Randomized Clinical Trial of Treatments for Symptomatic Conv. Insuff. In Children

Convergence Insufficieny Treatment Trial (CITT)Study Group Arch Ophthalmol. 2008;126(10):1336-49

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An audience survey...

How many use office based orthoptic therapy for CI?

What are the criteria for choosing office based treatment?

How many rely on home based pencil push-ups?

A brief survey...

How long do you persist with the home based/ office based treatment?

What are the methods used in office based orthoptic therapy?

This study

To compare

- Home-based pencil push-ups (HBPP)
- Home-based computerised vergence / accomodative therapy (HBCVAT+)
- Office based vergence /accom therapy with home reinforcement (OBVAT)
- Office-based Placebo therapy with home reinforcement (OBPT)

Pilot studies

■ Study 1: BI △ reading glasses no more effective than placebo reading glasses Br J Ophthalmol. 2005;89(10):1318-1323

Study 2: OBVAT more effective than HBPP or OBPT Arch Ophthalmol. 2005;123(1):14-24

Methods - Patient selection

- Age 9-17 yrs
- Exodeviation N > D by 4 Δ
- Near Point of Conv. (NPC) break ≥6cms
- Positive fusional vergence (PFV) <15 ^ BO blur or break
- PFV less than twice the near phoria
- CI Symptom Survey score of 16 or more

Convergence Insufficiency Symptom Survey

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.

		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 reread the same line of words when reading?					
		_×0	_×1	_×2	_×3	_×4

Total Score: ____

Exclusion criteria

- Convergence insufficiency previously treated
- Amblyopia
- Constant strabismus / History of strabismus surgery
- Manifest or latent nystagmus

Exclusion criteria

High refractive error: myopia ≥6 (in any meridian), hyperopia ≥5 (in any meridian), astigmatism ≥4.00
 Anisometropia ≥2 D spherical equivalent

Prior refractive surgery

Exclusion Criteria

• Vertical heterophoria $> 1\Delta$

Accommodative amplitude <5 D in either eye as measured by the Donders' push-up method

 Convergence insufficiency secondary to acquired brain injury or any other neurological disorder

Exclusion criteria

 Systemic diseases known to affect accommodation, vergence and ocular motility

 Developmental disability, mental retardation, attention-deficit/hyperactivity disorder, or a learning disability diagnosis

Protocol

- Randomization
- Masked (at least for patients) office based therapies
- At least 52 patients in each group for 90 % power (assuming 10 % attrition)

Examination procedures

- BCVANPC
- Fusional convergence and divergence amplitudes at near
- Near stereoacuity
- Monocular accomodative amplitude
- Monocular accommodative facility (the ability to quickly alternate viewing 20/30 print through +2 D and -2 D lenses),

Refractive errors

- +1.5 or more, -0.5 or more spherical errors
- 0.75 or more astigmatism
- 0.75 or more anisometropia (SE)
- Hyperopic correction reduced by up to 1.25
 Glasses given for 2 weeks before re-
- assessment

Protocols

HBPP was done 15 min/day 5 days per week HBCVAT+ Computer Orthoptics done 15min/day 5/7; and HBPP as above OBVAT 60min/wk in office; additional home based therapies OBPT tried to simulate VAT; Maintenance therapy of 15 min/wk of home therapy after 12 weeks

Table 2. Office-Based Vision Therapy/Orthoptics Procedures

Accommodative Procedures						
Vision Therapy/Orthoptics Procedure	Description of Procedure	Purpose of Procedure				
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				
Letter chart accommodative facility	The patient must alternately clear 20/30-size print at 40 cm and then at 6 m	the latency of the accommodative response				
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 voluntaril				
Brock string	Patient must accurately converge on target placed on a string; the target distance can be varied from several meters to 5 cm	converge; normalize the near point of convergence				
	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					

Phase One

Gross Convergence, Positive Fusional Vergence, and Monocular Accommodative Therapy Techniques

<u>Gross convergence</u> Brock string Barrel card Positive fusional vergence Vectograms (clown) Computer orthoptics (RDS) Life Saver Cards Monocular accommodative amplitude Loose lens accommodative rock Letter chart accommodative Rock

Home Vision Therapy/Orthoptics

Brock string Loose lens accommodative rock Letter chart accommodative rock Barrel card Life saver cards HTS

Phase Two Ramp Fusional Vergence and Monocular Accommodative Therapy Techniques

Ramp Fusional Vergence Vectograms (clown) Computer orthoptics (RDS) Aperture rule Eccentric circles Monocular Accommodative Facility Loose lens accommodative facility Letter chart accommodative facility

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)
 Eccentric circles

Phase Three Jump Fusional Vergence and Binocular Accommodative Facility Techniques

Jump fusional vergence Vectograms (clown) Computer orthoptics (RDS) Aperture rule Eccentric circles Loose prism facility Binocular accommodative facility Binocular accommodative 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)

