

Randomized Clinical Trial of Treatments for Symptomatic Convergence Insufficiency in Children

[Convergence Insufficiency Treatment Trial Study Group*](#)

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ABSTRACT

Objective To compare home-based pencil push-ups (HBPP), home-based computer vergence/accommodative therapy and pencil push-ups (HBCVAT+), office-based vergence/accommodative therapy with home reinforcement (OBVAT), and office-based placebo therapy with home reinforcement (OBPT) as treatments for symptomatic convergence insufficiency.

Methods In a randomized clinical trial, 221 children aged 9 to 17 years with symptomatic convergence insufficiency were assigned to 1 of 4 treatments.

Main Outcome Measures Convergence Insufficiency Symptom Survey score after 12 weeks of treatment. Secondary outcomes were near point of convergence and positive fusional vergence at near.

Results After 12 weeks of treatment, the OBVAT group's mean Convergence Insufficiency Symptom Survey score (15.1) was statistically significantly lower than those of 21.3, 24.7, and 21.9 in the HBCVAT+, HBPP, and OBPT groups, respectively ($P < .001$). The OBVAT group also demonstrated a significantly improved near point of convergence and positive fusional vergence at near compared with the other groups ($P \leq .005$ for all comparisons). A successful or improved outcome was found in 73%, 43%, 33%, and 35% of patients in the OBVAT, HBPP, HBCVAT+, and OBPT groups, respectively.

Conclusions Twelve weeks of OBVAT results in a significantly greater improvement in symptoms and clinical measures of near point of convergence and positive fusional vergence and a greater percentage of patients reaching the predetermined criteria of success compared with HBPP, HBCVAT+, and OBPT.

Application to Clinical Practice Office-based vergence accommodative therapy is an effective treatment for children with symptomatic convergence insufficiency.

Trial Registration clinicaltrials.gov Identifier: [NCT00338611](#)

INTRODUCTION

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Convergence insufficiency (CI) is a common binocular vision disorder¹⁻⁴ that is often associated with a variety of symptoms, including eyestrain, headaches, blurred vision, diplopia, sleepiness, difficulty concentrating, movement of print while reading, and loss of comprehension after short periods of reading or performing close activities.⁵⁻¹³

Various treatments^{10, 14-23} are commonly prescribed, including passive treatment with base-in prism reading glasses and active treatment, such as home-based therapy using pencil push-ups (HBPP) alone, home-based therapy using pencil push-ups plus other therapy techniques, office-based vision therapy, and orthoptics. Consensus regarding the most effective treatment is lacking and there are considerable differences among treatments in time and cost. Recent studies that surveyed the ophthalmic community suggest that HBPP is the most commonly prescribed treatment by both ophthalmologists and optometrists for young patients with symptomatic CI.²⁴⁻²⁶

Active therapies for the treatment of symptomatic CI typically involve the purposeful, controlled manipulation of target blur, vergence demand, and/or target proximity with the aim of normalizing the accommodative and vergence systems and their mutual interactions.²⁷ The various active treatment approaches for CI differ in their (1) ability to control and manipulate stimulus parameters (eg, vergence and accommodative demand), (2) dosage, (3) mode of administration, and (4) use of motor learning theory and patient feedback. It is unknown, however, whether these differences affect the outcome of treatment.

Until recently, there has been a scarcity of rigorously performed scientific studies that document the effectiveness of treatments for CI. In preparation for our randomized clinical trial, the Convergence Insufficiency Treatment Trial (CITT) Study Group completed 2 pilot studies that were placebo-controlled, randomized trials investigating the effectiveness of passive and active treatments for symptomatic CI in children.²⁸⁻²⁹ In the trial that evaluated the effectiveness of base-in prism reading glasses prescribed according to Sheard's criterion (convergence amplitudes less than twice the near phoria),³⁰ prism glasses were found to be no more effective than placebo reading glasses.²⁸ The other randomized trial that compared the effectiveness of HBPP, office-based vision therapy/orthoptics, and office-based placebo vision therapy/orthoptics found office-based vision therapy/orthoptics to be more effective than pencil push-ups or placebo therapy in improving both the signs and symptoms associated with CI.²⁹ A limitation of the latter study was a 19% (9 of 47) loss to follow-up before treatment completion. In addition, it was suggested that a more intensive home-based vision therapy/orthoptics regimen should have been included as a treatment arm.³¹

The purpose of this randomized clinical trial was to further evaluate the commonly used active treatments for CI. We compared the effectiveness of 12 weeks of treatment using HBPP, home-based computer vergence/accommodative therapy and pencil push-ups (HBCVAT+), office-based vergence/accommodative therapy with home reinforcement (OBVAT), and office-based placebo therapy (OBPT) in improving symptoms and signs associated with symptomatic CI in children.

METHODS

We followed the tenets of the Declaration of Helsinki throughout the study. The institutional review boards of all participating centers approved the protocol and informed consent forms. The parent or guardian (subsequently referred to as *parent*) of each study patient gave written informed consent and each patient assented to participation. There was an initial consent process for performing an eligibility examination followed by a second consent for the enrollment and randomization of eligible patients into the trial. Health Insurance Portability and Accountability Act authorization was obtained from parents. Study oversight was provided by an independent data and safety monitoring committee.

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PATIENT SELECTION

Major eligibility criteria for the trial was being aged 9 to 17 years and having exodeviation at near of at least 4 prism diopters (Δ) greater than at far, a receded near point of convergence (NPC) break (≥ 6 cm), insufficient positive fusional vergence at near (PFV) (convergence amplitudes) (ie, failing Sheard's criterion [PFV less than twice the near phoria]³⁰ or minimum PFV of $\leq 15\Delta$ base-out blur or break), and a CI Symptom Survey (CISS) score of 16 or greater. Because patients with symptomatic CI often have an associated accommodative insufficiency,¹² patients with symptomatic CI associated with accommodative insufficiency were included in the study. However, children with monocular accommodative amplitudes of less than 5 diopters (D) were excluded because the severity of their accommodative insufficiency may indicate an organic etiology. The [eTable](#) provides a complete listing of eligibility and exclusion criteria.

A refractive correction was prescribed for patients if they had a significant refractive error or a significant change in refractive correction. A significant refractive error or change was defined as 1.50 D or greater of hyperopia, 0.50 D or greater of myopia, 0.75 D or greater of astigmatism, 0.75 D or greater of anisometropia in spherical equivalent, or 1.50 D or greater of anisometropia in any meridian (based on cycloplegic refraction). For hyperopes, the investigator could reduce the prescription by up to 1.25 D. For myopia, full correction was required. After wearing the glasses for at least 2 weeks, eligibility testing was repeated to determine if the patient still met the eligibility criteria. Thus, the CISS and eligibility testing were always performed with appropriate refractive correction in place.

