Bell's palsy

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N. Julian Holland and Jonathan M. Bernstein

ABSTRACT

INTRODUCTION: Bell's palsy is characterised by an acute, unilateral, partial, or complete paralysis of the face. Bell's palsy occurs in a lower motor neurone pattern. The weakness may be partial or complete, and may be associated with mild pain, numbness, increased sensitivity to sound, and altered taste. Bell's palsy is idiopathic, but a proportion of cases may be caused by re-activation of herpes virus at the geniculate ganglion of the facial nerve. Bell's palsy is most common in people aged 15 to 40 years, with a 1 in 60 lifetime risk. Most people make a spontaneous recovery within 1 month, but up to 30% show delayed or incomplete recovery. METHODS AND OUTCOMES: We conducted a systematic review to answer the following clinical questions: What are the effects of drug treatments for Bell's palsy in adults and children? What are the effects of physical treatments for Bell's palsy in adults and children? We searched: Medline, Embase, The Cochrane Library, and other important databases up to October 2013 (Clinical Evidence reviews are updated periodically, please check our website for the most up-to-date version of this review). We included harms alerts from relevant organisations such as the US Food and Drug Administration (FDA) and the UK Medicines and Healthcare products Regulatory Agency (MHRA). RESULTS: We found 13 studies that met our inclusion criteria. We performed a GRADE evaluation of the quality of evidence for interventions. CONCLUSIONS: In this systematic review, we present information relating to the effectiveness and safety of the following interventions: antiviral treatment, corticosteroids (alone or with antiviral treatment), hyperbaric oxygen therapy, and facial re-training.

QUESTIONS

INTERVENTIONS

Key points

- Bell's palsy is an idiopathic, unilateral, acute paresis (partial weakness) or paralysis (complete palsy) of facial movement caused by dysfunction of the lower motor neurone of the facial nerve. Bell's palsy is a diagnosis of exclusion of other causes of facial nerve palsy.

  Most people with paresis make a spontaneous recovery within 3 weeks. Up to 30% of people, typically those with paralysis, have a delayed or incomplete recovery.
- Corticosteroids alone improve the rate of recovery and the proportion of people who make a full recovery, and reduce cosmetically disabling sequelae compared with placebo or no treatment.
- Antiviral treatment alone is no more effective than placebo at improving facial motor function and reducing the risk of disabling sequelae.
- We found no good evidence of significant benefit of combination corticosteroid-antiviral therapy over corticosteroid alone. However, there is a lack of data on people presenting with complete paralysis and any potential benefit of combination corticosteroid-antiviral therapy cannot be excluded.
- Hyperbaric oxygen may improve the time to recovery and the proportion of people who make a full recovery compared with corticosteroids. However, the evidence for this is weak and comes from one small RCT.
- Facial re-training may improve the recovery of facial motor function scores, including stiffness and lip mobility, and may reduce the risk of motor synkinesis in Bell's palsy, but the evidence is too weak to draw reliable conclusions.

DEFINITION

Bell's palsy is an idiopathic, unilateral, acute weakness of the face in a pattern consistent with peripheral facial nerve dysfunction, and may be partial or complete, occurring with equal frequency on either side of the face. Bell's palsy is idiopathic but there is weak evidence that Bell's palsy is cased by herpes simplex virus. [1] Additional symptoms of Bell's palsy may include mild pain in or behind the ear, oropharyngeal or facial numbness, impaired tolerance to ordinary levels of noise, and disturbed taste on the anterior part of the tongue. [2] Severe pain is more suggestive of herpes zoster virus infection and Ramsay Hunt syndrome. Bell's palsy is a diagnosis of exclusion. Other

causes of lower motor neurone weakness include middle ear infection, parotid malignancy, malignant otitis externa, [3] and lateral skull base tumours. Features such as sparing of movement in the upper face (central pattern), or weakness of a specific branch of the facial nerve (segmental pattern), suggest an alternative cause. [4] Bell's palsy is less commonly the cause of facial palsy in children aged under 10 years (<50%). [5]

INCIDENCE/ PREVALENCE

The incidence is about 20 in 100,000 people a year, with about 1 in 60 lifetime risk. [5] Bell's palsy has a peak incidence between the ages of 15 and 40 years. Men and women are equally affected, although the incidence may be higher in pregnant women. [5]

AETIOLOGY/ RISK FACTORS

The cause of Bell's palsy is uncertain. It is thought that re-activated herpes virus at the geniculate ganglion of the facial nerve may play a key role in the development of Bell's palsy. Herpes simplex virus (HSV)-1 has been detected in up to 50% of cases by some researchers. [6] However, one study demonstrated the replication of HSV, herpes zoster virus [HZV], or both, in <20% of cases. [7] Herpes zoster-associated facial palsy more frequently presents as zoster sine herpete (without vesicles), although 6% of people develop vesicles (Ramsay Hunt syndrome). [6] Infection of the facial nerve by HZV initially results in reversible neuropraxia, but irreversible Wallerian degeneration may occur. Treatment plans for the management of Bell's palsy should recognise the possibility of HZV infection. [8]

