Non-surgical interventions for convergence insufficiency (Protocol)

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[Intervention Protocol]

Non-surgical interventions for convergence insufficiency

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ABSTRACT

This is the protocol for a review and there is no abstract. The objectives are as follows:

The objective of this review is to assess the effectiveness of non-surgical treatment options for convergence insufficiency.

BACKGROUND

Description of the condition

Convergence insufficiency (CI) is a common binocular vision disorder (eye muscle co-ordination problem) in which the eyes have a strong tendency to drift outward (exophoria) when reading or doing close work. As a result the eyes do not converge adequately and this condition may lead to symptoms including eyestrain, headaches, double vision, print moving on the page, frequent loss of place when reading, inability to concentrate, and short attention span. Convergence insufficiency is diagnosed when exophoria is greater at near than at distance and the patient has at least one of the following: a remote near point of convergence or decreased positive fusional vergence.

There is considerable variability in the reported prevalence of CI. The estimates of prevalence based on population studies range from 2.25% to 8.3% (Letourneau 1979; Letourneau 1988; Porcar 1997; Rouse 1999). No supportive data could be found to indicate whether the prevalence of CI varies by ethnicity, race, age, or sex.

Description of the intervention

Various treatments are prescribed for treating CI including: base-in prism reading glasses, home-based pencil push-ups, home-based vision therapy, and office-based vision therapy (Chin 1995; Gallaway 2002; Griffin 2002; Grisham 1998; Hugonnier 1969; Pratt-Johnson 2001; Press 1997; Scheiman 2002a; Scheiman 2002b; von Noorden 1994; von Noorden 1996).

The home-based pencil push-ups technique is described by Duke-Elder (Duke-Elder 1973). "Exercises to improve the near point of convergence are carried out simply by the subject holding a target at arm's length and then gradually bringing it towards the eye, all the time maintaining bifoveal fixation. These exercises should be carried out several times each day for a few minutes." Use of a target providing physiological diplopia is often recommended (Hugonnier 1969; Press 1997; von Noorden 2001; Scheiman 2002a; Scheiman 2002b). Some clinicians recommend home-based therapy that is more intensive than pencil push-ups (Scheiman 2002a; Scheiman 2002b). Additional home-based techniques include the use of prism, stereoscopes and various computer software programs designed for vision therapy (Scheiman 2002a; Scheiman 2005). Office-based vision therapy involves a sequence of activities prescribed and monitored by an eye care professional to develop efficient visual skills. It incorporates purposeful, controlled manipulation of target blur, disparity, and proximity, with the aim of normalizing the accommodative and the vergence systems and their mutual interactions (Ciuffreda 2002).

These three vision therapy treatment approaches differ in: 1) ability to control/manipulate stimulus parameters; 2) dosage; 3) mode of administration; and 4) use of motor learning theory and patient feedback.

Controlling/manipulating stimulus parameters

To increase fusional vergence amplitudes a therapy procedure must either maintain accommodation at the plane of regard and change the vergence stimulus, or maintain vergence at the plane of regard and change the stimulus to accommodation (Scheiman 2002b). Instrumentation using a variety of stimuli are available that allow manipulation of these variables to create a vergence demand that is appropriate for an individual patient.

The three vision therapy treatment approaches described above vary significantly in their ability to allow the manipulation of stimulus parameters. With home-based pencil push-up therapy, the stimulus is a small letter on a pencil that is moved closer to the patient. To maintain single vision, a combination of proximal, accommodative, and fusional vergence is used with accommodation and convergence synchronized. In contrast, office-based vision therapy uses a wide variety of instrumentation that is designed to improve the dynamics of the fusional vergence and accommodative systems, typically using stimuli that require an accommodative demand different from the vergence demand. Hence, fusional vergence must be used while proximal and accommodative vergence is minimized. Home-based pencil push-ups plus computer-based vergence/accommodative therapy provides an intermediate level of manipulation of the vergence/accommodative relationship, but lacks the variety of stimuli available with office-based vergence/accommodative therapy.

Dosage

More time is generally spent in office-based vision therapy than either home-based option. In all three therapy approaches the patient must practice procedures at home. In the office-based treatment there is an additional 60 minutes per week of therapy in the doctors office. Total therapy time prescribed tends to be least with home-based pencil push-ups and most with office-based vision therapy.

Mode of administration

In office-based vision therapy a trained therapist administers the treatment, providing the patient with motivation and feedback regarding performance and varying procedures based on the patient's progress. In the two home-based vision therapy approaches, close supervision from a trained therapist is not available.

