A Randomized Clinical Trial of Treatments for Convergence Insufficiency in Children

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Objective: To compare vision therapy/orthoptics, pencil push-ups, and placebo vision therapy/orthoptics as treatments for symptomatic convergence insufficiency in children 9 to 18 years of age.

Methods: In a randomized, multicenter clinical trial, 47 children 9 to 18 years of age with symptomatic convergence insufficiency were randomly assigned to receive 12 weeks of office-based vision therapy/orthoptics, office-based placebo vision therapy/orthoptics, or home-based pencil push-ups therapy.

Main Outcome Measures: The primary outcome measure was the symptom score on the Convergence Insufficiency Symptom Survey. Secondary outcome measures were the near point of convergence and positive fusional vergence at near.

Results: Symptoms, which were similar in all groups at baseline, were significantly reduced in the vision therapy/ orthoptics group (mean symptom score decreased from 32.1 to 9.5) but not in the pencil push-ups (mean symptom score decreased from 29.3 to 25.9) or placebo vision therapy/orthoptics groups (mean symptom score decreased from 30.7 to 24.2). Only patients in the vision therapy/orthoptics group demonstrated both statistically and clinically significant changes in the clinical measures of near point of convergence (from 13.7 cm to 4.5 cm; $P<.001$) and positive fusional vergence at near (from 12.5 prism diopters to 31.8 prism diopters; $P<.001$).

Conclusions: In this pilot study, vision therapy/ orthoptics was more effective than pencil push-ups or placebo vision therapy/orthoptics in reducing symptoms and improving signs of convergence insufficiency in children 9 to 18 years of age. Neither pencil push-ups nor placebo vision therapy/orthoptics was effective in improving either symptoms or signs associated with convergence insufficiency.

Arch Ophthalmol. 2005;123:14-24

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CONVERGENCE INSUFFI-ciency (CI) is a common and distinct binocular vision disorder with a reported prevalence among children and adults in the United States of 2.25% to 8.30%.[1-4] Common symptoms include diplopia, asthenopia, headaches, and blurred vision usually associated with activities requiring close vision (eg, reading, computer viewing, or deskwork).[5-12] The exact impact of symptomatic CI on an individual's performance in school, at work, and on quality of life is unknown. Clinical signs of CI typically include exophoria that is greater at near than at distance, a receded near point of convergence measurement, and reduced positive fusional vergence at near measurement.[5,13,14]

There is a lack of consensus regarding the most appropriate treatment for CI. Various treatments are prescribed including base-in prism glasses, home-based pencil push-ups, home-based vision therapy/ orthoptics, and office-based vision therapy/ orthoptics.[10,15-24] Recent studies surveying the ophthalmic community to determine the most widespread treatment modality for symptomatic CI suggest that pencil push-ups is the most commonly prescribed treatment by both ophthalmologists and optometrists.[25,26]

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In spite of the popularity of pencil push-ups for CI, there has been only 1 clinical study of 25 patients evaluating the effectiveness of this treatment modality.[24] The patients with symptomatic CI who enrolled in the study were instructed to perform pencil push-ups at home for 15 minutes, 5 days a week; however, only 48% (12/ 25) completed the study, and of these, 58% (7/12) had improved symptoms and signs.

Of the various treatments commonly recommended for CI, only office-based vision therapy/orthoptics has been extensively evaluated. Grisham[27] reviewed the ophthalmic literature relative to treatment results for CI using vision therapy or orthoptics for the years 1940 to 1987 and summarized 17 studies with a total of 1931 patients. He calculated a weighted cure rate of 72%, an improved rate of 19%, and a 9% failure rate. All of the studies reviewed, however, had 1 or more of the following design flaws: lack of a clear definition of CI, inadequate definition of successful outcome, retrospective design, failure to use masked examiners for outcome measures, small sample size, or no control group. Although 2 of the studies reviewed by Grisham were prospective, double-blind, placebo-controlled studies showing that vergence therapy increased positive fusional vergence and decreased symptoms in patients with CI, these studies had small sample sizes.[28,29] In a recent randomized controlled study of 60 adult patients with CI, Birnbaum et al[30] found that office-based vision therapy was successful in 61.9% of patients while home-based vision therapy was successful in only 10.5% of patients. The study did not have a placebo control nor did the investigators use masked examiners to gather outcome data. The only study to specifically investigate CI in children was a clinical trial that attempted to use a placebo treatment group[31]; however, the investigators discontinued the placebo treatment group after a short time because of problems associated with patient retention and ethical concerns.

The Convergence Insufficiency Treatment Trial (CITT) Study Group designed this pilot study in preparation for a larger randomized clinical trial. This study was a masked, placebo-controlled, multicenter, randomized clinical trial in which children 9 to 18 years of age were randomly assigned to 1 of 3 treatments: pencil push-ups, office-based vision therapy/orthoptics, or office-based placebo vision therapy/orthoptics. A base-in prism treatment group was not included because unlike the other treatments, prism is a passive, compensatory treatment rather than an "active" treatment approach designed to remediate the condition. The purpose of this study was to determine if after 12 weeks of treatment, either or both of 2 popular treatments for CI (pencil push-ups and vision therapy/orthoptics) were more effective than placebo treatment and if so, if 1 treatment was more effective than the other in improving symptoms and signs associated with symptomatic CI in children.

METHODS

This study, supported by the National Eye Institute of the National Institutes of Health, Department of Health and Human Services, Bethesda, Md, was conducted by the CITT Group at 6 clinical sites at schools and colleges of Optometry in California, New York, Ohio, Oregon, Pennsylvania, and Texas. The protocol and informed consent forms were approved by each institutional review board, the parent or guardian (referred to subsequently as "parent") of each study patient gave written informed consent, and the child gave written assent, as required. The 2 primary sources of patients were internal referrals from the clinical centers (77%) and referrals from external (other eye care professionals and advertising) sources (23%).

PATIENT SELECTION

Eligibility testing included administration of the 13-item version of the CI Symptom Survey (CI Symptom Survey-V13, described later) to identify whether the subject with CI was symptomatic. At the time of eligibility testing, the revised CI Symptom Survey with 15 items had not yet been validated. The 13-item version was used only for eligibility testing, and the 15-item version was used to assess changes during treatment and was the primary outcome measure.