PROGNOSIS

Overall, Bell's palsy has a fair prognosis without treatment. Clinically important improvement occurs within 3 weeks in 85% of people and within 3 to 5 months in the remaining 15%. [5] People failing to show signs of improvement by 3 weeks may have suffered severe degeneration of the facial nerve, or may have an alternative diagnosis that requires identification by specialist examination or investigations, such as CT or MRI. Overall, 71% of people will experience complete recovery in facial muscle function (i.e., 61% of people with complete paralysis, 94% of people with partial paralysis). [5] The remaining 29% have permanent mild to severe residual facial muscle weakness, 17% with contracture, and 16% with hemifacial spasm or synkinesis. [5] Incomplete recovery of facial expression has a long-term impact on quality of life and self-esteem. The prognosis for children with Bell's palsy is generally better, with a high rate (>90%) of spontaneous recovery, in part because of the higher frequency of paresis. [5] However, children with paralysis have permanent facial muscle weakness as frequently as adults. [9]

AIMS OF INTERVENTION

To increase the proportion of people making a full or partial recovery; to increase the speed of recovery; to prevent progression from partial to complete facial palsy; to reduce the incidence of motor synkinesis and contracture; to reduce the risk of eye injury; to minimise any side effects of treatment.

OUTCOMES

Recovery of motor function: grade of recovery of motor function of the face ideally at 12 months (or other time point when clearly stated); **presence of sequelae** ideally at 12 months including motor synkinesis, autonomic dysfunction, or hemifacial spasm; **time to recovery** including time to full recovery; impact on quality of life; **adverse effects** of treatment.

METHODS

Clinical Evidence search and appraisal October 2013. The following databases were used to identify studies for this systematic review: Medline 1966 to October 2013, Embase 1980 to October 2013, and The Cochrane Database of Systematic Reviews 2013, issue 9 (1966 to date of issue). Additional searches were carried out in the Database of Abstracts of Reviews of Effects (DARE) and the Health Technology Assessment (HTA) Database. We also searched for retractions of studies included in the review. Titles and abstracts identified by the initial search, run by an information specialist, were first assessed against predefined criteria by an evidence scanner. Full texts for potentially relevant studies were then assessed against predefined criteria by an evidence analyst. Studies selected for inclusion were discussed with an expert contributor. All data relevant to the review were then extracted by an evidence analyst. Study design criteria for inclusion in this review were: published systematic reviews and RCTs, at least double-blinded and containing more than 20 individuals, of whom more than 80% were followed up. There was no minimum follow-up. We excluded all studies described as single-blinded, 'open', 'open label', or not blinded unless blinding was impossible. We included RCTs and systematic reviews of RCTs where harms of an included intervention were assessed, applying the same study design criteria for inclusion as we did for benefits. In addition, we use a regular surveillance protocol to capture harms alerts from organisations such as the FDA and the MHRA, which are added to the reviews as required. To aid readability of the numerical data in our reviews, we round many percentages to the nearest whole number. Readers should be aware of this when relating percentages to summary statistics such as relative risks (RRs) and odds ratios (ORs). We have performed a GRADE evaluation of the quality of evidence for interventions included in this review (see table, p 20). The categorisation of the quality of the evidence (high, moderate, low, or very low) reflects the quality of evidence

available for our chosen outcomes in our defined populations of interest. These categorisations are not necessarily a reflection of the overall methodological quality of any individual study, because the Clinical Evidence population and outcome of choice may represent only a small subset of the total outcomes reported, and population included, in any individual trial. For further details of how we perform the GRADE evaluation and the scoring system we use, please see our website (www.clinicalevidence.com).

QUESTION **What are the effects of drug treatments for Bell's palsy in adults and children?**

OPTION **CORTICOSTEROIDS**

- For GRADE evaluation of interventions for Bell's palsy, see table, p 20 .
- Corticosteroids alone improve rate of recovery and the proportion of people who make a full recovery, and reduce motor synkinesis and autonomic dysfunction compared with placebo or no treatment.
- Good evidence exists that corticosteroid therapy improves facial palsy in people with Bell's palsy independent of severity at presentation. Treatment is likely to be more effective when started within 72 hours of onset.
- Contraindications to corticosteroid therapy exist, and adverse effects are more likely following 7 days of treatment.
- The potential adverse effects of corticosteroid treatment include diabetes, hypertension, glaucoma, psychosis, fluid and electrolyte disturbances, gastrointestinal tract haemorrhage, and avascular necrosis of the femoral head. The increased incidence of abnormal glucose tolerance in people with Bell's palsy warrants caution.

Benefits and harms

Corticosteroids versus placebo or no specific treatment:

We found two systematic reviews (search dates 2008 [10] and 2009 [11]) comparing corticosteroids versus placebo or no specific treatment using different inclusion criteria. We also report the outcomes of the two large RCTs [12] [13] (included in both systematic reviews) that have enabled the meta-analyses and influenced the changed treatment recommendations in this area. We also found one further analysis [14] of the dataset included in the second large RCT; [13] it did not include any different outcomes or time points to those included in the original RCT and, therefore, has not been reported further here.

Recovery of motor function

Corticosteroids compared with placebo or no specific treatment Corticosteroids seem more effective than placebo or no treatment at improving the recovery of facial motor function up to 12 months (moderate-quality evidence).