Motor learning principles and patient feedback

Learning is a set of internal processes associated with practice or experience that result in a relatively permanent change in responding (Schmidt 1988). These processes are believed to be central nervous system phenomena in which sensory and motor information is organized and integrated (Aikon 1988; Arbib 1981; Lisberger 1988) with an ultimate goal of transferring the motor learning outside of the therapy setting.

For motor learning, numerous variables are considered important determinants. These include use of feedback, modeling and demonstration, transfer of training, part to whole task practice, variability in practice, and positive reinforcement. Of the three therapy approaches, office-based vision therapy uses these principles of motor learning and patient feedback most frequently and consistently (Birnbaum 1977; Scheiman 2002b).
Recent studies surveying the ophthalmic community suggest that home-based pencil push-ups is the most commonly prescribed treatment by both ophthalmologists and optometrists (Chin 1995; Scheiman 2002a; Scheiman 2005).

How the intervention might work

The two main categories of intervention for CI are base-in reading glasses and vision therapy, which can be subdivided into pencil push-ups, more intensive home-base vision therapy, and office-based vision therapy, as described above.
Patients with CI are often symptomatic because they need to use excessive convergence to compensate for high exophoria at near distance. Base-in prism reading glasses are believed to work by relieving the need to use this excessive convergence, thereby relieving discomfort. While the exact mechanism is not known for how vision therapy works, the hypothesis is that vision therapy increases positive fusional vergence and convergence ability, thereby relieving the symptoms associated with CI.

Why it is important to do this review

Although various treatments are prescribed for patients with CI there is a lack of consensus regarding the most effective treatment. Significant differences exist in the time commitment for the patient, number of office visits, cost, and complexity of the treatment. A systematic review of clinical trials will help summarize the available evidence on the effectiveness of interventions for patients with CI and will help clinicians select the most appropriate treatments for patients with this condition.

OBJECTIVES

The objective of this review is to assess the effectiveness of non-surgical treatment options for convergence insufficiency.

METHODS

Criteria for considering studies for this review

Types of studies

All relevant randomized and quasi-randomized clinical trials will be included in this review.

Types of participants

We will include trials in which participants have been treated for CI using non-surgical treatment. The definition of CI varies considerably from study to study. For this review CI will be defined as a condition characterized by higher exophoria at near than at far distance, and at least one of the following objective clinical signs:
(1) A receded near-point of convergence (6 cm or greater) (Hayes 1998; Scheiman 2003);
(2) Insufficient positive fusional vergence (i.e. less than twice the near phoria (Sheard's criterion) or positive fusional vergence less than 15 prism diopters) which is one standard deviation below the mean (Sheard 1930; Scheiman 2002b).

Types of interventions

We will include trials in which participants were treated with base-in reading glasses, home-based vision therapy, pencil push-ups, or office-based vision therapy. All trials that compared these non-surgical treatments with a placebo or no treatment or to each other will be included.

Types of outcome measures

Primary outcomes

The primary outcomes for this review will be near point of convergence and positive fusional vergence at near distance measured at the completion of the active treatment program. The primary outcomes will be assessed as both continuous and dichotomous variables when data are available.
(1) Continuous variable
Primary outcomes will be measured as the difference in the degree of change from baseline for each pair of interventions.
(2) Dichotomous variable
We will use currently accepted normative data to determine if patients achieve normal levels for these clinical findings.
A near point of convergence that is < 6 cm after completion of treatment will be considered a normal finding (Yes/No); positive fusional vergence at near that is either twice the magnitude of the exophoria at near or >15 prism diopters after completion of treatment will be considered normal values (Yes/No).
We will analyze primary outcomes at other follow-up times when long-term follow-up data are available.

Secondary outcomes

The secondary outcome for this review will be patient symptoms. Most studies have not used a formal instrument to assess symptoms before and after intervention. In recent years formal instruments have been validated for assessing symptoms before and after treatment of binocular vision disorders (Borsting 2003; Maples 2002; Rouse 2004). We will search for studies using some formal instrument for assessment of symptoms.
We will assess secondary outcomes at different follow-up times as reported in the included study.

Adverse outcomes

Adverse effects of interest include:
1) Worsening of diplopia (double vision);
2) Worsening of headaches;
3) Convergence spasm.
We will summarize the reported adverse effects related to intervention.

Quality of life data

We will describe data on quality of life when available.

Search methods for identification of studies

Electronic searches

We will search the Cochrane Central Library of Controlled Trials (CENTRAL) (which contains the Cochrane Eyes and Vision Group Trials Register) in *The Cochrane Library*, MEDLINE and EMBASE. There will be no date or language restrictions.
See: Appendices for details of search strategies for the electronic databases.