EXAMINATION PROCEDURES

Eligibility testing included administration of the CISS to identify whether the child was symptomatic.^{12-13,32-33} Other eligibility tests included best-corrected visual acuity at distance and near, a sensorimotor examination (cover testing at distance and near, NPC, and positive and negative fusional vergence at near [fusional convergence and divergence amplitudes]), near stereoacuity, monocular accommodative amplitude, monocular accommodative facility (the ability to quickly

achieve clear vision while alternately viewing 20/30 print through +2 D and -2 D lenses), a cycloplegic refraction, and an ocular health evaluation. Convergence Insufficiency Treatment Trial-trained and -certified ophthalmologists or optometrists performed all testing using a previously described standardized protocol.³⁴ Eligible patients who consented to participate were enrolled in the study, and the measures taken at their eligibility examination were used as the study baseline measures.

RANDOMIZATION

Using a permuted block design, we randomly assigned eligible patients who consented to participate with equal probability to HBPP, HBCVAT+, OBVAT, or OBPT. Randomization was achieved using a secure Web site created and managed by the data coordinating center. To ensure approximately equal numbers of patients in each treatment arm by site, randomization was stratified by clinical site.

TREATMENT PROTOCOLS

The therapy regimens each lasted 12 weeks. Patients were taught their assigned therapy procedures by CITT-trained and -certified therapists. Therapists were either optometrists, vision therapists, or orthoptists with at least 1 year of experience; most optometrists were residency-trained. Patients were required to demonstrate their understanding and ability to perform home therapy procedures in the office before the therapies were prescribed for home. Instructional handouts were also provided for the home treatment procedures. Patients in all groups maintained a home therapy log and recorded their performances for each home therapy session. Monthly office visits were scheduled for those assigned to the 2 home-based therapy groups. At these visits, the therapists answered questions, reviewed home therapy procedures, and estimated adherence (compliance). In addition, the therapist contacted the patients by telephone on a weekly basis, during which time the home therapy procedures and home logs were reviewed and attempts were made to motivate the patients to adhere to treatment. Those assigned to office-based therapy groups were scheduled for weekly office therapy visits.

All treatments included time for instruction, feedback, review of the home log, and discussion about adherence. For the office-based groups, this all occurred during the weekly office visits. For the home-based groups, these interactions occurred every 4 weeks in the office and weekly via a telephone call with the therapist. The total treatment time for each group included the time spent in therapy at home or in the office plus the contact with the therapist via the weekly phone calls (for the home-based therapy groups).

HOME-BASED PENCIL PUSH-UPS

The pencil push-ups procedure involved using a pencil with 20/60 reduced Snellen letters and a white index card placed in the background to provide a suppression check by using physiological diplopia awareness. The goal of the procedure was to move the pencil to within 2 to 3 cm of the brow, just above the nose on each push-up while trying to keep the target single and clear. Patients were instructed to perform the pencil push-ups procedure 15 minutes per day, 5 days per week. They maintained home therapy logs, recording the closest distance that they could maintain fusion after each 5 minutes of therapy.

HOME-BASED COMPUTER VERGENCE/ACCOMMODATIVE THERAPY AND PENCIL PUSH-UPS

Patients in this group were taught to perform the pencil push-up procedure as well as procedures on the Home Therapy System/Computerized Vergence System (HTS/CVS) computer software system (Computer Orthoptics, Gold Canyon, Arizona). Using this program, they performed fusional vergence and accommodative therapy procedures, including vergence base-in, vergence base-out, autoslide vergence, and jump ductions vergence programs using random-dot stereopsis targets. The accommodative rock program was used for accommodative therapy. Much like a clinician would do at each follow-up visit, this computer program automatically modified the therapy program after each session based on the patient's performance. Patients were instructed to do pencil push-ups 5 minutes per day, 5 days per week, and the HTS software program for 15 minutes per day, 5 days per week, and to save their data on a disk provided by the study and to bring the disk to each follow-up visit.

OFFICE-BASED VERGENCE/ACCOMMODATIVE THERAPY WITH HOME REINFORCEMENT

The OBVAT group received a weekly 60-minute in-office therapy visit with additional prescribed procedures to be performed at home for 15 minutes a day, 5 days per week. The therapy procedures are described in detail elsewhere²⁹ and those performed during the weekly OBVAT sessions are shown in the [eFigure](#). At each office-based therapy session, the patient performed 4 to 5 procedures with constant supervision and guidance from the therapist. There were no diagnostic tests performed during these sessions. The therapist followed a detailed and specific protocol from the CITT manual of procedures (<http://optometry.osu.edu/research/CITT/4363.cfm>); this document describes each procedure, amount of time procedure was performed, expected performance, and criteria for ending the procedure and advancing to a more difficult level.

OFFICE-BASED PLACEBO THERAPY

Patients in the OBPT group received therapy during a weekly 60-minute office visit and were prescribed procedures to be performed at home for 15 minutes per day, 5 days per week. The placebo therapy program consisted of 16 in-office therapy procedures and 4 home therapy procedures, which were designed to look like real vergence/accommodative therapy procedures yet not to stimulate vergence, accommodation, or fine saccadic eye movement skills beyond normal daily visual activities. The therapist followed a detailed protocol from the CITT manual of procedures. Five procedures were performed during each office therapy visit and 2 procedures were assigned for home therapy each week. Placebo procedures included traditional vergence/accommodative therapy procedures modified to be monocular rather than binocular; binocular procedures performed at 0 vergence disparity; and testing procedures that did not require significant demand on the vergence, accommodative, or fine saccadic eye movement systems. For example, in 1 placebo procedure, the patient wore the appropriate filter glasses and performed vergence therapy at 0 vergence demand on the Computer Orthopter (Computer Orthoptics). Some procedures were designed to have increasing levels of difficulty. As in real therapy, patients frequently wore filter glasses and were told that the glasses ensured that both eyes were being used together. Objectives and goals

were established for each placebo procedure to simulate real therapy. For motivational purposes, the therapist told the patient the objective of each procedure before beginning the technique.

MASKING OF THERAPISTS AND PATIENTS

Because experienced therapists provided the treatments, it was not feasible to mask them to patients' assigned treatment. However, each therapist followed a well-defined protocol for all treatments and was instructed to interact in an identical fashion with all patients. Although patients were obviously aware of whether they were assigned to office- or home-based therapy, those receiving office-based treatment were masked regarding whether they were assigned to vergence/accommodative or placebo therapy.

To determine the effectiveness of masking, patients assigned to either of the 2 office-based treatments were asked at the completion of their treatment whether they thought they were randomized into the active or placebo treatment. To assess examiner masking, examiners were asked if they thought they could identify the patient's treatment assignment at the completion of each masked examination. In addition, at the completion of the 12-week outcome examination, examiners were asked to guess the patient's group assignment and to report a level of confidence in the response.