Outcome measures at 12 wks

Primary –

 Normal CISS (<16 points) or Improved CISS (by 10 points)

Secondary –

Normal NPC (<6 cms) or improved NPC (by 4 cms)

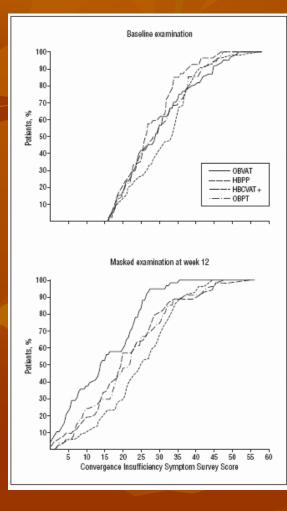
 Normal PFV (>twice phoria and >15 ^) or improved PFV (by 10^)

Results

218 / 221 patients completed followup

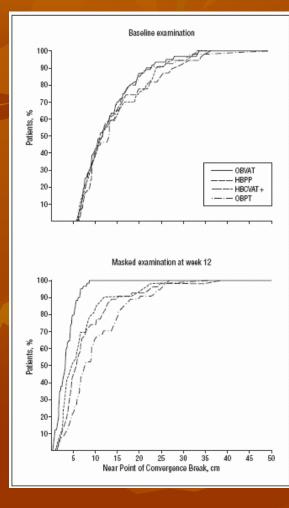
Excellent (>75 %) pt compliance with procedures
67 % of HBCVAT+
84 % of HBPP
87 % of OBPT
91 % of OBVAT

Results – CISS at 12 weeks



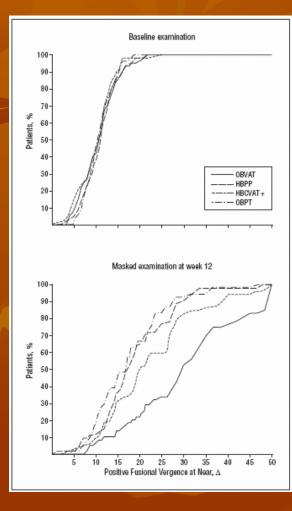
Normal and/or improved CISS
Significant Difference between OBVAT and other groups
No significant diff. between other groups

Results – NPC break at 12 weeks



Normal and/or improved NPC Significant Difference between OBVAT and other groups; No significant diff. between other groups except HBCVAT and **OBPT**

Results – PFV at 12 weeks



 OBVAT significantly better than others
 HBCVAT significantly better than HBPP and OBPT
 No diff. between HBPP and OBPT

	CISS								
	% of Patients								
Treatment Group	Patients, No.	Score ≥ 16 but Improved by ≥ 10	Score <16 but Improved by <10	Score <16 and Improved by ≥10	Score <16 and/o Improved by ≥10				
HBPP	53	13.2	9.4	24.5	47.1				
HBCVAT+ 52		15.4	5.8	17.3	38.5				
OBVAT	59	17.0	6.8	49.2	72.9				
OBPT	54	13.0	7.4	22.2	42.6				
		NPC Break ^a							
	_	% of Patients							
	Patients, No.	Receded NPC but Improved by ≥4 cm	Normal NPC but Improved by <4 cm	Normal NPC and Improved by ≥4 cm	Normal NPC and/o Improved by ≥4 cm				
НВРР	53	28.3	13.2	35.9	77.4				
HBCVAT+	52	23.1	5.8	48.1	77.0				
OBVAT	59	8.5	8.5	78.0	95.0				
OBPT	54	33.3	5.6	20.4	59.3				
		PFVb							
		% of Patients							
	Patients, No.	Insufficient PFV but Improved by >10Δ	Normal PFV but Improved by ≤10∆	Normal PFV and Improved by >10Δ	Normal PFV and/o Improved by >104				
	53	9,4	17.0	30.2	56.6				
HBPP HBCVAT+	52	7.7	7.7	44.2	59.6				
			7.7 10.2 18.5	44.2 69.5 24.1	59.6 83.1 44.5				

Analysis of results

- 73 % of OBVAT were asymptomatic by CISS score as compared to 47 % for HBPP
- Normal NPC + PFV seen in 73 % OBVAT and <40 % HBPP</p>
- All three criteria 73 % of OBVAT successfully treated

What factors make OBVAT better?

- Greater flexibility in manipulating treatment parameters
- Easy to teach/demonstrate
- Patient feedback

 Longer time spent (135 min/wk) compared to HBPP (90 min)

Comments

- Longer treatment means additional improvement?
- Role of convergence sustenance
- Compliance in HBPP?
- HBPP group could be worse in clinical practice ? (no weekly phone calls, monthly evaluations)
- Cost effectivity of OBVAT (1200 \$ for 12 weeks, lost work, lost school)