Other eligibility tests included best-corrected visual acuity (distance and near), a cycloplegic refraction, and a sensorimotor examination that included cover testing (distance and near) and measures of near point of convergence, positive and negative fusional vergence at near, near stereoacuity, accommodative amplitude, and accommodative facility. All testing was performed using a standardized protocol. Eligibility testing had to be performed within 2 months of randomization. The mean ± SD time from eligibility testing to randomization was 2.0 ± 5.0 days with a maximum lag in randomization of 30 days. More than half (55%) of the subjects were randomized on the day of eligibility testing.

If a patient was wearing glasses and no change in prescription was necessary, randomization could occur immediately. If significant refractive error was present or a significant change in refractive correction was required, new glasses were prescribed. A significant refractive error or change in correction was defined as 1.50 diopter (D) or higher hyperopia, 0.50 D or higher myopia, 0.75 D or higher astigmatism, 0.75 D or higher anisometropia in spherical equivalent, or 1.50 D or higher anisometropia in any meridian (based on cycloplegic refraction). After wearing the glasses for at least 2 weeks, eligibility testing was repeated to determine if the patient still met the eligibility criteria.

An expanded 15-item version of the CI Symptom Survey (CI Symptom Survey-V15)[32-35] was completed by the patient at the randomization visit (**Figure 1**). The questionnaire consisted of 15 items that were read aloud by the examiner to the child. The child was instructed to choose 1 of 5 possible answers (never, infrequently, sometimes, fairly often, always). Each answer was scored 0 to 4, with 4 representing the highest frequency of symptom occurrence (ie, always). The 15 items were summed to obtain the CI Symptom Survey score, with the lowest possible score (totally asymptomatic) being 0 and the highest possible score being 60 (most symptomatic). A symptom score of 16 or higher on the CI Symptom Survey-V15 was previously found to differentiate children with symptomatic CI from those with normal binocular vision.[35]

The near point of convergence was measured with the Astron International Accommodative Rule (Bernell Corporation, Mishawaka, Ind). The device consists of a rod with a movable, single column of letters (20/30 equivalent at 40 cm). Instructions were similar to the ones described by Hayes et al.[36] Positive fusional vergence (blur, break, and recovery) was measured with a horizontal prism bar (Gulden B-15 horizontal prism bar; [Gulden Ophthalmics, Elkins Park, Pa, 1 prism diopter [Δ] to 45 Δ) while the patient viewed a 20/30-size column of letters (Gulden Fixation Stick 15302; Gulden Ophthalmics) held at 40 cm.

Eligibility criteria for the trial included children aged 9 to 18 years inclusive, exophoria at near at least 4 Δ greater than at far, a receded near point of convergence break (6 cm or greater), and insufficient positive fusional convergence at near (ie, failing Sheard's criterion [positive fusional vergence less than twice the near phoria][37] or minimum positive fusional vergence of 15 Δ base-out break). Because our goal was only to include patients who were symptomatic, an earlier version of the CI Symptom Survey-V13 was also used to determine eligibility. This version included 13 items scored on a scale of 0 to

		Never	(Not Very Often) Infrequently	Sometimes	Fairly Often	Always
1.	Do your eyes feel tired when reading or doing close work?					
2.	Do your eyes feel uncomfortable when reading or doing close work?					
3.	Do you have headaches when reading or doing close work?					
4.	Do you feel sleepy when reading or doing close work?					
5.	Do you lose concentration when reading or doing close work?					
6.	Do you have trouble remembering what you have read?					
7.	Do you have double vision when reading or doing close work?					
8.	Do you see the words move, jump, swim or appear to float on the page when reading or doing close work?					
9.	Do you feel like you read slowly?					
10.	Do your eyes ever hurt when reading or doing close work?					
11.	Do your eyes ever feel sore when reading or doing close work?					
12.	Do you feel a "pulling" feeling around your eyes when reading or doing close work?					
13.	Do you notice the words blurring or coming in and out of focus when reading or doing close work?					
14.	Do you lose your place while reading or doing close work?					
15.	Do you have to re-read the same line of words when reading?					

Name _____

DATE (mm-dd-yy)

Clinician instructions: read the following subject instructions and then each item exactly as written. If subject responds with "yes" – please qualify with frequency choices. Do not give examples.

Subject instructions: Please answer the following questions about how your eyes feel when reading or doing close work.

Figure 1. Convergence Insufficiency Symptom Survey-V15.

3 with scores of 9 or higher indicating symptomatic CI.[32] **Table 1** provides a complete listing of the eligibility and exclusion criteria.

TREATMENT PROTOCOLS

The Ohio State University Optometry Coordinating Center, Columbus, the data-coordinating center for the study, randomly assigned eligible patients with equal probability to either pencil push-ups, vision therapy/orthoptics, or placebo vision therapy/orthoptics. Randomization was accomplished with the study's Web site using blocks of 6 so that the investigator could not predict the sequence of treatment assignments. To ensure approximately equal numbers of patients in each treatment arm, randomization was performed separately for each site.

Pencil Push-ups

Patients in the pencil push-ups group were taught a pencil push-up procedure that included monitoring for suppression. Patients were instructed to hold a pencil at arm's length directly between their eyes, and an index card, serving as a suppression control, was placed on the wall 6 to 8 ft away. Patients were instructed to look at the very tip of the sharpened pencil and to try and keep the pencil point single while moving it toward their nose. If 1 of the cards in the background disappeared, patients were instructed to stop moving the pencil and blink their eyes until both cards were present. Patients were told to continue moving the pencil slowly toward their nose until it could no longer be kept single and then to try and get the pencil point back into 1. If patients were able to regain single vision, they were asked to continue moving the pencil closer to their nose. If patients could not get the pencil back to 1, they were instructed to start the procedure again. Patients were instructed to do 3 sets of 20 pencil push-ups per day at home, 5 days per week for 12 weeks, and this treatment required an average of 15 minutes per day. Prior to doing the procedure at home, children had to demonstrate their understanding and ability to perform the procedure according to protocol.

