score <70 (excludes intellectual disability)
9. History of prior strabismus, intraocular, or refractive surgery
10. Convergence insufficiency previously treated with any form of office-based vergence/accommodative therapy or home-based vergence therapy (e.g., computerized vergence therapy)
11. Convergence insufficiency associated with head trauma or known disease of the brain
12. Diseases known to affect accommodation, vergence, or ocular motility such as multiple sclerosis, Graves orbitopathy, myasthenia gravis, diabetes mellitus, Parkinson disease
13. Inability to comprehend and/or perform any study-related test or therapy procedure
14. Speech-language disorder (e.g., stuttering) that would interfere with interpretation of digital recordings of reading tests

Eligibility Criteria	
15.	Significant hearing loss
16.	Household member enrolled in present CITT-ART or treated within the past 6 months with any form of office-based vergence/ accommodative therapy or home-based vergence therapy (e.g., computerized vergence therapy)
17.	Household member is an eye care professional, ophthalmic technician, ophthalmology or optometry resident, or optometry student

Table 2.

The SWAN Rating Scale.

Children differ in their abilities to focus attention, control activity, and inhibit impulses. For each item listed below, how does this child compare to other children of the same age? Please select the best rating based on your observations over the past month

Inattentive subscale	
1.	Give close attention to detail and avoid careless mistakes
2.	Sustain attention on tasks or play activities
3.	Listen when spoken to directly
4.	Follow through on instructions & finish school work/chores
5.	Organize tasks and activities
6.	Engage in tasks that require sustained mental effort
7.	Keep track of things necessary for activities
8.	Ignore extraneous stimuli
9.	Remember daily activities
Hyperactivity/Impulsivity subscale	
10.	Sit still (control movement of hands/ feet or control squirming)
11.	Stay seated (when required by class rules/social conventions)
12.	Modulate (control) motor activity (inhibit inappropriate running/climbing)
13.	Play quietly (keep noise level reasonable)
14.	Settle down and rest (control constant activity)
15.	Modulate verbal activity (control excess talking)
16.	Reflect on questions (control blurting out answers)
17.	Await turn (stand in line and take turns)
18.	Enter into conversations & games (control interrupting/intruding)

The 18-items are scored using a balanced 7-point Likert scale (−3 = far above average, −2 = above average, −1 = slightly above average, 0= average, 1= slightly below average, 2 = below average, 3 = far below average). Sub scale scores on the SWAN (Inattention and Hyperactivity/ Impulsivity) are calculated by summing the items and dividing by the number of items (e.g. 9 for each scale). Reprinted with permission from James Swanson, PhD.

Table 3.

Baseline Clinical and Demographic Characteristics by Treatment Group.

	Vergence/Accommodative Therapy (n = 206)	Placebo Therapy (n = 104)	Overall (n = 310)
Age (years) Mean (SD)	10.8 (1.5)	10.9 (1.4)	10.8 (1.5)
Convergence Insufficiency Symptom Survey score Mean (SD)	29.1 (8.5)	30.4 (8.8)	29.5 (8.6)
Exodeviation at distance (Δ) Mean (SD)	2.1 (2.9)	2.1 (3.5)	2.1 (3.1)
Exodeviation at near (Δ) Mean (SD)	9.9 (4.1)	10.0 (4.9)	9.9 (4.4)
Near Point of Convergence (cm) Mean (SD)	13.8 (7.9)	14.9 (8.1)	14.2 (8)
Near Point of Convergence recovery (cm) Mean (SD)	17.4 (8.7)	18.5 (8.6)	17.8 (8.7)
Positive Fusional Vergence Blur/Break (Δ) Mean (SD)	11.6 (4.3)	11.3 (4.1)	11.5 (4.2)
Female, No. (%)	123 (59.7%)	48 (46.2%)	171 (55.2%)
Hispanic or Latino, No. (%)	77 (37.4%)	38 (36.5%)	115 (37.1%)
Race, No. (%)			
Black or African American	52 (25.2%)	30 (28.8%)	82 (26.5%)
White	126 (61.2%)	51 (49.0%)	177 (57.1%)
Other	28 (13.6%)	23 (22.1%)	51 (16.5%)
Attention Deficit Hyperactivity Disorder – Parent report, No. (%)			
Based on previous diagnosis	38 (18.4%)	21 (20.2%)	59 (19%)
Based on use of ADHD medications	17 (8.3%)	11 (10.6%)	28 (9.0%)

SD = standard deviation; Δ = prism diopter; cm = centimeter

Table 4.

Baseline scores of measures of attention, overall group and by ADHD status.