Ref (type)	Population	Outcome, Interventions	Results and statistical analysis	Effect size	Favours
Recovery of motor function					
[10] Systematic review	1507 people 7 RCTs in this analysis	**Proportion of people with incomplete recovery of facial motor function , 6–9 months** 175/754 (23%) with corticosteroids 245/753 (33%) with placebo/no treatment	RR 0.71 95% CI 0.61 to 0.83	●○○	corticosteroids
[11] Systematic review	1285 people 10 RCTs in this analysis	**Proportion of people with unsatisfactory recovery** 102/629 (16%) with corticosteroids 245/656 (37%) with control	RR 0.69 95% CI 0.55 to 0.87 P = 0.001	●○○	corticosteroids
[12] RCT **4-armed trial**	551 people with Bell's palsy, moderate to severe weakness In review [10] [11]	**Proportion of people with complete recovery , 9 months** 237/251 (94%) with prednisolone 200/245 (82%) with no prednisolone The 4 arms assessed: prednisolone plus placebo, aciclovir plus placebo, prednisolone plus	OR 3.32 95% CI 1.72 to 6.44 P <0.001	●●○	prednisolone

Ref (type)	Population	Outcome, Interventions	Results and statistical analysis	Effect size	Favours
		aciclovir, and placebo plus placebo All participants started treatment within 72 hours (54% within 24 hours) Complete recovery defined as House-Brackmann grade 1 Final outcome data were available for 496/551 (90%) people			
[13] RCT **4-armed trial**	839 people with Bell's palsy, moderate to severe weakness In review [10] [11]	**Proportion of people with fully recovered facial function , 12 months** 300/416 (72%) with prednisolone (5 days of treatment then a 5-day taper) 237/413 (57%) with placebo The remaining arms assessed valaciclovir and prednisolone plus valaciclovir Treatment started within 72 hours of palsy onset Fully recovered facial function = Sunnybrook score of 100 points	ARR 15% 95% CI 8% to 21% P <0.0001	○○○	prednisolone

Presence of sequelae

Corticosteroids compared with placebo or no specific treatment Corticosteroids may be more effective than placebo or no treatment at reducing motor synkinesis, and autonomic dysfunction at 6 to 12 months, but we don't know about improving quality of life (low-quality evidence).

Ref (type)	Population	Outcome, Interventions	Results and statistical analysis	Effect size	Favours
Presence of sequelae					
[10] Systematic review	901 people 3 RCTs in this analysis	**Synkinesis and autonomic dysfunction** 56/455 (12%) with corticosteroids 92/446 (21%) with placebo/no treatment	RR 0.60 95% CI 0.44 to 0.81 P = 0.0008	●○○	corticosteroids
[11] Systematic review	Number of people not reported	**Synkinesis and autonomic dysfunction** with corticosteroids with control Absolute results not reported	RR 0.48 95% CI 0.36 to 0.65 P <0.001 NNT 7 95% CI 6 to 10	●●○	corticosteroids
[12] RCT **4-armed trial**	551 people with Bell's palsy, moderate to severe weakness In review [10] [11]	**Quality of life , 9 months** with prednisolone with no prednisolone Absolute results not reported The 4 arms assessed: prednisolone plus placebo, aciclovir plus placebo, prednisolone plus aciclovir, and placebo plus placebo All participants started treatment within 72 hours (54% within 24 hours)	P = 0.04 The RCT found no significant difference between groups at 3 months (P = 0.4)	○○○	placebo

Ref (type)	Population	Outcome, Interventions	Results and statistical analysis	Effect size	Favours
		Final outcome data were available for 496/551 (90%) people			
[13] RCT **3-armed trial**	743 people with Bell's palsy, moderate to severe weakness In review [10] [11]	**Synkinesis , 12 months** 51/370 (14%) with prednisolone 107/373 (29%) with placebo The remaining arms assessed valaciclovir and prednisolone plus valaciclovir Treatment started within 72 hours	ARR –15% 95% CI –21% to –9% P <0.0001	○○○	prednisolone

Time to recovery

Corticosteroids compared with placebo or no specific treatment Prednisolone is more effective than placebo or no treatment at reducing the time to recovery of facial nerve function (high-quality evidence).

Ref (type)	Population	Outcome, Interventions	Results and statistical analysis	Effect size	Favours
Time to recovery					
[13] **3-armed trial**	839 people with Bell's palsy, moderate to severe weakness In review [10] [11] 829 people analysed	**Median time to recovery** 75 days with prednisolone 104 days with placebo The remaining arm assessed valaciclovir Treatment started within 72 hours Fully recovered facial function = Sunnybrook score of 100 points	HR 1.40 95% CI 1.18 to 1.64 P <0.0001	●○○	prednisolone

No data from the following reference on this outcome. [10] [11] [12]

Adverse effects

Ref (type)	Population	Outcome, Interventions	Results and statistical analysis	Effect size	Favours
Adverse effects					
[10] Systematic review	Number of people not reported	**Adverse effects** with corticosteroids with placebo/no treatment Absolute results not reported	The review did not pool results of adverse effects data; see Further information on studies		
[11] Systematic review	Number of people not reported	**Major adverse effects** with corticosteroids with control Absolute results not reported	RR 0.56 95% CI 0.09 to 3.39 P = 0.44	⟷	Not significant
[11] Systematic review	Number of people not reported	**Minor adverse effects** with corticosteroids with control Absolute results not reported	RR 1.23 95% CI 0.93 to 1.64 P = 0.15	⟷	Not significant

Ref (type)	Population	Outcome, Interventions	Results and statistical analysis	Effect size	Favours
[12] [13] RCT	1390 people	**Minor adverse effects** with prednisolone with placebo Absolute numbers not reported	Both large RCTs included in the reviews reported minor adverse effects in up to 11% of participants, but there was no significant difference between corticosteroids and placebo	⟷	Not significant

Corticosteroids versus aciclovir:

See option on Antiviral treatment, p 7 .