Office-Based Vision Therapy/Orthoptics

The vision therapy/orthoptics group received therapy administered by a trained therapist during a weekly, 60-minute office visit, with additional procedures to be performed at home for 15 minutes a day, 5 times per week for 12 weeks. The office- and home-based procedures used are described in detail elsewhere[22] and are listed in **Table 2** along with a short description of each procedure. The items listed in Table 2 are the specific procedures performed by each patient in this treatment arm during the weekly office-based vision therapy/orthoptics sessions. In addition, treatment procedures were practiced at home. During a typical office-based treatment session, the patient practiced 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 very detailed and specific CITT protocol from the manual of procedures, which described the proper treatment technique, amount of time the technique was to be used, expected performance, and criteria for ending the procedure and advancing to a more difficult level. **Figure 2** outlines the treatment sequence. When a procedure was prescribed for home treatment, a handout with instructions was given to the patient.

Table 1. Eligibility and Exclusion Criteria

Eligibility Criteria

Ages 9-18 y inclusive

Best-corrected visual acuity of 20/25 OU at distance and near

Willingness to wear eyeglasses or contact lenses to correct refractive error, if necessary

Exophoria at near at least 4 Δ greater than at far

Insufficient positive fusional convergence (ie, failing Sheard's criterion[37] or <15-Δ break on positive fusional vergence testing using a prism bar)

Receded near point of convergence of greater than or equal to 6-cm break

Appreciation of at least 500 s of arc on the forms part of the Randot Stereotest

CI Symptom Survey-V13 (original 13-item version) score ≥9

Informed consent and willingness to participate in the study and be randomized

Exclusion Criteria

CI previously treated with pencil push-ups (no more than 2 mo of treatment within the past year)

CI previously treated with office-based vision therapy/orthoptics (no more than 2 mo of treatment within the past year)

Amblyopia

Constant strabismus

History of strabismus surgery

Anisometropia >1.50-D difference between eyes

Prior refractive surgery

Vertical heterophoria > 1 Δ

Systemic diseases known to affect accommodation, vergence, and ocular motility, such as multiple sclerosis, Graves thyroid disease, myasthenia gravis, diabetes, and Parkinson disease

Any ocular or systemic medication known to affect accommodation or vergence

Monocular accommodative amplitude <4 D in either eye as measured by the Donder push-up method

Manifest or latent nystagmus

Attention-deficit/hyperactivity disorder or learning disability diagnosis by parental report

Household member or sibling already enrolled in the CITT

Any eye care professional, technician, medical student, or optometry student

Abbreviations: CI, convergence insufficiency; CITT, Convergence Insufficiency Treatment Trial; D, diopter; Δ, prism diopter.

Placebo Office-Based Vision Therapy/Orthoptics

Like the vision therapy/orthoptics group, the placebo vision therapy/orthoptics group received therapy administered by a trained therapist during a 60-minute office visit and was prescribed procedures to be performed at home for 15 minutes, 5 times per week for 12 weeks. The procedures for placebo vision therapy/orthoptics were designed to simulate real vision therapy/orthoptics procedures without the expectation of affecting vergence, accommodation, or saccadic function. Examples included using stereograms monocularly to simulate vergence therapy and using plano lenses (instead of plus and minus lenses) to simulate accommodative treatment.

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

EXAMINATION PROCEDURES

Protocol-specified follow-up visits were conducted after a mean±SD of 4±1 and 8±1 weeks of treatment. The primary outcome assessment was made at the visit following a mean±SD of 12±2 weeks of treatment. At these follow-up visits, an examiner who was masked to the patient's treatment group administered the CI Symptom Survey-V15, the cover test (distance and near), and near point of convergence and positive fusional vergence at near measurements.

ADHERENCE TO THE TREATMENT PROTOCOL

Adherence to the home-treatment protocol was assessed by having the parent or child maintain a calendar on which the treatment (minutes of home therapy) performed each day was logged. The calendars were reviewed at follow-up visits. At each outcome visit, the therapist made an assessment of the patient's adherence to the prescribed treatment (percentage of time, 0%, 1%-24%, 25%-49%, 50%-74%, 75%-99%, or 100%)

At the coordinating center, each follow-up examination form was reviewed to assess whether the investigator was properly following the examination and treatment protocols, and any necessary feedback was provided to the investigator.

OUTCOME MEASURES AND CRITERIA FOR SUCCESS

Patients with CI who seek treatment do so because they are symptomatic. Thus, treatment for CI can only be considered successful if the patient has fewer symptoms after treatment. To measure symptoms and changes in symptoms, we used the score on the CI Symptom Survey-V15 as the primary outcome measure. In preliminary work during the pilot study, the median CI Symptom Survey score among patients with CI (aged 9-18 years) was 31 (range, 14-50). In contrast, the median score among patients with normal binocular vision was 7 (range, 0-26). The majority of patients with CI (aged 9-18 years) have CI Symptom Survey scores of 16 or higher (sensitivity, 95.7%), while patients with normal binocular vision predominantly scored lower than 16 (specificity, 85.7%).[35] We, therefore, defined a CI Symptom Survey score of less than 16 after 12 weeks of treatment as a successful outcome. We also evaluated 2 secondary outcome measures (near point of convergence and positive fusional vergence at near).

For most eye care professionals, the goal of the treatment for CI is not only to eliminate symptoms but also to improve the patient's near point of convergence and positive fusional vergence at near measurements. Thus, we used another set of criteria to define patients as "cured" or "improved." Patients who achieved scores of less than 16 on the CI Symptom Survey and had a normal near point of convergence measurement (break of < 6 cm) and normal positive fusional vergence measurement (passing Sheard's criterion[37] or 15-Δ break or greater on positive fusional vergence testing using a prism bar) at near were considered cured. Patients who achieved a decrease in symptoms (<16 on the CI Symptom Survey) and achieved normal values in either the near point of convergence or positive fusional vergence at near measures were considered improved. Patients were considered to have failed at the outcome visit if they continued to have a symptom score greater than 16 on the CI Symptom Survey or if the symptom score improved but both the near point of convergence and positive fusional vergence at near measurements did not meet the normal criteria.