FOLLOW-UP EXAMINATIONS

Protocol-specified follow-up visits were conducted after 4 and 8 weeks of treatment. The primary outcome assessment was made at the visit following the 12th week of treatment. At these follow-up visits, an examiner who was masked to the patient's treatment group administered the CISS and a sensorimotor examination that included cover testing at distance and near, NPC, PFV, accommodative amplitude, and accommodative facility testing. After the clinical testing was completed, the CISS was readministered.

TREATMENT ADHERENCE DATA

To assess adherence with home-based therapy, at each masked examination the therapist was asked, "What percent (0%, 1%-24%, 25%-49%, 50%-74%, 75%-99%, or 100%) of the time do you feel the patient adhered to the home protocol?" The therapists' estimate was based on a review of the home log, electronic data from the computer therapy program, and a discussion with the patient about home therapy. Thus, this estimate was primarily based on patient reports. The response options of 0%, 1% to 24%, 25% to 49%, and 50% to 74% were combined into 1 category (0%-74%) for data analysis because only 16% of patients were categorized into the response options below 75%.

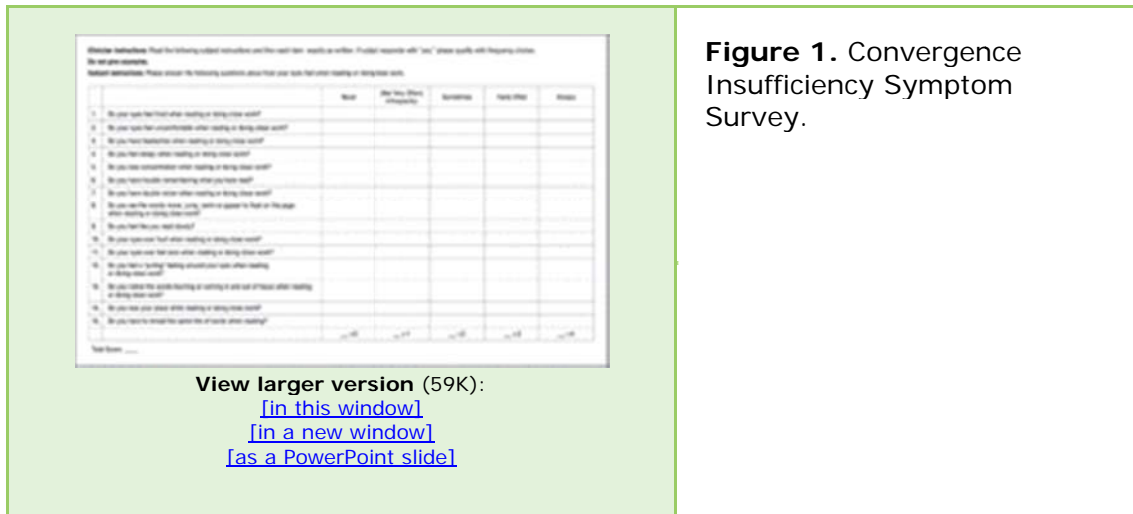
MAINTENANCE THERAPY

Patients who demonstrated sufficient improvement on the CISS at the 12-week outcome visit were considered asymptomatic (CISS score <16) and were prescribed maintenance therapy of 15 minutes per week using home therapy procedures specific to the patient's assigned treatment group. Patients not demonstrating

sufficient improvement on the CISS, and thus considered symptomatic (CISS score ≥ 16), were referred to a non-CITT eye care provider to receive alternative treatment for their CI.

OUTCOME MEASURES

Patients with CI who seek treatment usually do so because they are symptomatic (or perceived to be by their parents), and successful treatment should result in a lessening or abatement of symptoms. Thus, we used symptom level (as measured by the CISS) as the primary outcome measure (Figure 1). The questionnaire consisted of 15 items that were read aloud to the child by the examiner. The examiner read the questions while the child looked at a card with 5 answer options and was instructed to choose 1 of those possible answers (never, infrequently, sometimes, fairly often, or always). Each response was scored on a scale of 0 to 4, with 4 representing the highest frequency of symptom occurrence (ie, always). The 15 items were summed to obtain the total CISS score. The lowest possible score (least symptomatic) was 0 and the highest was 60 (most symptomatic). Based on our previous work,^{13, 32} a CISS score of less than 16 is considered asymptomatic and a decrease of at least 10 or more points is considered improved.



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The goal of treatment for CI is not only to eliminate patient symptoms, but also to improve the patient's convergence ability. Thus, we used NPC and PFV as secondary outcome measures. A normal NPC was defined as less than 6 cm and an improved NPC was defined as an improvement (decrease) in NPC of 4 cm or more from baseline to the 12-week outcome examination. To be classified as having normal PFV, a patient had to pass Sheard's criterion (ie, PFV blur or if no blur, then break value at least twice the near phoria magnitude) and have a PFV blur/break of more than 15 Δ . Improvement in PFV was defined as an increase of 10 Δ or more from baseline to the 12-week outcome examination.

To evaluate each treatment's ability to improve both signs and symptoms, we also developed a composite outcome classification that considered the change in all 3 outcome measures from baseline to the 12-week examination. A successful outcome was a score of less than 16 on the CISS, a normal NPC (<6 cm), and a normal PFV (>15 Δ and passing the Sheard's criterion). Improved was defined as a score of less than 16 or a 10-point decrease in the CISS score, and at least 1 of the following: normal NPC, an improvement in NPC of more than 4 cm, normal PFV, or an increase in PFV of more than 10 Δ . Patients who did not meet the criteria for successful treatment or improved outcome were considered nonresponders.

STATISTICAL ANALYSIS

All sample size calculations were performed using PASS 2000 software³⁵ and assuming a 2-sided test with 90% power. For a given outcome measure, the common standard deviation (SD) obtained from the CITT pilot study²⁹ was used as an estimate of variability. To control for multiple comparisons (4 groups, with 2 compared at a time [6 pair-wise comparisons]), the α level used for determining sample size was set at 0.0083 (0.05/6).

The CITT was powered to reject the null hypothesis of no difference between groups, assuming that the true population differences between groups are 10 points on the CISS, 4 cm in NPC, and 10 Δ in PFV. These differences were based on clinician expert opinion and the repeatability of each measure.^{13, 36} The sample size of 52 children per group was based on the required sample size for the 3 outcome variables and adjusted for a 10% loss to follow-up.

All data analyses were performed using SAS, version 9.1 (SAS Institute, Cary, North Carolina). All analyses followed the intention-to-treat principle. The mean of the 2 measures of the CISS score and the 3 measures of both the NPC and PFV obtained at each study visit were used for analyses. Positive fusional vergence at near was obtained from the base-out to blur measure if present; otherwise, base-out to break was used.