Corticosteroids versus plus antiviral treatment versus either treatment alone:

See option on Corticosteroids plus antiviral treatment, p 9 .

Further information on studies

[10] The review found that three included RCTs reported no adverse effects, one included a trial that reported three participants receiving prednisolone suffered from temporary sleep disturbances, and four included trials that gave a detailed account of 177 non-serious adverse effects with no significant difference between those receiving corticosteroids and those receiving placebo.

Comment:

Clinical guide:

Bell's palsy is a diagnosis of exclusion. Other causes of lower motor neurone facial weakness such as middle ear infection, parotid malignancy, malignant otitis externa, and lateral skull base tumours should be considered.

In people presenting with mild facial paresis from Bell's palsy, there is a high rate of spontaneous resolution without treatment.

Good evidence exists that corticosteroid therapy improves facial palsy in people with Bell's palsy independent of severity at presentation.

Corticosteroid therapy is likely to be more effective when started within 72 hours of onset.

Contraindications to corticosteroid therapy exist, and adverse effects are more likely following 7 days of treatment.

The potential adverse effects of corticosteroid treatment include diabetes, hypertension, glaucoma, psychosis, fluid and electrolyte disturbances, gastrointestinal tract haemorrhage, and avascular necrosis of the femoral head. The increased incidence of abnormal glucose tolerance in people with Bell's palsy warrants caution.

All children presenting with facial palsy and adults with delayed recovery should be referred for assessment by an otolaryngologist - head and neck surgeon or other appropriate specialist.

Specialist management is required when a specific cause of the facial weakness is identified (i.e. not Bell's palsy) such as acute otitis media, cholesteatoma, parotid malignancy, tumour, Lyme disease, or malignant otitis externa. Ramsay Hunt syndrome (herpes zoster oticus) is suggested by otalgia, vesicles in the ear or mouth, and hearing loss or imbalance and antiviral therapy is indicated. Facial weakness is much less likely to be caused by Bell's Palsy in children (<50% of cases) and urgent specialist evaluation is warranted.

OPTION ANTIVIRAL AGENTS

- For GRADE evaluation of interventions for Bell's palsy, see table, p 20 .
- Antiviral treatment alone is no more effective than placebo at improving recovery of facial motor function and reducing the risk of motor synkinesis or crocodile tears, and is also less effective than corticosteroid treatment at improving recovery of facial motor function.

Benefits and harms

Antiviral agents versus placebo:

We found two systematic reviews (search date 2009, 7 RCTs, 1987 people; [15] and search date 2009, 18 RCTs – 7 of which are reported in the first review, 2786 people [11]), which compared antiviral treatment versus placebo or corticosteroids. We also found one further analysis [14] of the dataset of an RCT [13] included in the first review. [15] It did not include any different outcomes or time points to those included in the original RCT and, therefore, has not been reported further here.

Recovery of motor function

Antiviral agents compared with placebo Antiviral treatment seems no more effective than placebo at increasing the rate of complete recovery at the end of treatment (moderate-quality evidence).

Ref (type)	Population	Outcome, Interventions	Results and statistical analysis	Effect size	Favours
Recovery of motor function					
[15] Systematic review	1228 people 5 RCTs in this analysis	**Proportion of people with incomplete recovery , end of trial** 73/625 (11%) with antivirals 95/603 (16%) with placebo	RR 0.71 95% CI 0.48 to 1.05 P = 0.08	⟷	Not significant
[15] Systematic review	631 people included in the 2 largest trials in the review 2 RCTs in this analysis Subgroup analysis	**Proportion of people with incomplete recovery , end of trial** 101/303 (33%) with antivirals 91/328 (28%) with placebo	RR 1.14 95% CI 0.80 to 1.62 P = 0.48	⟷	Not significant

No data from the following reference on this outcome. [11]

Presence of sequelae

Antiviral treatment compared with placebo Antiviral treatment may be no more effective than placebo at reducing the risk of motor synkinesis or crocodile tears at the end of treatment (low-quality evidence).