Table 2. Office-Based Vision Therapy/Orthoptics Procedures

Vision Therapy/Orthoptics Procedure	Description of Procedure	Purpose of Procedure
Accommodative Procedures		
Loose-lens accommodative facility	The patient must alternately clear 20/30- to 20/50-size print at 40 cm though plus and minus lenses	Improve amplitude of accommodation; increase velocity of accommodative response; decrease the latency of the accommodative response
Letter chart accommodative facility	The patient must alternately clear 20/30-size print at 40 cm and then at 6 m	
Binocular accommodative facility	Same procedure as loose-lens accommodative facility performed binocularly	
Convergence Procedures		
Barrel card	Patient must accurately converge on targets on a handheld card 5 cm from the eyes	Develop the kinesthetic awareness of converging and diverging; develop the ability to voluntarily converge; normalize the near point of convergence
Brock string	Patient must accurately converge on target placed on a string; the target distance can be varied from several meters to 5 cm	
Fusional Vergence Procedures		
Vectograms	Patient must maintain single binocular vision as targets are disparated to create base-out or base-in vergence demand	Increase positive and negative fusional vergence amplitudes
Computer orthoptics (random dot stereogram procedure)	Patient must maintain single binocular vision as random dot stereograms are disparated to create base-out or base-in vergence demand	
Aperture rule	Patient must converge or diverge to achieve single binocular vision with targets with increasingly larger base-out or base-in vergence demand	
Eccentric circles free-space fusion cards	Patient must converge or diverge to achieve single binocular vision with targets with increasingly large base-out or base-in vergence demand	
Life Saver free-space fusion cards	Patient must converge or diverge to achieve single binocular vision with targets with increasingly larger base-out or base-in vergence demand	
Loose prism facility	Patient must converge or diverge to achieve single binocular vision with through prisms of varying magnitude	

STATISTICAL METHODS

No formal sample size calculations were performed a priori because 1 of the goals of the pilot study was to estimate the variability of our new outcome measure. At study completion, the observed variability in the CI Symptom Survey was used to determine the statistical power available to detect meaningful differences between the 3 treatment groups. The calculations were performed using PASS software (NCSS, Kaysville, Utah) with $\alpha = .05$, assuming a 2-sided test. The group means specified were determined from the mean CI Symptom Survey of patients with normal binocular vision and the observed means at baseline.[35] It was assumed that the posttreatment mean of the most effective treatment group would approximate the mean among patients with normal binocular vision, the mean for the placebo group would decrease 20% from its baseline value, and the mean for the other treatment group would fall in the middle of these 2 groups. By assuming that the third mean would fall in the middle of the other 2, the power to detect differences is minimized. These assumptions about the mean values of the 3 groups yield the smallest value for power and are therefore the most conservative. Under these assumptions, our sample size yields a power of 92.8%.

All statistical analyses were performed using SAS software (Version 8.2; SAS Institute, Cary, NC). Comparisons of the clinical measures at baseline were performed using 1-way analysis of variance. Analysis of covariance was used to compare the outcome measures using the baseline value as a covariate. When the group effect was significant, post hoc comparisons of the groups were performed adjusting the overall error rate (α) using the method proposed by J. W. Tukey, PhD (unpublished data, 1953), and Kramer.[38] To determine if significant changes occurred from baseline to the outcome visit in any of the treatment groups, a Wilcoxon signed rank test was used to compare the mean change to zero.
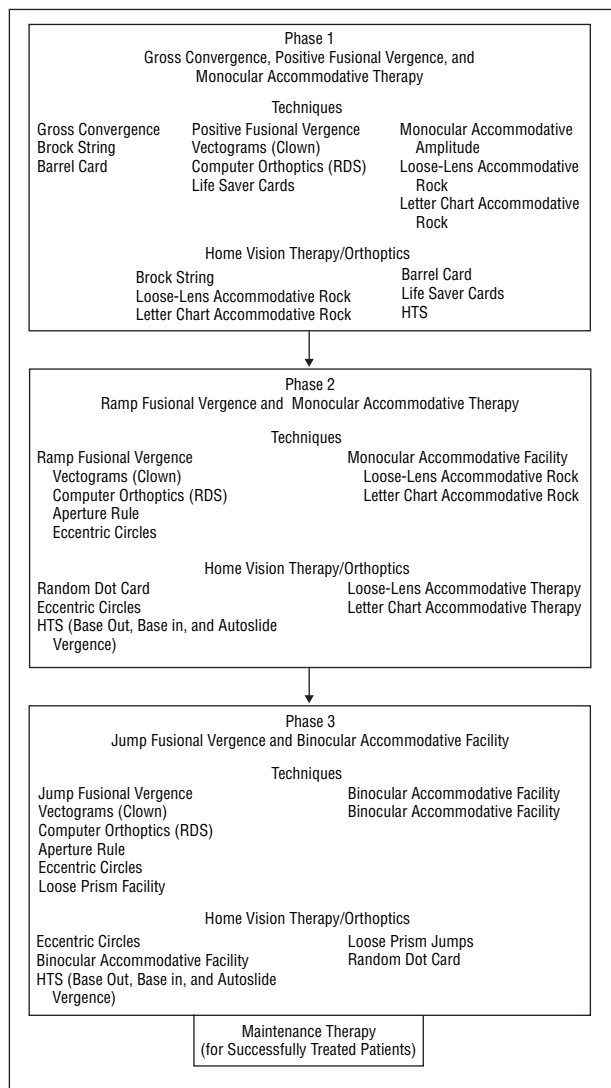
RESULTS

ENROLLMENT

A total of 47 patients were enrolled in the study between October 2000 and November 2001. The number of patients enrolled per site at the 5 sites ranged from 1 to 28 (median, 7). The mean ± SD age of the patients was 11.5 ± 2.2 years; 57% were female, 47% were white, 33% were African American, 7% were Hispanic, and 13% were other. At baseline, the mean ± SD clinical findings for the enrolled patients were orthophoria at distance; 9.0 ± 4.4 Δ exophoria at near; near point of convergence break/recovery of 15.0 ± 8.0 cm/18.0 ± 8.8 cm; and positive fusional vergence break/recovery at near of 12.0 ± 3.6 Δ/8.0 ± 3.7 Δ. **Table 3** provides the study population demographics and clinical measures at baseline.