As planned a priori, a 4-group by 3-period repeated-measures analysis of covariance (ANCOVA) was used to compare the treatment groups at week 12. Using data from both the 4- and 8-week visits maximizes the degrees of freedom, thus ensuring the most appropriate estimate of the mean square error used in group mean comparisons. The baseline value of the outcome measure was used as a covariate because our initial pilot data showed a strong correlation between baseline and all subsequent values. In addition, all clinical and demographic variables collected at baseline were examined as potential confounders of the true relationship between a particular outcome measure and treatment group. For these analyses, the α level for inclusion in the final ANCOVA model was set at 0.10. If the final ANCOVA model indicated a significant group effect or group x time interaction, Tukey's method of adjustment for multiple pairwise group comparisons was used to hold the overall error rate at $\alpha = 0.05$. The mean square error from the ANCOVA model was also used to construct 95% confidence intervals for the mean difference between groups.

A χ^2 test was used to compare the percentage of patients in each group who were classified as having successful or improved outcomes or as a nonresponder. Post hoc pairwise group comparisons of the percentage in each classification were

achieved using logistic regression models. The baseline value of each outcome measure was included in the regression model. An unweighted κ statistic and the 95% confidence interval were used to assess the agreement between the examiner's guess and the patient's actual group assignment.

RESULTS

ENROLLMENT

Between July 2005 and October 2006, 221 patients were enrolled in the study. The number of patients enrolled at the 9 sites ranged from 14 to 35 (median, 25). The mean age of the patients was 11.8 years (SD, 2.3 years); 59% were female, 55% were white, 30% were African American, and 34% were Hispanic. At baseline, the mean (SD) clinical findings were 2 Δ (2.8 Δ) exodeviation at distance; 9.3 Δ (4.4 Δ) exodeviation at near; NPC break/recovery of 14.2 (7.5) cm/17.9 (8.2) cm; and PFV break/recovery at near of 12.7 (4.6) Δ /8.8 (4.5) Δ . [Table 1](#) provides the study population demographics and pertinent clinical measures at baseline by treatment group. While children with constant strabismus were excluded, patients with intermittent exotropia were eligible for the study and a small number (4-7 patients) were randomized to each treatment group. Although there was an imbalance at baseline in medication used among the 4 groups (highest in the OBPT group), only psychotropic medications had potential effects on accommodation, and the groups were balanced for these medications. Based on initial bivariate analyses, no confounders were identified for inclusion in the ANCOVA model for any of the 3 outcome measures.

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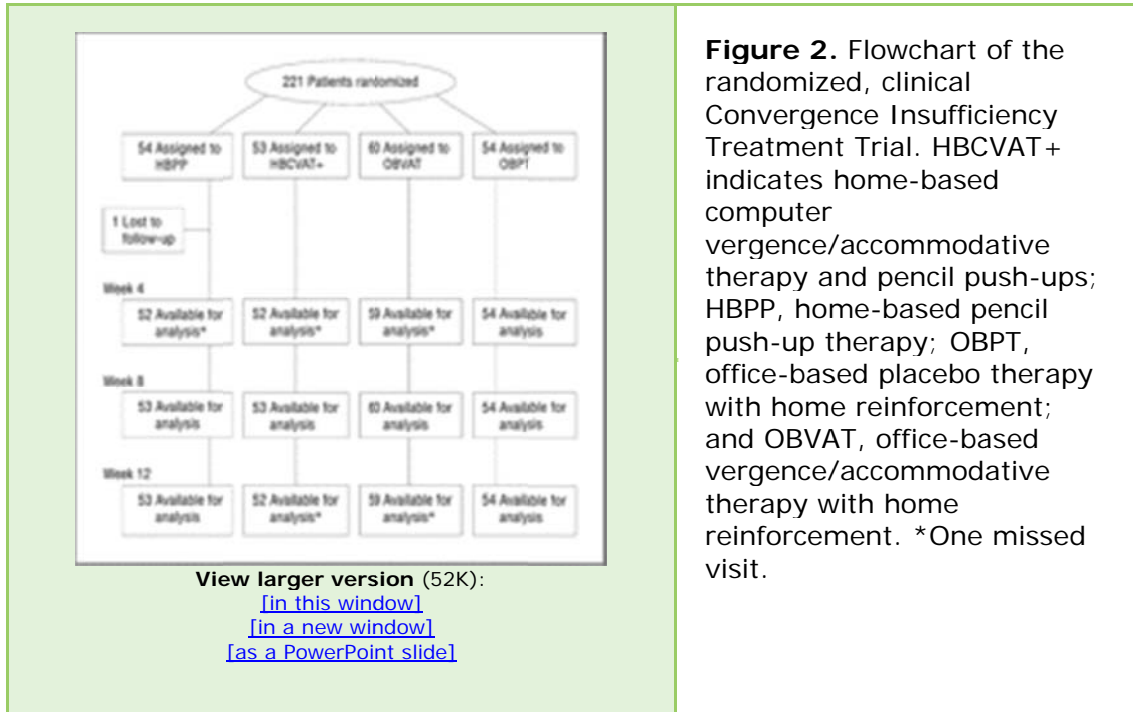
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Table 1. CITT Population Demographics and Clinical Measures at Baseline

PATIENT FOLLOW-UP

Of the 221 patients who entered the trial, 218 (99%) completed the 12-week outcome examination ([Figure 2](#)). Less than 2% of all study visits through week 12 were missed. The highest percentage of missed visits occurred in the OBPT group (18 of 648 visits [2.8%]). Of the 720 study visits scheduled in the OBVAT group, only 17 were missed (2.4%). In both of the home-based treatment groups, the percentage of visits missed was less than 1.5% (1.3% of 639 visits in the HBPP

group and 1.4% of 636 visits in the HBCVAT+ group).



TREATMENT ADHERENCE DATA

At 12 weeks, the percentage of CITT patients rated by therapists as compliant with the home therapy protocol at least 75% of the time was 67.3% in the HBCVAT+ group, 84.9% in the HBPP group, 87% in the OBPT group, and 91.4% in the OBVAT group (Table 2). Accounting for the observed differences in estimated adherence did not affect the results of the treatment group comparisons for symptom score, NPC, or PFV (data not shown).

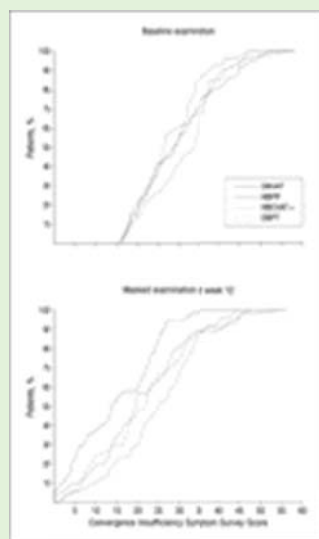
<p>View this table: [in this window] [in a new window] [as a PowerPoint slide]</p>	<p>Table 2. Patients Rated by Therapist as Compliant With Home Therapy Protocol at Least 75% of the Time</p>
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MASKING

Eighty-five percent of the patients assigned to placebo therapy and 93% of those assigned to vergence/accommodative therapy believed that they had been assigned to the active therapy group. None of the examiners felt that they could identify the patients' group assignment at the 4- or 8-week masked examinations, and only 1 examiner felt that he could identify the group assignment at outcome. One-third of the examiners responded that their patient was assigned to the OBVAT group, 24% responded that he/she was assigned to HBCVAT+, 21% said their patient was assigned to HBPP, and 21% said their patient was assigned to the OBPT group. Examiners, when asked to guess, were correct in identifying the patient's group assignment only 34% of the time, which is less than is expected by chance (ie, 50% correct vs incorrect, $P < .001$). There was low agreement between the actual group assignment and the examiner's guess of assigned treatment group ($\kappa = 0.11$, 95% confidence interval, 0.04-0.20).