Ref (type)	Population	Outcome, Interventions	Results and statistical analysis	Effect size	Favours
Presence of sequelae					
[15] Systematic review	99 people Data from 1 RCT	**Motor synkinesis or crocodile tears** 7/53 (13%) with antivirals 13/46 (28%) with placebo	RR 0.47 95% CI 0.20 to 1.07 P = 0.07	⟷	Not significant
[11] Systematic review	Number of people not reported 2 RCTs in this analysis	**Motor synkinesis or crocodile tears** with antivirals with placebo Absolute results not reported	RR 0.75 95% CI 0.51 to 1.11 P = 0.15	⟷	Not significant

Time to recovery

No data from the following reference on this outcome. [11] [15]

Adverse effects

Ref (type)	Population	Outcome, Interventions	Results and statistical analysis	Effect size	Favours
Adverse effects					
[15] Systematic review	1544 women 3 RCTs in this analysis	**Adverse effects** 97/774 (13%) with antivirals 92/770 (12%) with placebo	RR 1.06 95% CI 0.81 to 1.38 P = 0.67	⟷	Not significant
[11] Systematic review	Number of people not reported	**Major adverse effects** with antivirals with placebo Absolute results not reported The review did not use a subgroup analysis for antivirals versus placebo, so these results are based on all antiviral trials in the review	RR 0.97 95% CI 0.27 to 3.74 P = 0.67	⟷	Not significant
[11] Systematic review	Number of people not reported	**Minor adverse effects** with antivirals with placebo Absolute results not reported The review did not use a subgroup analysis for antivirals versus placebo, so these results are based on all antiviral trials in the review	RR 1.02 95% CI 0.79 to 1.33 P = 0.87	⟷	Not significant

Antiviral agents versus corticosteroids:

We found two systematic reviews (search date 2009, 7 RCTs, 1987 people; [15] and search date 2009, 18 RCTs – 7 of which are reported in the first review, 2786 people [11]), which compared antiviral treatment versus placebo or corticosteroids.

Recovery of motor function

Antiviral agents compared with corticosteroids Antiviral treatment is less effective than corticosteroids at reducing the proportion of people with incomplete recovery at the end of treatment (high-quality evidence).

Ref (type)	Population	Outcome, Interventions	Results and statistical analysis	Effect size	Favours
Recovery of motor function					
[15] Systematic review	768 people 3 RCTs in this analysis	**Proportion of people with incomplete recovery , end of trial** 113/384 (29%) with antivirals 58/384 (15%) with corticosteroids	RR 2.82 95% CI 1.09 to 7.32 P = 0.03	●●○	corticosteroids

No data from the following reference on this outcome. [11]

Presence of sequelae

No data from the following reference on this outcome. [11] [15]

Time to recovery

No data from the following reference on this outcome. [11] [15]

Adverse effects

Ref (type)	Population	Outcome, Interventions	Results and statistical analysis	Effect size	Favours
Adverse effects					
[15] Systematic review	667 people 2 RCTs in this analysis	**Adverse effects** 42/330 (13%) with antivirals 45/337 (13%) with corticosteroids	RR 0.96 95% CI 0.65 to 1.14 P = 0.82	⟷	Not significant

No data from the following reference on this outcome. [11]

Antiviral agents plus corticosteroids versus either treatment alone:
See option on Corticosteroids plus antiviral treatment, p 9 .

Further information on studies

[11] The second review supported the findings of the first review in rates of incomplete facial recovery for antiviral agents versus placebo, as it analysed the same two large RCTs assessed by the first review. The review included some single-blinded studies in the meta-analysis.

Comment: Aciclovir is taken five times per day and demonstrates poorer bioavailability than valaciclovir (a pro-drug of aciclovir). [16] Valaciclovir is more effective in the management of shingles. In pregnant women, antiviral treatments such as aciclovir should only be prescribed under the guidance of an obstetrician.

OPTION CORTICOSTEROIDS PLUS ANTIVIRAL TREATMENT

- For GRADE evaluation of interventions for Bell's palsy, see table, p 20 .
- For people with paresis, there is good evidence that corticosteroid monotherapy, started as soon as practicable, is appropriate in the absence of specific contraindications. For people in this group, such a high proportion fully recover that any potential benefit of antiviral therapy is unlikely to be clinically significant.
- We found no good evidence of significant benefit of combination corticosteroid-antiviral therapy over corticosteroid alone. However, there is a lack of data on people presenting with complete paralysis and any potential benefit of combination corticosteroid-antiviral therapy cannot be excluded.
- There is good evidence that people presenting with paralysis should also be offered corticosteroid monotherapy in absence of specific contraindications. Combination corticosteroid/antiviral therapy may be considered, as a

lack of an important additional benefit of combination therapy could not be conclusively ruled out by the three largest trials, and the risk of adverse effects of oral antiviral therapy is very low.

- A proportion of people will progress from paresis to paralysis and therapy recommendations may warrant review if this occurs. This is particularly relevant if the person develops signs of Ramsay Hunt syndrome.

Benefits and harms

Corticosteroids plus antiviral treatment versus placebo/no treatment:

We found three systematic reviews (search dates 2009 [11] [15] [17]), which assessed the effects of corticosteroids plus antiviral treatment compared with placebo, no treatment, or either corticosteroids or antivirals alone in people with Bell's palsy. All the reviews included different RCTs in their meta-analyses; only one review reported our outcomes of interest. [15]

Recovery of motor function

Corticosteroids plus antiviral treatment compared with placebo Corticosteroids plus antiviral treatment seem more effective than placebo at reducing the risk of incomplete recovery of facial function at the end of treatment (moderate-quality evidence).