PATIENT FOLLOW-UP AND ADHERENCE TO TREATMENT

The primary outcome examination was completed within the mean ± SD 12 ± 2–week window by 15 (88%)

Figure 2 content

Phase 1
Gross Convergence, Positive Fusional Vergence, and Monocular Accommodative Therapy

Techniques

Gross Convergence	Positive Fusional Vergence	Monocular Accommodative
Brock String	Vectograms (Clown)	Amplitude
Barrel Card	Computer Orthoptics (RDS)	Loose-Lens Accommodative Rock
	Life Saver Cards	Letter Chart Accommodative Rock

Home Vision Therapy/Orthoptics

Brock String — Barrel Card
Loose-Lens Accommodative Rock — Life Saver Cards
Letter Chart Accommodative Rock — HTS

Phase 2
Ramp Fusional Vergence and Monocular Accommodative Therapy

Techniques

Ramp Fusional Vergence — Monocular Accommodative Facility
Vectograms (Clown) — Loose-Lens Accommodative Rock
Computer Orthoptics (RDS) — Letter Chart Accommodative Rock
Aperture Rule
Eccentric Circles

Home Vision Therapy/Orthoptics

Random Dot Card — Loose-Lens Accommodative Therapy
Eccentric Circles — Letter Chart Accommodative Therapy
HTS (Base Out, Base in, and Autoslide Vergence)

Phase 3
Jump Fusional Vergence and Binocular Accommodative Facility

Techniques

Jump Fusional Vergence — Binocular Accommodative Facility
Vectograms (Clown) — Binocular Accommodative Facility
Computer Orthoptics (RDS)
Aperture Rule
Eccentric Circles
Loose Prism Facility

Home Vision Therapy/Orthoptics

Eccentric Circles — Loose Prism Jumps
Binocular Accommodative Facility — Random Dot Card
HTS (Base Out, Base in, and Autoslide Vergence)

Maintenance Therapy
(for Successfully Treated Patients)

Figure 2. Vision therapy/orthoptics protocol. HTS indicates home therapy system software; RST, random dot stereogram procedure.

Figure 3 content

Patients Randomized Allocated to Treatment

17 Allocated to Vision Therapy/Orthoptics → 2 Lost to Follow-up; 2 Lost Contact → 15 Included in Analysis

15 Allocated to Pencil Push-ups → 4 Lost to Follow-up; 1 Lost Contact; 3 Examination out of Window → 11 Included in Analysis

15 Allocated to Placebo Vision Therapy/ Orthoptics → 3 Lost to Follow-up; 1 Lost Contact; 2 Parental Concerns → 12 Included in Analysis

Figure 3. Flow diagram of Convergence Insufficiency Treatment Trial Study Group randomized clinical trial.

of 17 patients assigned to vision therapy/orthoptics, 12 (80%) of 15 patients assigned to placebo vision therapy/ orthoptics, and 11 (73%) of 15 patients assigned to pencil push-ups. The completion rate was not related to treatment assignment (χ^2 P =.59). Of the 9 patients not completing the primary outcome examination, 4 were lost to follow-up, 2 parents decided after randomization that they preferred to have their children treated outside of the study, and 3 did not complete the outcome examination within the visit window (**Figure 3**). There were no statistically significant or clinically relevant differences in demographic or clinical measures at eligibility found between these patients and those who completed the study within the treatment window. All P values comparing the 2 groups were greater than .10.
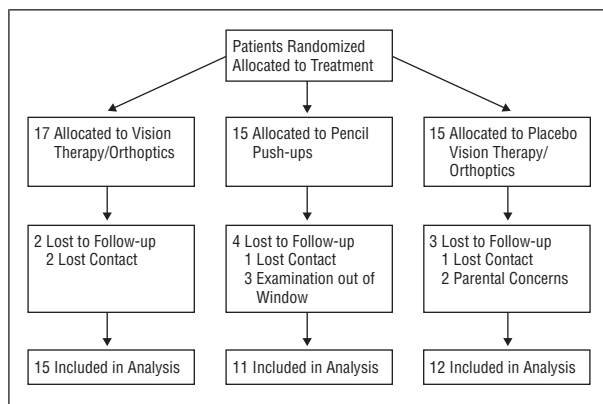
Given the comparability of those patients who completed the study and those patients who chose to drop out or did not complete the outcome examination within the window, all subsequent results are reported for only those patients with data at the 12-week visit.

BASELINE DATA

The baseline data for the primary and secondary outcome measures are summarized in Table 3. There were no statistically significant or clinically relevant differences between patients assigned to the 3 treatment groups (P>.50 for all comparisons).
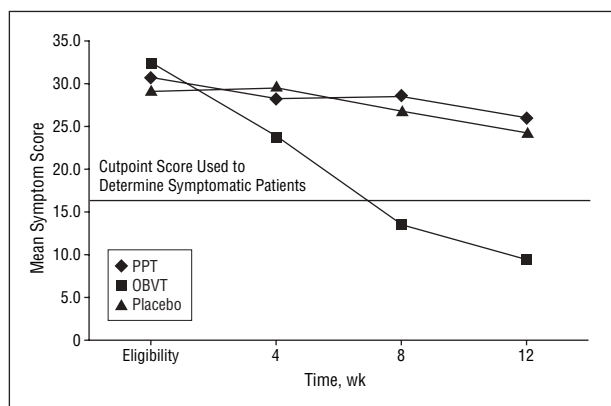
PRIMARY OUTCOME MEASURE: CI SYMPTOM SCORE

The mean±SD CI Symptom Survey score for those in the vision therapy/orthoptics group showed both a statistically and clinically significant reduction in symptoms (P<.001) from 32.1±7.9 to 9.5±8.2 (**Table 4**). Patients

Table 4. Comparing Treatment Groups With Respect to Clinical Measures at Baseline and the 12-Week Outcome Examination*

Characteristic	Pencil Push-Ups (n = 11)	Vision Therapy/ Orthoptics (n = 15)	Placebo Vision Therapy/ Orthoptics (n = 12)
CI Symptom Survey score at baseline	29.3 (5.4)	32.1 (7.9)	30.7 (10.6)
CI Symptom Survey score at outcome	25.9 (7.3)	9.5 (8.2)	24.2 (11.9)
NPC break at baseline, cm	14.6 (7.4)	13.7 (7.4)	15.5 (6.8)
NPC break at outcome, cm	9.1 (5.1)	4.5 (3.6)	9.3 (4.4)
PFV break at baseline, Δ	12.6 (3.2)	12.5 (4.3)	12.1 (3.4)
PFV break at outcome, Δ	14.5 (5.3)	31.8 (10.0)	19.8 (10.3)

Abbreviations: CI, convergence insufficiency; NPC, near point of convergence; PFV, positive fusional vergence; Δ, prism diopter.
*Values are expressed as mean (SD).