Scale		Overall		no ADHD		ADHD	
		n	Mean (SD)	n	Mean (SD)	n	Mean (SD)
SWAN Parent-report	Inattentive	303	0.21 (1.1)	245	0.01 (1.10)	58	1.05 (0.8)
	Hyperactivity/ Impulsivity	308	−0.29 (1.1)	250	−0.44 (1.1)	58	0.37 (1.01)
SWAN Teacher-report	Inattentive	258	0.0 (1.2)	207	−0.24 (1.2)	51	0.98 (0.9)
	Hyperactivity/ Impulsivity	254	−0.60 (1.3)	203	−0.78 (1.2)	51	0.10 (1.2)
SNAP Parent-report	Inattentive	306	1.11 (0.7)	248	0.97 (0.7)	58	1.69 (0.6)
	Hyperactivity/ Impulsivity	305	0.62 (0.6)	248	0.52 (0.5)	57	1.06 (0.7)
Homework Problems Checklist	Total score	309	19.8 (13.4)	250	17.63 (12.8)	59	28.71 (11.8)
	Inattention/ Avoidance of Homework	309	14.46 (9.4)	250	13.02 (9.1)	59	20.58 (8.2)
	Poor Productivity/ Nonadherence with Homework Rules	309	4.62 (4.5)	250	3.98 (4.2)	59	7.32 (4.8)
d2 Test of Attention	Number Attempted	306	100.89 (10.5)	247	101.16 (10.5)	59	99.75 (10.8)
	Number Correct	306	102.50 (11.3)	247	103.01 (11.1)	59	100.51 (12.2)
	Concentration Performance	304	103.02 (13.0)	245	104.12 (13.0)	59	98.47 (11.8)

Strengths and Weaknesses of ADHD Symptoms and Normal Behavior (SWAN), Swanson, Nolan, and Pelham (SNAP), Homework Problems Checklist (HPC)

Table 5.

Parent- and teacher reported SWAN outcomes: Mean (95% CI) at baseline and outcome visit, by group.

Scale	Group	n	Baseline	Week 16[†]	Cohen's *d* (95% CI)	
					Within-group[a]	Between-group[b]
SWAN Inattentive: Parent-report	V-A[c] Therapy	195	0.26 (0.11 to 0.41)	−0.22 (−0.33 to −0.12)	1.00 (0.79 to 1.21)	−0.036 (−0.28 to 0.21)
	Placebo Therapy	99	0.11 (−0.09 to 0.31)	−0.24 (−0.39 to −0.09)	1.04 (0.75 to 1.34)	
SWAN Hyperactivity/ Impulsivity: Parent-report	V-A Therapy	195	−0.31 (−0.46 to −0.16)	−0.54 (−0.66 to −0.43)	0.55 (0.35 to 0.76)	0.003 (−0.24 to 0.24)
	Placebo Therapy	102	−0.19 (−0.40 to 0.02)	−0.54 (−0.70 to −0.38)	0.55 (0.27 to 0.83)	
SWAN Inattentive: Teacher-report	V-A Therapy	133	−0.03 (−0.25 to 0.19)	−0.28 (−0.41 to −0.15)	0.50 (0.26 to 0.75)	−0.102 (−0.39 to 0.19)
	Placebo Therapy	70	−0.03 (−0.33 to 0.26)	−0.36 (−0.54 to-0.18)	0.67 (0.33 to 1.01)	
SWAN Hyperactivity/ Impulsivity: Teacher-report	V-A Therapy	129	−0.72 (−0.95 to −0.50)	−0.87 (−1.01 to −0.74)	0.40 (0.15 to 0.65)	0.032 (−0.26 to 0.32)
	Placebo Therapy	73	−0.55 (−0.85 to −0.24)	−0.85 (−1.03 to −0.67)	0.37 (0.04 to 0.69)	

[†]Adjusted means and confidence intervals reported at Week 16.

[a]Calculated as Baseline visit minus Week 16 visit.

[b]Calculated as Week 16 outcome of Placebo Therapy minus V-A Therapy divided by common standard error.

[c]V-A stands for vergence/accommodation

Table 6.

Parent-reported attention and homework outcomes: Mean (95% CI) at baseline and outcome visit, by group.