PRIMARY OUTCOME MEASURE

[Figure 3](#) displays the cumulative distribution plots of the mean symptom level for the 4 treatment groups at baseline and after 12 weeks of treatment. At the 12-week outcome examination, patients assigned to the OBVAT group reported a significantly lower mean symptom level compared with patients in the 3 other treatment groups ([Table 3](#)). The mean CISS score at 12 weeks in patients in the OBVAT group was 6.8 points lower than that in patients assigned to OBPT (95% confidence interval, 3.4-10.3; $P < .001$). A mean difference of 7.9 points was found between the OBVAT and HBPP groups (95% confidence interval, 4.4-11.4; $P < .001$). The largest difference in mean symptom level was 8.4 points (95% confidence interval, 4.9-11.9; $P < .001$), observed between the OBVAT and HBCVAT+ groups. No significant differences were observed among the HBPP, HBCVAT+, and OBPT groups (pairwise $P \geq .38$ for all).



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Figure 3. Cumulative distribution of Convergence Insufficiency Symptom Survey scores collected during the eligibility examination and at the masked examination at week 12. HBCVAT+ indicates home-based computer vergence/accommodative therapy and pencil push-ups; HBPP, home-based pencil push-up therapy; OBPT, office-based placebo therapy with home reinforcement; and OBVAT, office-based vergence/accommodative therapy with home

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View this table: [in this window] [in a new window] [as a PowerPoint slide]	Table 3. Means and 95% Confidence Intervals for Each Outcome by Treatment Group and Time
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As seen in [Table 4](#), the percentage of patients in each group who were considered asymptomatic (ie, CISS score <16) or improved (ie, change in score of ≥ 10 points at the outcome examination) was significantly higher in the OBVAT group compared with the other treatment groups (HBPP, $P = .013$; HBCVAT+, $P < .001$; OBPT, $P = .004$). There was no significant difference in the percentage of patients considered asymptomatic or improved between the OBPT group and the 2 home-based groups (pairwise $P > .60$ for all).

View this table: [in this window] [in a new window] [as a PowerPoint slide]	Table 4. Improvement in Signs and Symptoms of Convergence Insufficiency by Therapy Group
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We also used an alternate definition of success in which patients who achieved a symptom score of less than 16 were only considered to have had successful treatment if improvement was 10 or more points ([Table 4](#)). This eliminated the chance that patients with CISS scores that just met the eligibility criterion (≥ 16) would be classified as achieving successful treatment when the change in the CISS score was within the normal variability of the survey. Sixty-six percent of patients in the OBVAT group met this criterion, which was significantly greater than that observed in any of the other treatment groups (38% in HBPP, $P = .003$; 33% in HBCVAT+, $P < .001$; 35% in OBPT, $P = .001$); there were no statistical differences among the latter 3 treatment groups (pairwise $P > .50$ for all).

SECONDARY OUTCOME MEASURES

NPC Break

[Figure 4](#) displays the cumulative distribution plots of the mean NPC break for the 4 treatment groups at baseline and after 12 weeks of treatment. At the outcome visit, the mean NPC was significantly improved in the OBVAT group compared with the other 3 groups (pairwise $P \leq .005$ for all) ([Table 3](#)). While the mean NPC of both home-based groups measured significantly closer than that of the OBPT group (pairwise $P \leq .01$ for all), there were no statistically significant differences between the 2 home-based therapy groups ($P = .33$).

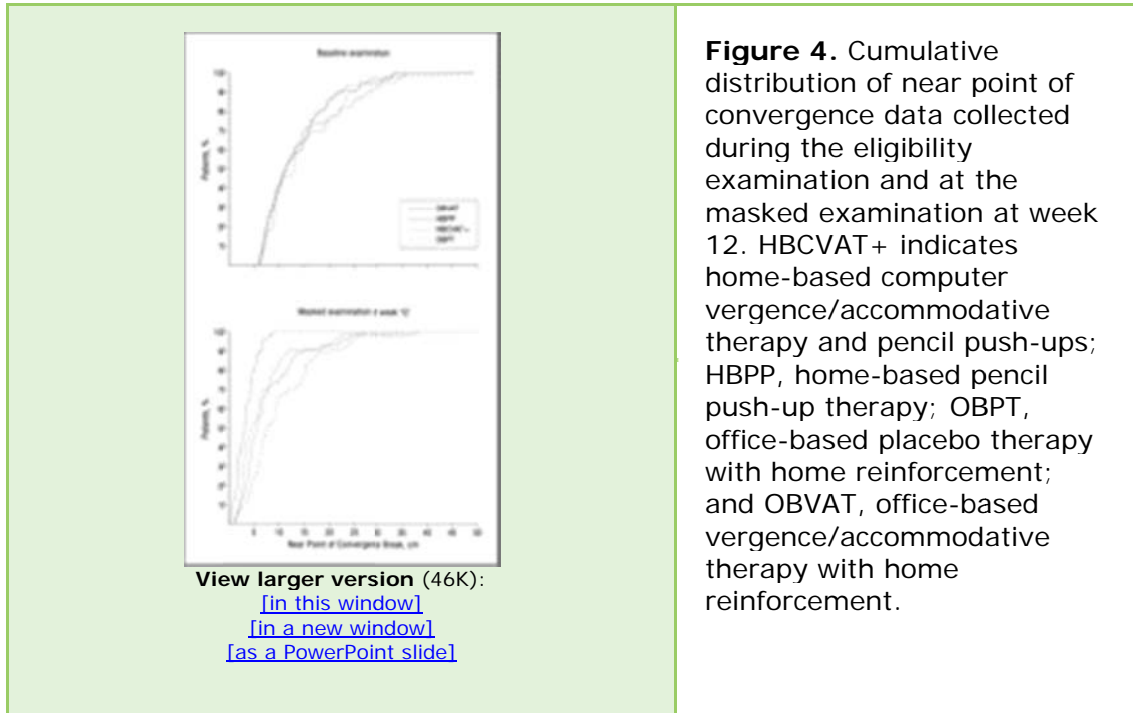


Figure 4. Cumulative distribution of near point of convergence data collected during the eligibility examination and at the masked examination at week 12. HBCVAT+ indicates home-based computer vergence/accommodative therapy and pencil push-ups; HBPP, home-based pencil push-up therapy; OBPT, office-based placebo therapy with home reinforcement; and OBVAT, office-based vergence/accommodative therapy with home reinforcement.