Figure 5. Mean near point of convergence (NPC) measurements after 4, 8, and 12 weeks of treatment. PPT indicates pencil push-ups therapy; OBVT, office-based vision therapy.
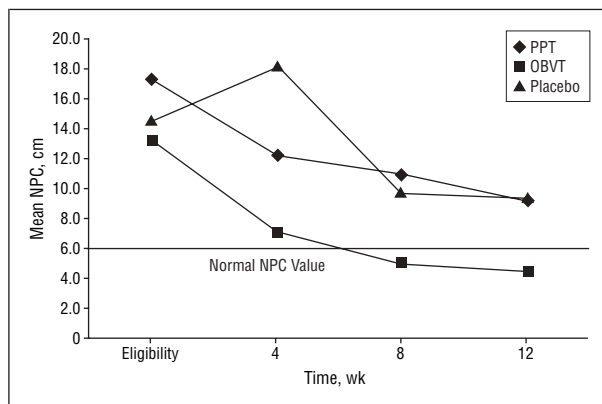
Figure 4. Mean convergence insufficiency symptom score after 4, 8, and 12 weeks of treatment. PPT indicates pencil push-ups therapy; OBVT, office-based vision therapy.

in the placebo vision therapy/orthoptics group had a small but clinically insignificant decrease in mean±SD symptom score from 30.7±10.6 to 24.2±11.9 (P=.04). In the pencil push-ups group, there was neither a statistical nor clinically significant change in the symptom score (mean±SD, 29.3±5.4 to 25.9±7.3; P=.24).

Although there were no differences in the CI Symptom Survey score among the 3 treatment groups at baseline (P=.70), there were significant differences among the groups at the completion of treatment. The mean symptom score in the vision therapy/orthoptics group was significantly different from the mean symptom score of both the pencil push-ups and the placebo vision therapy/orthoptics groups (P<.001 for both comparisons). There was no difference between the pencil push-ups and placebo vision therapy/orthoptics groups (P=.79).

Figure 4 shows the mean CI Symptom Survey score at baseline and after 4, 8, and 12 weeks of treatment for patients in each treatment arm. After approximately 8 weeks of treatment, the mean CI Symptom Score for patients assigned to vision therapy/orthoptics fell below what would be considered symptomatic (score of <16). Neither the mean score for the pencil push-ups group nor

the placebo vision therapy/orthoptics group ever fell below this level.

SECONDARY MEASURES

The near point of convergence break improved significantly in the vision therapy/orthoptics group, decreasing from mean±SD 13.7±7.4 cm to 4.5±3.6 cm (P<.001). There was a moderate improvement in the placebo vision therapy/orthoptics group decreasing from mean±SD 15.5±6.8 cm to 9.3±4.4 cm (P=.03) and in the pencil push-ups group (mean±SD, 14.6±7.4 cm to 9.1±5.1 cm; P=.08). Eighty percent (12/15) of the patients in the vision therapy/orthoptics group achieved a normal near point of convergence break measurement of less than 6 cm at the end of treatment, while only 16.7% (2/12) of the placebo vision therapy/orthoptics group and 27.3% (3/11) of the pencil push-ups group achieved this result. A comparison of the mean values at the end of treatment demonstrated a significant difference between the 3 groups (P=.01). Post hoc testing revealed that the mean near point of convergence break for the vision therapy/orthoptics group was significantly different than the mean of both the pencil push-ups group (P=.03) and the placebo vision therapy/orthoptics group (P=.02). There was not a significant difference when comparing the pencil push-ups group with the placebo vision therapy/orthoptics group (P=.99). **Figure 5** shows the mean near point of convergence break at baseline and after 4, 8, and 12 weeks of treatment. After approximately 6 weeks of treatment, the near point of convergence break reached normal values in the vision therapy/orthoptics group. Neither the mean score for the pencil push-ups group nor the placebo vision therapy/orthoptics group ever reached this level.

The positive fusional vergence break at near increased significantly in the vision therapy/orthoptics group from mean±SD 12.5±4.3 Δ to 31.8±10.0 Δ (P<.001). Patients in the placebo vision therapy/orthoptics group experienced a mild improvement from mean±SD 12.1±3.4 Δ to 19.8±10.3 Δ (P=.03), and those in the pencil push-ups group showed no statistical improvement (mean±SD, 12.6±3.2 Δ to 14.5±5.3 Δ; P=.22). The mean positive fusional vergence break values at the outcome visit differed significantly between the 3 groups (P<.001).

The mean for patients in the vision therapy/orthoptics group was significantly different (improved) compared with the mean for patients in the pencil push-ups group ($P<.001$) and patients in the placebo vision therapy/orthoptics group ($P=.001$). No difference was observed between the pencil push-ups and placebo vision therapy/orthoptics groups ($P=.34$). **Figure 6** shows the mean positive fusional vergence measurement at baseline and after 4, 8, and 12 weeks of treatment. After approximately 6 weeks of treatment, the positive fusional vergence measurement reached normal values in the vision therapy/orthoptics group. Neither the mean score for the pencil push-ups group nor the placebo vision therapy/orthoptics group ever reached this level.

ADHERENCE DATA

To assess adherence, the therapists asked the patients questions about the home-based treatment and then answered the following question on the CITT follow-up form: "What percent of the time do you feel the patient adhered to the treatment protocol?" The choices were 0%, 1% to 24%, 25% to 49%, 50% to 74%, 75% to 99%, or 100%.

