Physical therapy for Bell´ s palsy (idiopathic facial paralysis) (Protocol)

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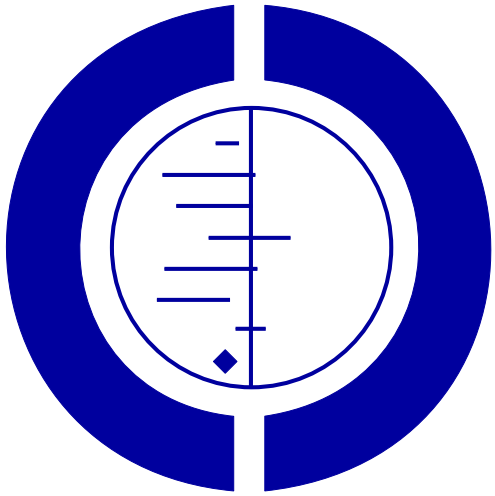

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ABSTRACT

This is the protocol for a review and there is no abstract. The objectives are as follows:
The effectiveness of physical therapies on the outcome of Bell's palsy (idiopathic facial palsy) will be reviewed.

BACKGROUND

Idiopathic facial palsy, also called Bell's palsy, is an acute disorder of the facial nerve, which may begin with symptoms of pain in the mastoid region and produce full or partial paralysis of movement of one side of the face (Adour 1982; Valença 2001). Its cause is not known (Peitersen 2002). Increasing evidence suggests that the main cause of Bell's palsy is reactivation of latent herpes simplex virus type 1 in the cranial nerve ganglia (Diego 1999; Holland 2004; Valença 2001). How the virus damages the facial nerve is uncertain (Gilden 2004).

The annual incidence of Bell's palsy varies widely, ranging between 11.5 and 40.2 cases per 100,000 population (Diego 1999; Peitersen 2002). There are peaks of incidence in the 30 to 50 year and 60 to 70 year old age groups (Gilden 2004; Gonçalvez 1997).

Bell's palsy has a fair prognosis without treatment (Holland 2004). According to Peitersen (Peitersen 2002), complete recovery was observed in 71% of all patients. Ninety-four per cent of patients with incomplete and 61% with complete paralysis made a complete recovery. The main question is whether results would be better if some treatment were given.

About 23% of people with Bell's palsy are left with either moderate to severe symptoms, hemifacial spasm, partial motor recovery, crocodile tears, contracture or synkinesis (involuntary twitching of the face or blinking). Recurrence occurs in 8.3% (Valença 2001).

The prognosis depends to a great extent on the time at which recovery begins. Early recovery gives a good prognosis and late recovery a bad prognosis. If recovery begins in one week, 88% obtain full recovery, in one to two weeks 83% and in two to three weeks 61%. Normal taste, stapedius reflex and tearing give a significantly better prognosis than if these functions are impaired. Recovery is less likely to be satisfactory with complete rather than incomplete paralysis, with pain behind the ear and in older people (Danielidis 1999). Other poor prognostic factors include hypertension and diabetes mellitus (Gilden 2004; Peitersen 2002).

Evaluation of therapy is made difficult because of the high rates of spontaneous and complete recovery (Peitersen 2002). The principles of treatment in the acute phase have not changed over the past 20 years (Adour 1982). They focus on protection of the cornea from drying and abrasion due to impaired lid closure and tear production. Lubricating drops are recommended during the day and a simple eye ointment at night (Holland 2004; Valença 2001).

Cochrane reviews conclude that the available evidence does not show significant benefit from aciclovir or similar agents (Allen 2005), steroid therapy (Salinas 2005) or acupuncture (He 2005)) They recommend large trials with 12 months follow up. Based on a lower standard of evidence, the American Academy of Neurology Practice Parameter recommended corticosteroids and antiviral agents in the first week of paralysis (Grogan 2001). The parameter made no recommendation about physical therapy, although it is commonly used. A Cochrane review of exercise for people with peripheral neuropathy suggested that progressive resisted exercises may improve muscle strength in affected muscles (White 2005).

Some authors suggest that facial nerve decompression be consid-

ered, although there are no data from clinical trials to support its use (Adour 2002; Gilden 2004; Grogan 2001; Peitersen 2002).

Thermal methods, electrotherapy (which uses an electrical current to cause a single muscle or group of muscles to contract), massage, facial exercises and biofeedback are forms of physical therapy that have been used (Mosforth 1958; Peitersen 2002). Exercise therapy has been used more than other interventions (Beurskens 2003; Ross 1991; Segal 1995). There is no known systematic review of these treatments.

OBJECTIVES

The effectiveness of physical therapies on the outcome of Bell's palsy (idiopathic facial palsy) will be reviewed.

CRITERIA FOR CONSIDERING STUDIES FOR THIS REVIEW

Types of studies

We will include all randomised or quasi-randomised (alternate or other systematic allocation) controlled trials involving any physical therapy compared with no treatment, placebo treatment, drug treatment, acupuncture or other physical therapy interventions.

Types of participants

We will include participants with a diagnosis of Bell's palsy, defined as idiopathic lower motor neuron facial palsy of sudden onset. Participants of any age will be included, and all degrees of severity will be included. People with facial palsy due to Ramsay-Hunt syndrome or other recognised causes will not be included.