Scale	Group	n	Baseline	Week 16[†]	Cohen's *d* (95% CI) Within-group[a]	Cohen's *d* (95% CI) Between-group[b]
SNAP Inattentive: Parent-report	V-A[C] Therapy	182	1.12 (1.01 to 1.23)	0.80 (0.73 to 0.87)	0.82 (0.61 to 1.04)	−0.083 (−0.33 to 0.17)
	Placebo Therapy	95	1.08 (0.95 to 1.21)	0.76 (0.67 to 0.85)	1.00 (0.70 to 1.31)	
SNAP Hyperactivity/ Impulsivity: Parent-report	V-A Therapy	190	0.62 (0.53 to 0.71)	0.44 (0.38 to 0.49)	0.65 (0.45 to 0.86)	0.071 (−0.17 to 0.31)
	Placebo Therapy	100	0.66 (0.54 to 0.78)	0.46 (0.39 to 0.54)	0.55 (0.27 to 0.83)	
Homework Problems Checklist (HPC) Total Score	*No reported use of ADHD medications*					
	V-A Therapy	181	19.41 (17.41 to 21.41)	12.80 (11.75 to 13.85)	1.65 (1.41 to 1.89)	0.085 (−0.16 to 0.33)
	Placebo Therapy	95	17.32 (15.02 to 19.62)	13.18 (11.70 to 14.65)	1.87 (1.52 to 2.21)	
	Reported ADHD medication use					
	V-A Therapy	17	29.94 (23.71 to 36.17)	24.11 (17.79 to 30.43)	1.33 (0.59 to 2.07)	0.88 (0.043 to 1.67)
	Placebo Therapy	10	31.30 (23.18 to 39.42)	27.97 (20.03 to 35.91)	0.30 (−0.58 to 1.19)	
HPC Inattention/ Avoidance of Homework	V-A Therapy	198	14.72 (13.38 to 16.06)	10.13 (9.36 to 10.91)	1.57 (1.34 to1.79)	0.095 (−0.14 to 0.33)
	Placebo Therapy	103	14.05 (12.27 to 15.83)	10.44 (9.36 to 11.52)	1.60 (1.29 to 1.92)	
HPC Poor Productivity/ Nonadherence with Homework Rules	*No reported use of ADHD medications*					
	V-A Therapy	181	4.64 (3.94 to 5.34)	2.83 (2.46 to 3.19)	1.21 (0.98 to 1.43)	0.087 (−0.16 to 0.34)
	Placebo Therapy	95	3.61 (2.90 to 4.32)	2.96 (2.45 to 3.47)	1.01 (0.71 to 1.32)	
	Reported ADHD medication use					
	V-A Therapy	17	7.71 (5.14 to 10.28)	7.01 (4.57 to 9.45)	0.41 (−0.27 to 1.09)	0.97 (−0.12 to 1.76)
	Placebo Therapy	10	8.00 (5.15 to 10.85)	8.53 (5.47 to 11.60)	−0.35 (−1.19 to 0.50)	
d2 Test of Attention: Total number attempted	V-A Therapy	197	101.83 (100.3 to 103.4)	107.02 (106.0 to 108.0)	1.16 (0.95 to 1.38)	−0.14 (−0.38 to 0.10)
	Placebo Therapy	100	99.55 (97.6 to 101.5)	108.03 (106.6 to 109.5)	1.31 (1.00 to 1.61)	
d2 Test of Attention: Number correct	V-A Therapy	197	103.37 (101.7 to 105.0)	109.99 (108.9 to 111.0)	1.53 (1.30 to 1.75)	−0.20 (−0.44 to 0.041)
	Placebo Therapy	101	101.31 (99.2 to 103.4)	111.48 (110.0 to 112.9)	1.79 (1.46 to 2.11)	
d2 Test of Attention: Concentration performance	V-A Therapy	195	104.17 (102.2 to 106.2)	112.03 (110.4 to 113.7)	0.89 (0.68 to 1.10)	−0.13 (−0.37 to 0.11)
	Placebo Therapy	100	101.25 (99.2 to 103.4)	113.55 (111.2 to 115.9)	1.11 (0.81 to 1.41)	

[†]Adjusted means and confidence intervals reported at Week 16.

[a]SNAP & HPC: Calculated as Baseline minus Week 16 visit; d2 Test of Attention: Calculated as Week 16 minus Baseline visit.

[b] SNAP & HPC: Calculated as Week 16 outcome of Placebo Therapy minus V-A Therapy divided by common standard error; d2 Test of Attention: Calculated as Week 16 outcome of V-A Therapy minus Placebo Therapy divided by common standard error.

[c] V-A stands for vergence/accommodation

Table 7.

Change in clinical symptoms and signs of CI, by Group Mean (95% CI).

			Cohen's *d*	
Clinical symptom/sign	**Group**	**Adjusted change[a]**	**Within Group[a]**	**Between Group[b]**
Convergence Insufficiency Symptom Score (CISS)	V-A Therapy (n=199)	11.8 (10.3 to 13.4)	0.94 (0.73 to 1.15)	0.14 (−0.093 to 0.38)
	Placebo Therapy (n=104)	10.4 (8.4 to 12.4)	0.85 (0.57 to 1.14)	
Near Point of Convergence (NPC; cm)	V-A Therapy (n=198)[π]	10.4 (9.6 to 11.3)	2.36 (2.11 to 2.62)	0.99 (0.74 to 1.24)
	Placebo Therapy (n=104)	6.2 (5.2 to 7.2)	0.94 (0.65 to 1.22)	
Positive Fusional Vergence (PFV, Δ)	V-A Therapy (n=198)[π]	23.2 (20.8 to 25.6)	3.88 (3.42 to 4.35)	1.48 (1.21 to 1.77)
	Placebo Therapy (n=104)	8.8 (6.1 to 11.5)	1.46 (1.15 to 1.77)	
Accommodative Amplitude (D)	V-A Therapy (n=198)[π]	6.5 (5.0 to 8.0)	1.48 (1.25 to 1.70)	0.50 (0.26 to 0.74)
	Placebo Therapy (n=104)	2.5 (0.7 to 4.4)	0.47 (0.19 to 0.75)	

[a] Change from Baseline visit; Calculated such that values greater than zero indicate improvement.

[b] Calculated as change from Baseline to Week 16 of V-A Therapy minus Placebo Therapy divided by common standard error.

[π] Missing data for one participant.

[c.] V-A stands for vergence/accommodation