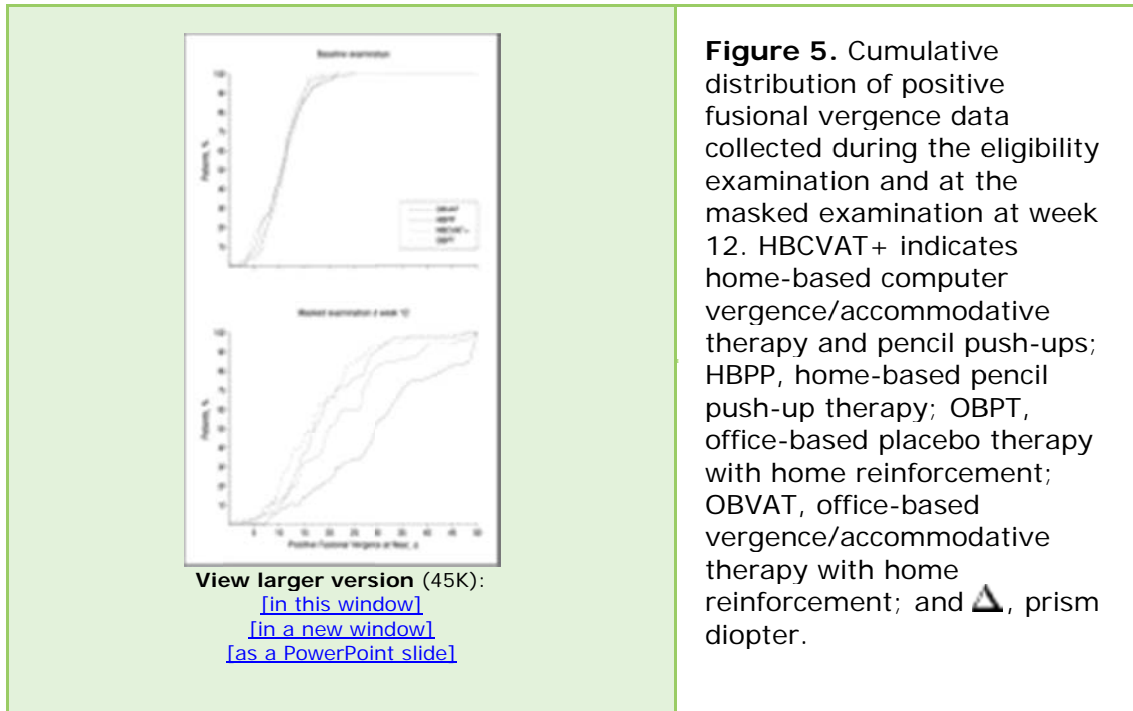
The percentage of patients who had normal (break < 6 cm) or improved (decrease of ≥ 4 cm) NPC at the 12-week outcome examination was significantly greater in the OBVAT group compared with the other treatment groups (HBPP, $P = .008$; HBCVAT+, $P = .006$; OBPT, $P < .001$) ([Table 4](#)). There were slightly more patients with a normal or improved NPC in both the HBPP and HBCVAT+ groups compared with the OBPT group; however, the difference was not statistically significant ($P = .06$ and $.07$, respectively). There was no significant difference between the 2 home-based groups ($P = .93$).

We also used an alternate definition of successful treatment in which patients who achieved a normal NPC were only considered to have had a successful treatment if improvement was greater than 4 cm ([Table 4](#)). Eighty-seven percent of patients in the OBVAT group achieved this criterion, a significantly higher percentage than that found in any of the other treatment groups (71% in HBCVAT+, $P = .023$; 64% in HBPP, $P = .002$; and 54% in OBPT group, $P < .001$). There was also a significant difference between the HBCVAT+ and the OBPT groups ($P = .032$); no differences

were found between the HBPP group and either the HBCVAT+ ($P = .37$) or OBPT ($P = .20$) groups. This conservative estimate would not include some patients who would be considered to have had clinically successful treatment (eg, a 7 cm NPC at baseline, which improves to 3.5 cm).

PFV at Near

[Figure 5](#) displays the cumulative distribution plots of the mean PFV at near for the 4 treatment groups at baseline and after 12 weeks of treatment. At the outcome examination, the mean PFV for patients in the OBVAT group was significantly greater than all other groups (pairwise $P < .001$ for all). The mean PFV in the HBCVAT+ group was significantly better (higher) than in the HBPP ($P = .037$) and OBPT ($P = .008$) groups. There was no significant difference in response in the HBPP and OBPT groups ($P = .57$).



As seen in [Table 4](#), the percentage of patients with normal or improved PFV at the outcome examination was significantly higher in the OBVAT group compared with all other treatment groups (HBPP, $P = .002$; HBCVAT+, $P = .007$; OBPT, $P < .001$). There were no significant differences in the percentage of patients with normal or improved PFV in the latter 3 treatment groups (pairwise $P > .10$ for all).

As with CISS score and NPC break, an alternate definition of success was used in which patients who achieved a normal PFV were only considered to have had a successful treatment outcome if improvement was greater than 10 Δ ([Table 4](#)).

Seventy-three percent of patients in the OBVAT group achieved this criterion, a significantly higher percentage than that in any of the other treatment groups (52% in the HBCVAT+ group, $P = .02$; 40% in the HBPP group, $P < .001$; and 26% in the OBPT group, $P < .001$). There was also a significant difference between the HBCVAT+ and OBPT groups ($P = .007$); however, no other significant differences were detected ($P > .10$ for all). Again, this conservative estimate would not include some patients who would be considered clinically successful (eg, 10 Δ exophoria at near with a PFV at near of 16 Δ at baseline, which improves to 25 Δ).

Successful, Improved, and Nonresponder Criteria

Using the composite outcome classification, which combines symptoms, NPC, and PFV, the proportion of patients found to have had successful treatment or improved outcome in the OBVAT group was significantly greater than that in any of the other groups ($P < .002$ for all). While nearly three-quarters of patients in the OBVAT group (73%) had either successful or improved outcomes, less than half the patients in the HBPP group (43%), one-third of the patients in the HBCVAT+ group (33%), and just more than one-third in the placebo group (35%) were similarly classified.

Secondary Measures Combined

Previous studies have assessed treatment effectiveness by evaluating whether improvements occurred in both NPC and PFV. Seventy-three percent, 40%, 37%, and 22% of patients in the OBVAT, HBPP, HBCVAT+, and OBPT groups, respectively, achieved both a normal NPC and PFV. The percentage of patients who achieved both a normal NPC and a normal PFV was significantly higher in the OBVAT group compared with the other treatment groups ($P < .001$ for each pairwise comparison). No other group differences were significant ($P > .11$ for each pairwise comparison).