Ref (type)	Population	Outcome, Interventions	Results and statistical analysis	Effect size	Favours
Recovery of motor function					
[15] Systematic review	1987 people 7 RCTs in this analysis	**Proportion of people with incomplete recovery , end of trial** 51/330 (15%) with corticosteroids plus antiviral treatment 91/328 (28%) with placebo	RR 0.56 95% CI 0.41 to 0.76 P = 0.002	●●○	corticosteroids plus antiviral treatment

No data from the following reference on this outcome. [11] [17]

Presence of sequelae

No data from the following reference on this outcome. [11] [15] [17]

Time to recovery

No data from the following reference on this outcome. [11] [15] [17]

Adverse effects

Ref (type)	Population	Outcome, Interventions	Results and statistical analysis	Effect size	Favours
Adverse effects					
[15] Systematic review	658 people 2 RCTs in this analysis	**Adverse effects** 52/330 (16%) with corticosteroids plus antiviral treatment 45/328 (14%) with placebo	RR 1.15 95% CI 0.79 to 1.66 P = 0.46	⟷	Not significant

No data from the following reference on this outcome. [11] [17]

Corticosteroids plus antiviral treatment versus corticosteroids alone:

We found three systematic reviews (search dates 2009 [11] [15] [17]) and one subsequent RCT, [18] which assessed the effects of corticosteroids plus antiviral treatment compared with placebo, no treatment, or either corticosteroids or antivirals alone in people with Bell's palsy. All the reviews included different RCTs in their meta-analyses, although they all had some RCTs in common, so we report all three here. We also found one further analysis [14] of an RCT [13] included in the first systematic review. [15] It did not include any different outcome or time points to those included in the original RCT and, therefore, has not been reported further here.

Recovery of motor function

Corticosteroids plus antiviral treatment compared with corticosteroids alone We don't know whether corticosteroids plus antiviral treatment are more effective than corticosteroids alone at reducing the risk of incomplete recovery of facial function at the end of treatment (low-quality evidence).

Ref (type)	Population	Outcome, Interventions	Results and statistical analysis	Effect size	Favours
Recovery of motor function					
[15] Systematic review	1228 people 6 RCTs in this analysis	**Proportion of people with incomplete recovery** with corticosteroids plus antiviral treatment with corticosteroids alone Absolute results not reported There was significant heterogeneity in the included data and the antiviral regimen differed between studies	RR 0.64 95% CI 0.50 to 0.82 There are issues surrounding interpretation of these data (see Comments)	●○○	corticosteroids plus antiviral treatment
[11] Systematic review	1298 people 8 RCTs in this analysis	**Proportion of people with unsatisfactory facial recovery , end of trial** 88/662 (13%) with corticosteroids plus antiviral treatment 117/636 (18%) with corticosteroids alone	RR 0.75 95% CI 0.56 to 1.00 P = 0.05 Significance was borderline There are issues surrounding interpretation of these data (see Comments)	●●○	corticosteroids plus antiviral treatment
[17] Systematic review	1145 people 6 RCTs in this analysis 5 RCTs were included in both previously reported reviews	**Proportion of people with partial facial recovery , longest follow-up time** 521/571 (91%) with corticosteroids plus antiviral treatment 506/574 (88%) with corticosteroids alone	OR 1.50 95% CI 0.83 to 2.69 P = 0.18 The OR favoured combination therapy in 4 trials, but the CIs crossed 1 in 3 of these trials. The 2 highest quality trials had ORs that were <1, favouring corticosteroids alone There are issues surrounding interpretation of these data (see Comments)	⟷	Not significant
[19] RCT	829 people with severe palsy (House-Brackmann grade 5 or 6) In review [15] Subgroup analysis	**Proportion of people with complete recovery** 39/60 (65%) with valaciclovir (for 1 week) plus prednisolone (for 10 days) 40/61 (66%) with corticosteroids alone Complete recovery defined as House-Brackmann grade 1	ARR –1% 95% CI –17% to +18% P = 1.00	⟷	Not significant

Ref (type)	Population	Outcome, Interventions	Results and statistical analysis	Effect size	Favours
[18] RCT	206 people with severe palsy	**Complete recovery , 6 months** 82/99 (83%) with with methylprednisolone (tapered for 10 days) plus famciclovir (7 days) 71/107 (66%) with methylprednisolone (tapered for 10 days)	P = 0.01	○○○	famciclovir plus prednisolone

Presence of sequelae

Corticosteroids plus antiviral treatment compared with corticosteroids alone We don't know whether corticosteroids plus antiviral treatment and corticosteroids alone differ in effectiveness at reducing the risk of motor synkinesis or crocodile tears at the end of treatment (low-quality evidence).

Ref (type)	Population	Outcome, Interventions	Results and statistical analysis	Effect size	Favours
Presence of sequelae					
[15] Systematic review	99 people Data from 1 RCT	**Motor synkinesis or crocodile tears , end of trial** 7/53 (13%) with corticosteroids plus antiviral treatment 13/46 (28%) with corticosteroids alone	RR 0.47 95% CI 0.20 to 1.07 P = 0.07	⟷	Not significant

No data from the following reference on this outcome. [11] [17] [18]

Time to recovery

No data from the following reference on this outcome. [11] [15] [17] [18]

Adverse effects

No data from the following reference on this outcome. [11] [15] [17] [18]

Corticosteroids plus antiviral treatment versus antiviral treatment alone:

We found three systematic reviews (search dates 2009 [11] [15] [17]), which assessed the effects of corticosteroids plus antiviral treatment compared with placebo, no treatment, or either corticosteroids or antivirals alone in people with Bell's palsy. All the reviews included different RCTs in their meta-analyses; only one review reported our outcomes of interest. [11]

Recovery of motor function

Corticosteroids plus antiviral treatment compared with antiviral treatment alone Corticosteroids plus antiviral treatment are more effective than corticosteroids alone at reducing the risk of incomplete recovery of facial function at the end of treatment (high-quality evidence).