Types of intervention

We will include any form of physical therapy treatment. Types of physical therapy interventions include: facial exercises such as strengthening and stretching, endurance, therapeutic and facial mimic exercises ("mime therapy") (Beurskens 2003), electrotherapy, biofeedback, transcutaneous electrical nerve stimulation (TENS) or electrical neural muscular stimulation (ENMS), thermal methods, massage, alone or in combination with any other therapy.

Types of outcome measures

The primary outcome measure will be incomplete recovery six months after randomisation. Incomplete recovery will be defined in two ways. Participants who have House Grade III (moderate dysfunction) or worse (House 1985) at entry will be considered to have incomplete recovery if they still have House Grade III or worse. For participants who have House Grade II at entry, incomplete recovery will be defined as a persistent House Grade II or worse after six months. If the House Grade score is not available, another similar facial nerve disability score may be used instead, such as that of Van Swearingen (Van Swearingen 1996).
Secondary outcome measures will be:
(1) motor synkinesis, crocodile tears or facial spasm six months after onset
(2) incomplete recovery after one year
(3) adverse effects attributable to the intervention.

SEARCH METHODS FOR IDENTIFICATION OF STUDIES

See: Cochrane Neuromuscular Disease Group methods used in reviews.

(1) We will search the Cochrane Neuromuscular Disease Group Trials register using the terms 'Bell's palsy' or 'idiopathic facial paralysis' or 'facial palsy'. We will also search the Cochrane Central Register of Controlled Trials (*The Cochrane Library*, Issue 3, 2006), MEDLINE (January 1966 to the present), EMBASE (January 1980 to the present), LILACS (January 1982 to the present), PEDro (from 1929 to the present), HealthSTAR (February 1994 to the present) and CINAHL (January 1982 to the present). There will be no language restrictions or restrictions due to date of publication. The "optimal" sensitive search strategies designed to identify clinical trials will be used as described by Dickersin et al. (Dickersin 1994) and Castro et al. (Castro 1999), in the Cochrane Handbook. They will be combined with the following phrases, adapted to each database as appropriate:

#1 (physical therapy) OR physio* OR rehabilitation OR (exercises therapy) OR (physical education training) OR (physical fitness) OR (physical activit*) OR kinesiotherapy OR stretching OR strengthening OR endurance OR biofeedback OR electromyography OR electromyogram* OR ultrasound OR laser OR (short wave therapy) OR iontophor* OR manipulat* OR cryotherapy

AND

#2 (Bell palsy) OR (Bell's palsy) OR (facial paralysis) OR (facial palsy) OR (facial neuropathy) OR (facial nerve) OR (idiopathic facial paralysis)

(2) We will check references of all identified trials.
(3) We will contact physical therapy companies in order to obtain data on unpublished trials.
(4) We will contact first authors of all included trials for further information or information regarding unpublished trials.

METHODS OF THE REVIEW

Study selection

Titles and abstracts identified from the register will be scrutinized by two authors (LJT, VPV). The full texts of all potentially relevant studies will be obtained for independent assessment by the authors. Two authors will decide which trials fit the inclusion criteria. Disagreements about inclusion criteria will be resolved by consensus and consultation with a third author (BGOS).

Assessment of methodological quality

The assessment of methodological quality will take into account secure method of randomisation, allocation concealment, observer blinding, patient blinding, differences at baseline of the experimental groups, and completeness of follow-up. These items will be assessed according to the Cochrane Collaboration standard scheme: grade A: adequate, grade B: unclear, grade C: inadequate or not done. Two authors (LJT, VPV) will assess quality independently. Disagreement between the authors will be resolved by discussion if necessary with a third author (BGOS).

Data extraction

Data on participants, methods, interventions, outcomes and results will be extracted by two authors independently using a specially constructed data extraction form. Missing data will be obtained from the trial authors whenever possible.

Analysis of data

Data will be entered and analysed with the Review Manager 4.2 (RevMan) software. For dichotomous data, relative risks (RR) with 95% confidence intervals (CI) will be estimated based on the fixed-effect model or on the random effects model if heterogeneity is present. The number needed to treat (NNT) and number needed to harm (NNH) will be calculated if possible. For continuous outcomes, weighted mean differences (WMD) between groups will be estimated.

Heterogeneity will be assessed by chi-squared test and will be assumed to be present when the significance level is lower than 0.10 ($p<0.10$). When significant heterogeneity is present, an attempt will be made to explain the differences based on clinical characteristics of the included studies. A sensitivity analysis will be performed, omitting trials which included participants with different clinical characteristics or trials with lower methodological quality.

When there are sufficient trials of the same intervention, we will construct a funnel plot (of trial effect versus trial size) to assess potential publication bias.

Subgroup analysis:

Separate subgroup analyses of participants with more severe disability (House Grade III or worse) and less severe disability (House Grade II or better) will be undertaken. We will also consider patients treated before and after two weeks from onset.

If the information from randomised controlled trials is inadequate, adverse events and costs will be considered in the discussion section of the review taking into account observational studies.

POTENTIAL CONFLICT OF INTEREST

None known.

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COVER SHEET

Title	Physical therapy for Bell´ s palsy (idiopathic facial paralysis)
Authors	Teixeira LJ, Soares BGDO, Vieira VP
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