Attention-Deficit/Hyperactivity Disorder

Children with parent-reported attention-deficit/hyperactivity disorder (ADHD) scored higher on the CISS at baseline than children without parent-reported ADHD, and there were slight differences in the distribution of these children among treatment groups at baseline. However, ADHD was not a confounder and did not affect the mean treatment differences among the groups. There was also no interaction between ADHD and treatment ($P = .93$). We examined the 3-way interaction between ADHD, treatment, and time and found no significant effect ($P = .26$).

ADVERSE EVENTS

Six adverse events that included eyes or vision were reported. All were unexpected and further evaluations determined that none of the events were serious or related to the study treatment.

COMMENT

We compared the effectiveness of 3 active vision therapy approaches in 221 children with symptomatic CI. Office-based vergence/accommodative therapy with home reinforcement was significantly more effective than HBPP, HBCVAT+, and OBPT in improving both the symptoms and clinical signs associated with symptomatic CI. Although symptoms did improve in the 2 home-based therapies, these treatments were no more effective in improving symptoms than office-based placebo therapy.

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We established 4 criteria, a priori, to determine the clinical relevance of the data from this study: (1) the score differences on the CISS between treatment groups at outcome, (2) the proportion of children who achieved a normal or improved symptom score on the CISS at outcome, (3) the change in secondary outcome measures, NPC, and PFV (convergence amplitudes) at outcome, and (4) the proportion of patients classified as having had successful or improved outcomes when using the composite outcome classification (combining the treatment effects of all 3 outcome measures).

The first criterion, the treatment group difference in the CISS score at outcome, was difficult to establish a priori. Our survey instrument had not been incorporated into clinical practice, and, consequently, the magnitude of the difference between 2 treatment regimens that indicated clinical relevance had not been established. Based on the group mean differences found for the CISS in our previous pilot study,²⁹ the CITT was designed to have 90% power to reject the null hypothesis of no group mean differences if the true population difference between groups in the CISS score was 10 points. This difference of 10 points, along with data on the variability in CISS scores obtained from 3 separate randomized trials conducted by the CITT Study Group, translates into an effect size of greater than 1 SD.

In the present study, we did not find a difference in group means of 10 or more points on the CISS. Instead, we found statistically significant group differences that ranged from 7 to 8.5 points between the OBVAT group and each of the other 3 treatment groups. This translates to an effect size that ranges from 0.77 to 0.94 SD. Using Cohen's³⁷ guidelines for interpretation of effect size (0.2 is small, 0.5 is medium, 0.8 is large), the group differences we found are considered large. Sloan et al³⁸ contend that an effect size of 0.5 is a conservative estimate of a clinically meaningful difference that is scientifically supportable and unlikely to be one that can be disregarded. Thus, group differences observed in this study are considered clinically meaningful, though they are less than the a priori estimate of a 10 or more points change between groups. Looking retrospectively and reviewing the literature on effect size, the 10-point difference was a significant overestimate of the potential treatment effect. Further study and refinement of the CISS will help clarify the issue.

The second criterion used to assess clinical relevance was whether there were differences among treatment groups in patients' ability to achieve a normal or improved symptom level on the CISS. After treatment, 73% of patients assigned to OBVAT met this criterion, in contrast to 47% assigned to HBPP, 39% assigned to HBCVAT+, and 43% assigned to OBPT. Changing the criterion to require that

patients achieved both a score of less than 16 and a change of 10 or more points on the CISS resulted in lower success rates for all groups, but the differences among treatment groups remained the same.

The third criterion used was an evaluation of the secondary outcome measures, NPC and PFV (convergence amplitudes), as they are often used clinically to determine treatment success for CI. The proportion of patients who achieved a clinically normal level for both measures was 73% in the OBVAT group compared with no more than 40% in each of the other 3 treatment groups.

The fourth a priori criterion for determining clinical significance was the proportion of patients classified as having successful or improved outcomes when using the composite outcome classification (combining the treatment effects of all 3 outcomes). A significantly higher proportion of children assigned to OBVAT (73%) compared with the 3 other treatment groups was classified as having successful treatment or improved outcome. No significant differences were observed between the 2 home-based groups and the placebo therapy group. Thus, based on the analysis of all 4 a priori criteria, we conclude that there are both statistically significant and clinically meaningful differences between the groups.

The results of this large, randomized clinical trial are similar to those from the only previous randomized trial of vision therapy/orthoptics for CI in children²⁹ in which 3 treatment groups were studied: HBPP, office-based vision therapy/orthoptics, and OBPT. In that pilot study, only the OBVAT group experienced a significant improvement in symptoms, NPC, and PFV.

The current study was not designed to show the maximal possible improvement with treatment. Longer treatment may have resulted in additional changes in signs and symptoms. Office-based vergence/accommodative therapy programs for CI often include 12 to 24 office visits.¹⁹⁻²¹ Our 12-week treatment program was based on the assumption that this represented the maximum length of time that a symptomatic patient who was not improving would stay on the assigned treatment. Because our 12-week treatment program is at the low end of the range of time recommended for office-based CI therapy, it is possible that OBVAT might have been effective in more patients had the treatment program been longer. Likewise, a longer treatment program may have resulted in additional improvements by those assigned to the home-based treatment groups. It is also possible that using more home-based therapy procedures or prescribing longer periods of daily home-based therapy may have produced different results. Answers to these questions will have to await further study.

While a placebo effect could be associated with any of the 4 treatments owing to the patient's expectation that the treatment would be effective, office-based therapy might be more susceptible to this effect owing to the enthusiasm, caring, and compassion of a therapist who spends 60 minutes per week with the patient.³⁹ However, this is the second randomized trial of OBVAT that was designed to control for the effect of the therapist as a placebo⁴⁰; placebo therapy was designed to simulate bona fide therapy procedures and therapists were trained to behave identically for patients in both of the office-based therapy groups. The data reported herein confirm that we were successful in achieving this objective, as 85% of the patients assigned to OBPT believed they had been assigned to the actual OBVAT group. This compares well with our previous pilot study in which 90% of the

patients assigned to placebo therapy believed they had been assigned to actual therapy.²⁹ A no treatment group was not included; therefore, it is not known whether any improvements were due to regression to the mean or natural history of the disease. However, this should have affected all treatment groups similarly because there were no statistically significant or clinically relevant differences in any primary or secondary outcome measure among the treatment groups at baseline. Therefore, the observed differences in effectiveness between the OBVAT and placebo therapy groups are most likely attributable to treatment effect.

The OBVAT used in this study represents a typical approach used in clinical practice.²¹ We conclude that this specific therapy protocol was successful in this study and should be applicable to children with similar clinical findings. A better understanding of which procedures were most effective will require additional research.