Ref (type)	Population	Outcome, Interventions	Results and statistical analysis	Effect size	Favours
Recovery of motor function					
[11] Systematic review	660 people 2 RCTs in this analysis	**Proportion of people with unsatisfactory facial recovery , end of trial** 51/330 (15%) with corticosteroids plus antiviral treatment 101/330 (31%) with antiviral treatment alone	RR 0.48 95% CI 0.29 to 0.79 P = 0.04	●●○	corticosteroids plus antiviral treatment

No data from the following reference on this outcome. [15] [17]

Presence of sequelae

No data from the following reference on this outcome. [11] [15] [17]

Time to recovery

No data from the following reference on this outcome. [11] [15] [17]

Adverse effects

No data from the following reference on this outcome. [11] [15] [17]

Comment:

We have reported the results of a number of recent systematic reviews with meta-analyses to demonstrate that trial selection may influence conclusions. Only the systematic reviews that incorporate small and historical trials seem to show potential benefit of combination therapy, and publication bias, with loss of negative trials, may be contributing to this finding. [20] Browning (2010) concluded that meta-analyses of combination therapy only suggest a marginal benefit when small poorer-quality trials are included and that antivirals (in combination with corticosteroids) should only be considered when a viral aetiology is suspected (i.e., Ramsay Hunt syndrome). [21] Debate continues about whether the recent multicentre trials were underpowered to demonstrate a benefit in the paralysis subgroup (type II error). This concern is further exacerbated by significant variation in dosing of the antivirals in the included trials and, particularly, the variable bioavailability of aciclovir. Whether people with evidence of herpes zoster virus (HZV) replication (zoster sine herpete) or people with paralysis benefit from higher doses of antiviral drug requires further research. Even the maximum dose studied (valaciclovir 1 g three times daily) may only achieve 'partial inhibitory' concentrations for HZV. [22] In summary, the 'Scottish study' provides good evidence that aciclovir 2000 mg daily offers no significant additional benefit to corticosteroids for most people. [12] The 'Swedish study' confirms that even a considerably higher dose of antivirals still seems not to offer benefit, [13] even when a subgroup analysis of severe palsies was undertaken. [19]

Clinical guide:

For most people with Bell's palsy with paresis at presentation (about 70%), we found no good evidence of a clinically important additive effect of combination therapy (corticosteroid plus antivirals). For people with paralysis at presentation (about 30%), further research is required to assess whether combination therapy (antivirals plus corticosteroids) has a significant additive or synergistic effect.

People with complete palsies or those with features suggestive of herpes zoster infection (i.e., zoster sine herpete) should be informed of the weak evidence of potential benefit from antivirals in addition to corticosteroids and be allowed to make an informed decision. Antiviral dosing would need to be adequate to treat HZV infection (e.g., 1 g valaciclovir three times daily).

A proportion of people will progress from paresis to paralysis and therapy recommendations may warrant review if this occurs. This is particularly relevant if the person develops signs of Ramsay Hunt syndrome.

OPTION HYPERBARIC OXYGEN THERAPY

- For GRADE evaluation of interventions for Bell's palsy, see table, p 20 .
- Hyperbaric oxygen may improve time to recovery and the proportion of people who make a full recovery compared with corticosteroids; however, the evidence for this is weak and comes from one small RCT.

Benefits and harms

Hyperbaric oxygen versus corticosteroids:

We found one double-blind RCT (79 people with Bell's palsy) comparing hyperbaric oxygen therapy (HBOT) plus placebo tablets (42 people) versus prednisolone plus placebo HBOT (dives achieving a normal partial pressure of oxygen only, 37 people). [23]

Recovery of motor function

Hyperbaric oxygen compared with corticosteroids We don't know whether hyperbaric oxygen is more effective than corticosteroids at increasing complete recovery rates at 9 months, as the RCT did not test the significance of differences between groups. However, absolute rates of recovery were higher in the hyperbaric oxygen group (low-quality evidence).

Ref (type)	Population	Outcome, Interventions	Results and statistical analysis	Effect size	Favours
Recovery of motor function					
[23] RCT	79 people with Bell's palsy	**Proportion of people with complete recovery of facial palsy** 40/42 (95%) with hyperbaric oxygen therapy (HBOT) 28/37 (76%) with prednisolone Prednisolone group also received placebo HBOT (dives achieving a normal partial pressure of oxygen only) HBOT was administered at 2.8 atmospheres for 60 minutes twice-daily, 5 days a week, with dives discontinued when facial function returned to normal (maximum of 30 dives)	P value not reported		

Presence of sequelae

No data from the following reference on this outcome. [23]

Time to recovery

Hyperbaric oxygen compared with corticosteroids Hyperbaric oxygen may be more effective than corticosteroids at reducing time to recovery (low-quality evidence).