There were no differences in the therapists' assessment of patient adherence between the 3 treatment groups at any visit. After 4 weeks of treatment, the therapists estimated that 100% of patients in the vision therapy/orthoptics group, 92% of patients in the placebo vision therapy/orthoptics group, and 91% of the patients in the pencil push-ups group were performing their home therapy at least 75% of the time (Kruskal-Wallis $P=.66$). At 8 weeks, the therapists' estimates were 93% for the vision therapy/orthoptics group, 91% for the placebo vision therapy/orthoptics group, and 92% for the pencil push-ups group (Kruskal-Wallis $P=.57$). Estimated adherence lessened for both the pencil push-ups group and vision therapy/orthoptics group at the 12-week visit, but the estimates were still not significantly different. In the vision therapy/orthoptics group, therapists estimated that 73% of the patients performed their home therapy at least 75% of the time. This compares with the 92% estimated for patients in the placebo vision therapy/orthoptics group and 73% estimated for patients in the pencil push-ups group (Kruskal-Wallis $P=.34$).

PLACEBO TREATMENT: WERE PATIENTS MASKED?

To determine the effectiveness of masking the patients assigned to the 2 office-based treatments (ie, vision therapy/orthoptics and placebo vision therapy/orthoptics), patients were asked at the 12-week examination if they thought they were randomized to the "true" or the "placebo" treatment. In addition, they were asked how sure they were about their answer. The results indicated that 90% of the patients assigned to placebo vision therapy/orthoptics believed they had been assigned to the real vision therapy/orthoptics group, and 55.6% of these were very sure or pretty sure of their answer. Of the patients assigned to real vision therapy/orthoptics, 100% believed they had been assigned to real vision therapy/orthoptics group, and 75% were very sure or pretty sure
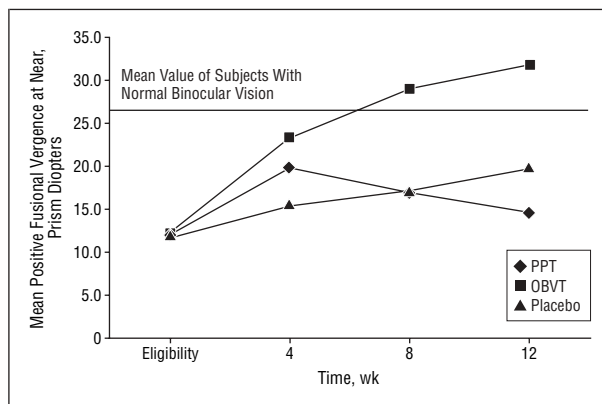
Figure 6. Mean positive fusional vergence at near after 4, 8, and 12 weeks of treatment. PPT indicates pencil push-ups therapy; OBVT, office-based vision therapy.

of their answer. These findings demonstrate the effectiveness of patient masking in the placebo arm.

"CURED" AND "IMPROVED" CRITERIA

Patients who achieved a score of less than 16 on the CI Symptom Survey-V15 and had both normal near point of convergence and positive fusional vergence at near measurements were considered "cured." In the vision therapy/orthoptics group, 8 (53.3%) of 15 patients achieved these criteria, while 1 (8.3%) of 12 in the placebo vision therapy/orthoptics group and 0 (0%) of 11 in the pencil push-ups did so. Patients who achieved a decrease in symptoms (<16 on the CI Symptom Survey-V15) and achieved normal values in either the near point of convergence or positive fusional vergence at near measurement were considered "improved." In the vision therapy/orthoptics group, 12 (80%) of 15 patients achieved this criteria, while 1 (8.3%) of 12 in the placebo vision therapy/orthoptics group and 0 (0%) of 11 in the pencil push-ups group did so.

COMMENT

In this first randomized, placebo-controlled, multicenter, clinical trial studying the treatment of symptomatic CI in children, vision therapy/orthoptics improved both the signs and symptoms associated with CI. Pencil push-ups, a treatment procedure commonly prescribed for CI by both optometrists and ophthalmologists, was not effective in decreasing signs or symptoms. In fact, pencil push-ups treatment was no more effective than placebo vision therapy/orthoptics.

It is easy to understand the clinical popularity of the pencil push-ups technique because of its simplicity and cost-effectiveness. Since it can be taught to the patient in a very short period and requires few follow-up visits, pencil push-ups is significantly less expensive and time consuming for the patient. Office-based vision therapy/orthoptics typically involves an average of 12 to 15 more office visits than pencil push-ups. At an approximate cost of $75 per session, this translates to an additional cost of approximately $900 to $1125 for those undergoing office-based vision therapy/orthoptics vs pencil push-ups.

Consequently, if pencil push-ups is as effective or more effective than vision therapy/orthoptics in the treatment of CI, there will be a substantial savings in health care expenditures. Our preliminary pilot data, however, do not support the use of pencil push-ups as a treatment for CI in children aged 9 to 18 years.

Based on a previous study of the CI Symptom Survey-V15, a symptom score of less than 16 is considered clinically asymptomatic.[35] In the vision therapy/orthoptics group, the mean CI Symptom Survey score decreased from 32.1 (significantly symptomatic) at baseline to 9.5 at the 12-week outcome evaluation, and 80% of these patients achieved a symptom score of less than 16 by the end of treatment. In contrast, neither the pencil push-ups nor the placebo vision therapy/orthoptics groups achieved a mean CI Symptom Survey score of less than 16 at the outcome evaluation. In fact, only 1 of the 11 subjects assigned to the pencil push-ups group and 3 of the 12 subjects in the placebo vision therapy/orthoptics group achieved symptom scores less than 16 at the end of treatment.

Patients in the vision therapy/orthoptics group improved significantly in both the near point of convergence and the positive fusional vergence break at near measurements. In contrast, the majority of patients in the pencil push-ups and placebo vision therapy/orthoptics groups were symptomatic and still had abnormal near point of convergence and positive fusional vergence at near measurements at the outcome evaluation. After 12 weeks of treatment, 8 (53%) of the 15 patients in the vision therapy/orthoptics group were considered "cured" and 80%, "improved." In contrast, none of the 11 patients assigned to pencil push-ups and only 1 (8%) of 12 patients in the placebo vision therapy/orthoptics group were "cured" or "improved."