While this study was not designed to determine which factors within a particular group contributed to the outcome, the procedures that comprise the OBVAT provide therapists with the greatest ability to control and manipulate stimulus parameters (eg, vergence amplitude and accommodative demand) and to incorporate motor learning theory (eg, modeling and demonstration, transfer of training, patient feedback). The weekly visits with the therapist during OBVAT also permit the inclusion of a variety of procedures that stress convergence and accommodative abilities not typically addressed in home therapy programs. There were also differences among the treatment groups in time spent performing therapy and interacting with the therapist. The 2 office-based groups had a mean prescribed therapy time of 135 minutes per week; the HBCVAT+ group averaged 115 minutes; and the HBPP group averaged 90 minutes, which included weekly telephone calls with the therapist. However, this study was not designed to equalize time spent performing therapy and/or interacting with a therapist; rather, it was designed as an effectiveness study to evaluate 3 clinical treatments typically provided in clinical practice. It is possible that the difference in treatment effect found in this study could be related to the OBVAT group having been prescribed more minutes of therapy per day than the home-based groups. However, having a patient perform a greater amount of daily home-based therapy, particularly pencil push-ups, is likely impractical.

There are limited data in the literature that suggest there is a relationship between CI and ADHD.⁴¹⁻⁴² Although we asked parents whether their child had ADHD (ie, parental report), this study was not designed to assess this relationship and was not powered for such subgroup analyses, nor was the diagnosis of ADHD definitive. However, investigation of this possible association is of interest and merits additional research.

We could not identify any other sources of bias or confounding factors to explain our findings. Accounting for slight differences in the distribution of baseline factors between groups in the analyses did not alter the interpretation of the results. The follow-up visit rate was excellent and almost identical in all 4 groups. The investigators performing the 4-, 8-, and 12-week examinations were masked to the treatment group, and the patients in the 2 office-based treatment groups were effectively masked as well. We did have slight differences in adherence among the groups, however, and accounting for these differences in estimated adherence did not affect the results of the treatment group comparisons for the CISS score, NPC,

or PFV. The placebo effect was accounted for by incorporating the OBPT group.

When translating these study results into clinical practice, it is important to recognize that they can only be applied to children with symptomatic CI who are aged 9 to 17 years. Adults with symptomatic CI may respond differently, as suggested by our pilot study.⁴³ Our findings indicate that the specific form of vision therapy/orthoptics we used, OBVAT with home reinforcement, is the most effective of the treatments we studied in this trial, with about 75% of patients achieving normalization of or improvement in symptoms and signs within 12 weeks.

With regards to home-based therapy, it is important to note that the data reported in this study for the HBPP group were derived from a therapy program designed with considerably closer follow-up than is typical in clinical practice. Patients were called on a weekly basis by a therapist, completed a home log, and returned for office visits every fourth week. It is possible that this treatment would be less effective if prescribed according to usual clinical practice, which does not include weekly telephone calls from a therapist and often has less frequent follow-up. The results of the CITT pilot study, in which the HBPP group did not receive weekly phone calls, provide some support for this hypothesis, as none of the 11 patients were classified as having successful or improved outcomes.²⁹

It is easy to understand the clinical popularity of home-based treatment because of its simplicity and cost-effectiveness. Both HBPP and HBCVAT+ can be taught to patients in a short time and require fewer follow-up visits than office-based therapy (4 visits for home-based treatments compared with 12 visits for office-based treatment). While our study was not designed to conduct a cost-utility analysis, this is worthwhile to explore in future research.

There are a number of interesting clinical questions that cannot be answered at this time. It is possible that there may be psychological effects from the interaction between the therapist and the patient that could affect the office-based and home-based treatment groups' results differentially (if these effects were present, and if they were dependent on patient-therapist contact time). In this study, we did not have a placebo home-based therapy group and thus, do not know whether the changes found in the 2 home-based groups are due to a real or placebo treatment effect. It is possible that different protocols that more closely monitor and encourage adherence would affect the outcomes. For the OBVAT regimen, we do not know which procedures were most effective or whether the treatment protocol can be modified to make it more effective. This includes understanding the nature of the synergistic role of the active home treatment component as well as the therapist interaction. It is also not known whether the treatment effect will be sustained over time. Therefore, a conclusion about the long-term benefit of treatment must await the results of the 12-month follow-up study we are conducting.

CONCLUSIONS

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This large-scale multi-center, randomized clinical trial of treatments for children with symptomatic CI demonstrates that a 12-week regimen of OBVAT with home reinforcement is more effective than a 12-week program of HBPP or HBCVAT+ in improving symptoms and signs associated with CI.

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The CITT Study Group

Clinical Sites

Sites are listed in order of the number of patients enrolled in the study, with the number of patients in parentheses after the site name and location. Personnel are listed as PI for principal investigator, SC for site coordinator, E for examiner, and VT for vision therapist.

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(E); Ida Chung, OD (E); and Kaity Colon (SC).

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Southern California College of Optometry, Fullerton (23): Dr Cotter (PI); Eric Borsting, OD, MS (E); Dr Rouse (E); Carmen Barnhardt, OD, MS (VT); Raymond Chu, OD, MS (VT); Susan Parker (SC); Rebecca Bridgeford (SC); Jamie Morris (SC); and Javier Villalobos (SC).

University of California–San Diego Ratner Children's Eye Center, San Diego (17): Dr Granet (PI); Lara Hustana, OD (E); Shira Robbins, MD (E); Erica Castro (VT); and Cintia Gomi, MD (SC).

Mayo Clinic, Rochester, Minnesota (14): Dr Mohny (PI); Jonathan Holmes, MD (E); Melissa Rice, OD (VT); Virginia Karlsson, BS, CO (VT); Becky Nielsen (SC); Jan Sease, COMT, BS (SC); and Tracee Shevlin (SC).

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CITT Data Coordinating Center

Ms Mitchell (PI); Tracy Kitts (project coordinator); Melanie Bacher (programmer); Linda Barrett (data entry); Loraine Sinnott, PhD (biostatistician); Kelly Watson (student worker); and Pam Wessel (office associate).

National Eye Institute, Bethesda, MD

Dr Redford; and Paivi Miskala, PhD.

CITT Executive Committee

Dr Scheiman; Ms Mitchell; Dr Cotter; Dr Hertle; Dr Kulp; Dr Redford; and Dr Rouse.

Data and Safety Monitoring Committee

Marie Diener-West, PhD (chair); Rev Andrew Costello, CSsR; William V. Good, MD; Ron D. Hays, PhD; Argye Hillis, PhD (through March 2006); and Ruth Manny, OD, PhD.

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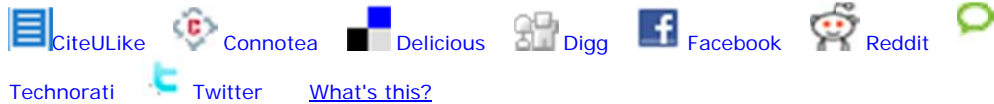
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