Searching other resources

We will search the reference lists of identified trial reports to find additional trials. We will contact the primary investigators of identified trials for details of additional trials. Manual searches of several optometric journals will be conducted (Optometry, Journal of Behavioral Optometry (1990 to present), Optometry Vision Development (1969 to present), American Orthoptic Journal (1951 to present), Australian Orthoptic Journal (1973 to present), British and Irish Orthoptic Journal (formerly the British Orthoptic Journal) (1954 to present)). There will be no language restriction for trials.

Data collection and analysis

Selection of studies
Two authors will independently review the titles and abstracts resulting from the literature searches according to the inclusion criteria stated above. Abstracts will be classified as 'definitely exclude', 'unsure' or 'definitely include'. We will obtain the full text for articles in the 'unsure' and 'definitely include' categories and re-assess them for inclusion. After examining the full text, the authors of studies labeled as 'unsure' will be contacted for further clarification. Studies labeled as 'excluded' by both authors will be excluded from the review and the reasons for exclusion documented. Included studies will be further assessed for their methodological quality.
Data extraction and management
Two review authors will independently extract the data onto paper data collection forms. Discrepancies will be resolved by discussion. One review author will enter all data into Review Manager (RevMan 4.2). A second author will independently re-enter the data, using the double data-entry facility in order to verify the data entered. Details will be extracted from the studies on the following: methods, participants, interventions, outcomes, adverse events, quality of life issues, economic data and notes.
Assessment of methodological quality of included studies
Two review authors will assess the sources of systematic bias in trials according to the methods described in Section 6 of' the *Cochrane Handbook for Systematic Reviews of Interventions* (Higgins 2006). The following parameters will be considered: (a) quality of allocation concealment (selection bias); (b) masking of outcome assessment (detection bias); (c) completeness to follow up; and (d) intention-to-treat analysis (attrition bias). Each of the parameters will be graded as: A = adequate or yes, B = unclear or not reported; or C = inadequate or no. Concordance between review authors will be recorded and disagreements will be resolved thorough discussion. Masking of participants and care providers will not be used as a quality parameter for this review because of the nature of the intervention.
Measures of treatment effect
Data analysis will follow the guidelines in Section 8 of the *Cochrane Handbook for Systematic Reviews of Interventions* (Deeks 2006). For dichotomous outcomes (*see* subheading Types of outcome measures), a summary risk ratio will be calculated. For continuous outcomes, the mean difference will be calculated.
Unit of analysis issues
If cluster-randomized trials and cross-over trials are included, we will extract data from an analysis that properly accounts for the non-independence of the cluster and cross-over design. If the primary studies failed to report appropriate analyses, we will perform the analyses following section 8.11 of the *Cochrane Handbook for Systematic Reviews of Interventions* (Deeks 2006).
Dealing with missing data
We will contact the authors of trials for additional information. If the authors do not respond within a reasonable period of time,

we will continue the review based on the available information.

Assessment of heterogeneity

We will assess clinical heterogeneity qualitatively by examining the characteristics of the included trial. We will assess statistical heterogeneity quantitatively using the Chi-square test and the I^2 values. A p-value of less than 0.1 from the Chi-square test and I^2 statistic of greater than 50% would indicate substantial statistical heterogeneity.

Assessment of reporting biases

We will use a funnel plot to assess publication bias when sufficient trials are identified.

Data synthesis (meta-analysis)

If little variation is detected between trials (I^2 will be low), we will combine the results in a meta-analysis using a fixed-effects model. Otherwise, we will use a random-effects model to pool the results. If substantial clinical or statistical heterogeneity is present we will not combine study results but will present them with estimate of effect and associated confidence interval.

Investigation of heterogeneity

We will examine potential sources of heterogeneity qualitatively. Variables that can be related to heterogeneity and are candidates for stratified analysis include patient characteristics, types of intervention, and study design parameters.

Sensitivity analysis

We will conduct sensitivity analyses to determine the impact of exclusion of studies with lower methodological quality, unpublished studies and industry-funded studies.

ACKNOWLEDGEMENTS

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* *Indicates the major publication for the study*

APPENDICES

Appendix 1. CENTRAL search strategy

#1 MeSH descriptor Ocular Motility Disorders
#2 MeSH descriptor Convergence, Ocular
#3 MeSH descriptor Accommodation, Ocular
#4 MeSH descriptor Vision, Binocular
#5 MeSH descriptor Exotropia
#6 convergence near insufficienc*
#7 heterophori*
#8 exotropi*
#9 exophori*
#10 (#1 OR #2 OR #3 OR #4 OR #5 OR #6 OR #7 OR #8 OR #9)
#11 prism*
#12 pencil near push*
#13 orthoptic*
#14 (exercis* or therap* or treat*) near (home*)
#15 (exercis* or therap* or treat*) near (office*)
#16 vision therap*
#17 sterogram*
#18 (#11 OR #12 OR #13 OR #14 OR #15 OR #16 OR #17)
#19 (#10 AND #18)