Patients randomized to the placebo vision therapy/orthoptics group did show statistically significant improvement (but not clinically significant) in their mean symptom survey score and near point of convergence and positive fusional vergence measures, while those randomized to the pencil push-ups group did not. These observed improvements cannot be due to the procedures performed by patients during their placebo vision therapy/orthoptics sessions because the stimuli used did not demand any changes in vergence or accommodation. However, patients largely believed that they were receiving real vision therapy/orthoptics. Added to the placebo effect of the therapist, it is not surprising that patients in the placebo vision therapy/orthoptics group showed improvements both in their subjective symptom assessment and in the objectively measured test results. The psychological benefit this group enjoyed was equal to that in the real vision therapy/orthoptics group, yet those patients assigned to the vision therapy/orthoptics group showed clinically significant improvements that can be attributed to the vergence and accommodation training used. The pencil push-ups group was at a comparative disadvantage because they were not afforded this psychological benefit. We will be controlling for this effect in the large-scale trial by adding a treatment arm where patients assigned to pencil push-ups also work with the orthoptist on a weekly basis.

There is some tendency for the outcome measures of the placebo vision therapy/orthoptics and the pencil push-ups groups to improve over time out to week 12. This is particularly true of the near point of convergence measure. As we discussed earlier, the typical number of visits for vision therapy/orthoptics is more than 12 visits. We chose a 12-week treatment period because we felt this represented the maximum length of time that the 3 fixed treatment regimens could be maintained before a symptomatic patient who was not improving might insist on a change in treatment. We can only speculate on the behavior of each of our outcome variables after week 12 for the 3 treatment groups. It is possible that with a longer treatment period there may have been clinically significant changes in both the pencil push-ups and placebo vision therapy/orthoptics groups. It is also possible that additional improvements would have been achieved by those patients in the vision therapy/orthoptics group.

We are unable to compare our results directly with the previous randomized trial of orthoptics for CI in children,[31] because they had no placebo group, did not use a validated symptom questionnaire, and their outcome visit was unmasked. Nevertheless, our "cure" rate of 53% and "cured" or "improved" rate of 81% for the vision therapy/orthoptics treatment group differ from those reported in a review of 17 studies of vision therapy/orthoptics, which reported a higher overall "cure" rate of 72% and "cured" or "improved" rate of 91%.[27] However, these studies did not have the rigor of a clinical trial design.

We attempted to control for the effect of the "therapist as a placebo,"[39] because it has been reported that the enthusiasm, caring, and compassion of a therapist may play a key role in treatment outcome.[40] We did this by designing placebo therapy that simulated bona fide procedures and training the therapists to behave identically for patients in both the vision therapy/orthoptics and placebo vision therapy/orthoptics groups. We believe that the data reported herein confirm that we were successful in achieving this objective, because 90% of the patients assigned to placebo vision therapy/orthoptics believed they had been assigned to the real vision therapy/orthoptics group.

The office-based vision therapy/orthoptics treatment program used in this study has been reported in detail elsewhere and represents an approach typically used in clinical practice.[22] It is impossible to state whether all of the procedures were absolutely necessary. We can only conclude that this specific vision therapy/orthoptics protocol was successful in this study and should be applicable to children with similar clinical findings. To achieve a better understanding of which procedures were most effective will require additional research.

This study was designed as a pilot study to prepare the CITT Study Group for a large-scale randomized clinical trial. As such, there are a number of limitations that must be considered when interpreting the results of this study. First, the sample size of 47 patients was small, which affects the precision of our treatment effects. Second, although the retention rate for this study was acceptable and patient loss was not related to treatment assignment, 9 (19%) of 47 patients either dropped from the

Convergence Insufficiency Treatment Trial (CITT) Study Group

The CITT Study Group includes the authors and the investigators listed below.

Clinical Sites

Listed in order of number of patients enrolled into the study, with site name, city, state, and number of patients in parentheses. Personnel are listed as (PI) for principal investigator, (I) for investigator, (C) for coordinator, and (T) for therapist. *Pennsylvania College of Optometry, Philadelphia* (28): Mitchell Scheiman (PI); Michael Gallaway (I); Jo Ann Bailey (I); Karen Pollack (T). *Southern California College of Optometry, Fullerton* (8): Susan A. Cotter (PI); Michael W. Rouse (I); Eric Borsting (I); Carmen N. Barnhardt (I); Susan M. Shin (I); Raymond H. Chu (T); Soonsi Kwon (T); John H. Lee (T); Yvonne Flores (C). *State University Of New York, College of Optometry, New York* (7): Jeffrey Cooper (PI), Jerry Feldman (I), Audra Steiner (I), Rose Hughes (T), Jennifer Colavito (T), Esperaza Samonte (C). *The Ohio State University College of Optometry, Columbus* (3): Marjean Taylor Kulp (PI), Michael J. Earley (I), Andrew J. Toole (I), Heather R. Gebhart (T), Ann M. Hickson (T). *Pacific University College of Optometry, Forest Grove, Ore* (1): Richard London (PI), Jayne L. Silver (T). *The Ohio State University College of Optometry, Optometry Coordinating Center, Columbus*: Lynn Mitchell (PI), Linda Barrett (I).

study (n=6) or did not complete the 12 weeks of treatment within the window for the outcome visit (n=3). A third potential issue was the 12-week treatment period. One could argue that a longer treatment period may have resulted in additional changes in signs and symptoms. We struggled with this issue in the planning stages of this study knowing that in-office vision therapy/orthoptics often requires on average from 12 to 24 office visits.[20-22] However, we selected 12 visits because this represented the maximum length of time we believed that the 3 fixed treatment regimens could be maintained before a symptomatic patient who was not improving might insist on a change in treatment. In addition, pencil push-ups treatment is rarely recommended for longer than 8 to 12 weeks. The results of our study can only be applied to children aged 9 to 18 years, and the results of these treatments may be different in other populations, such as adults. Finally, it will be critical in future studies to investigate the long-term outcome of any treatment for CI.

CONCLUSION

This multicenter, randomized clinical trial of the treatment of symptomatic CI in children demonstrated that vision therapy/orthoptics is effective in improving both the symptoms and signs associated with CI and that the effectiveness of vision therapy/orthoptics in children cannot be explained on the basis of a placebo effect. Based on the results of this pilot study, it would appear that pencil push-ups, a commonly prescribed treatment for CI, is not effective in improving symptoms or signs associated with CI in children. The data from this study support the need for a similar multicenter, randomized study with a larger sample size and long-term follow-up to further clarify the treatment of CI and to control for the possible biasing effects of differences in patient compliance and differences in patient/therapist contact time among treatment groups. This large-scale randomized clinical trial has been funded by the National Eye Institute and recruitment is underway.

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