Appendix 2. MEDLINE search strategy

1 exp clinical trial/[publication type]
2 (randomized or randomised).ab,ti.
3 placebo.ab,ti.
4 dt.fs.
5 randomly.ab,ti.
6 trial.ab,ti.
7 groups.ab,ti.
8 or/1-7
9 exp animals/
10 exp humans/
11 9 not (9 and 10)
12 8 not 11
13 exp ocular motility disorders/
14 exp convergence ocular/
15 exp accommodation ocular/
16 exp vision binocular/
17 exp exotropia/
18 (convergence adj3 insufficienc$).tw.
19 heterophoria.tw.
20 exotropi$.tw.
21 exophori$.tw.
22 or/13-21
23 prism$.tw.
24 (pencil adj2 push$).tw.
25 orthoptics.tw.
26 ((exercise$ or therap$ or treat$) adj10 home$).tw.

27 ((exercise$ ortherap$ or treat$) adj10 office$).tw.
28 vision therapy.tw.
29 sterogram$.tw.
30 or/23-29
31 22 and 30
32 12 and 31
The search filter for trials at the beginning of the MEDLINE strategy is from the published paper by Glanville et al (Glanville 2006).

Appendix 3. EMBASE search strategy

1 exp randomized controlled trial/
2 exp randomization/
3 exp double blind procedure/
4 exp single blind procedure/
5 random$.tw.
6 or/1-5
7 (animal or animal experiment).sh.
8 human.sh.
9 7 and 8
10 7 not 9
11 6 not 10
12 exp clinical trial/
13 (clin$ adj3 trial$).tw.
14 ((singl$ or doubl$ or trebl$ or tripl$) adj3 (blind$ or mask$)).tw.
15 exp placebo/
16 placebo$.tw.
17 random$.tw.
18 exp experimental design/
19 exp crossover procedure/
20 exp control group/
21 exp latin square design/
22 or/12-21
23 22 not 10
24 23 not 11
25 exp comparative study/
26 exp evaluation/
27 exp prospective study/
28 (control$ or prospectiv$ or volunteer$).tw.
29 or/25-28
30 29 not 10
31 30 not (11 or 23)
32 11 or 24 or 31
33 exp eye movement disorder/
34 exp binocular convergence/
35 exp accommodation/
36 exp binocular vision/
37 exp divergent strabismus/
38 (convergence adj3 insufficienc$).tw.
39 heterophoria.tw.
40 exotropi$.tw.
41 exophori$.tw.
42 or/33-41

43 prism$.tw.
44 (pencil adj2 push$).tw.
45 orthoptics.tw.
46 ((exercise$ or therap$ or treat$) adj10 home$).tw.
47 ((exercise$ or therap$ or treat$) adj10 office$).tw.
48 vision therapy.tw.
49 sterogram$.tw.
50 or/43-49
51 42and 50
52 32 and 51

WHAT'S NEW

19 August 2008	Amended	Converted to new review format.

HISTORY

Protocol first published: Issue 4, 2007

CONTRIBUTIONS OF AUTHORS

Conceiving the review: JG

Designing the review: MS, JG, TL

Coordinating the review: MS, TL

Data collection for the review

- Designing search strategies: CEVG Trials Search Coordinator, MS, JG

- Undertaking searches: CEVG Trials Search Coordinator

- Screening search results: MS, JG

- Organizing retrieval of papers: MS

- Screening retrieved papers against inclusion criteria: MS

- Appraising quality of papers: MS, JG, TL

- Extracting data from papers: MS, JG, TL

- Writing to authors of papers for additional information: MS, TL

- Providing additional data about papers: MS

- Obtaining and screening data on unpublished studies: MS

Data management for the review

- Entering data into RevMan: MS, TL

Analysis of data: MS, JG, TL

Interpretation of data

- Providing a methodological perspective: JG, MS, TL

- Providing a clinical perspective: MS

- Providing a policy perspective: MS, JG

- Providing a consumer perspective: JG

Writing the review: MS, JG, TL

Providing general advice on the review: MS, JG

Securing funding for the review: JG, TL

Performing previous work that was the foundation of the current study: MS, TL

DECLARATIONS OF INTEREST

Mitchell Scheiman, OD is the Study Chair of the Convergence Insufficiency Treatment Trial (CITT) Study which is a randomized clinical trial to examine the effects of treatments for convergence insufficiency in children. The first phase of the study will be completed on February 1, 2007. He was also the study chair of three other randomized clinical trials studying treatments for convergence insufficiency.

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Internal sources

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