Ref (type)	Population	Outcome, Interventions	Results and statistical analysis	Effect size	Favours
Time to recovery					
[23] RCT	79 people with Bell's palsy	**Time to recovery** 22 days with hyperbaric oxygen therapy (HBOT) 34.4 days with prednisolone Prednisolone group also received placebo HBOT (dives achieving a normal partial pressure of oxygen only) HBOT was administered at 2.8 atmospheres for 60 minutes twice-daily, 5 days a week, with dives discontinued when facial function returned to normal (maximum of 30 dives)	P <0.001	○○○	HBOT

Adverse effects

No data from the following reference on this outcome. [23]

Comment: One prospective observational study (82 people receiving long-term hyperbaric oxygen therapy [HBOT] for chronic conditions) found that complications and adverse effects of HBOT included barotrauma to the ear, round window blowout, 'sinus squeeze', visual refractive changes, numb fingers, dental problems, and claustrophobia. Severe adverse effects tended to be rare but may require specific intervention (e.g., seizures, pulmonary oxygen toxicity, altered drug metabolism, and pneumothorax). People with known poor Eustachian tube function may warrant grommet insertion to reduce the risks of barotrauma to the ear. [24]

Clinical guide:
HBOT is expensive and the repeated therapies are inconvenient for the person. Grommet insertion will be required in some people. Further research is warranted and this might focus on people in whom corticosteroids are contraindicated or as adjuvant therapy with corticosteroids for dense facial palsy to try to decrease the rate of incomplete recovery.

QUESTION What are the effects of physical treatments for Bell's palsy in adults and children?

OPTION FACIAL RE-TRAINING

- For GRADE evaluation of interventions for Bell's palsy, see table, p 20 .
- Facial re-training may improve recovery of facial motor function scores, including stiffness and lip mobility, and may reduce the risk of motor synkinesis in Bell's palsy, but the evidence is too weak to draw reliable conclusions.

Benefits and harms

Facial re-training versus waiting list control:

We found two systematic reviews (search dates 2007 [25] and 2008 [26]), which assessed the effects of physiotherapy in people with Bell's palsy. In the first review (4 RCTs, 132 people), three of the included RCTs did not fulfil *Clinical Evidence* inclusion criteria (<20 people) and, therefore, will not be discussed further here. We report results from the remaining RCT below. [27] The second review (6 RCTs, including the RCT previously reported, 547 people with Bell's palsy) compared either electrostimulation or exercises versus waiting list control. [26] Only the three trials comparing exercises versus waiting list controls met the inclusion criteria for this review and we report their results below. One

of the trials included people with acute Bell's palsy; in one trial, published in Chinese, the starting point is unclear (possibly Bell's palsy for <9 months); and one RCT included chronic patients with failure to recover at 9 months only).

Recovery of motor function

Facial re-training compared with waiting list control Facial re-training using mime therapy or exercise may be more effective than waiting list control at improving facial function scores at 3 months, but may be no more effective at reducing the risk of incomplete recovery at 3 months. However, evidence was weak (low-quality evidence).

Ref (type)	Population	Outcome, Interventions	Results and statistical analysis	Effect size	Favours
Recovery of motor function					
[27] RCT	48 people with peripheral facial paralysis for at least 9 months In review [25]	**Mean change in physical Facial Disability Index (FDI) score , 3 months** From 56.8 to 73.5 with mime therapy From 63.2 to 59.6 with waiting list control Improvement in social and physical aspects of facial disability were measured using the FDI questionnaire. The FDI uses a 100-point scale, with a higher score indicating less handicap and less impairment	P <0.02	○○○	mime therapy
[28] RCT	48 people with peripheral facial paralysis for at least 9 months In review [25]	**Mean change in social FDI scores** From 68.6 to 80.7 with mime therapy From 72.6 to 66.2 with waiting list control Improvement in social and physical aspects of facial disability were measured using the FDI questionnaire. The FDI uses a 100-point scale, with a higher score indicating less handicap and less impairment	P <0.01	○○○	mime therapy
[28] RCT	48 people with peripheral facial paralysis for at least 9 months In review [25]	**Mean change in stiffness scores , 3 months** From 3.72 to 2.37 with mime therapy From 3.68 to 3.54 with waiting list control Facial stiffness was patient-assessed on a 5-point scale (1 = no stiffness and 5 = very stiff)	P <0.001	○○○	mime therapy
[28] RCT	48 people with peripheral facial paralysis for at least 9 months In review [25]	**Mean change in pout score , 3 months** From 14.7 to 21.0 with mime therapy From 16.3 to 15.7 with waiting list control Lip mobility was physician-assessed by measuring the pout and lip-length indices	P <0.001	○○○	mime therapy
[28] RCT	48 people with peripheral facial paralysis for at least 9 months In review [25]	**Mean change in lip-length score , 3 months** From 17.6 to 23.7 with mime therapy	P <0.03	○○○	mime therapy

Ref (type)	Population	Outcome, Interventions	Results and statistical analysis	Effect size	Favours
		From 21.6 to 19.6 with waiting list control Lip mobility was physician-assessed by measuring the pout and lip-length indices			
[26] Systematic review	34 people with chronic Bell's palsy Data from 1 RCT	**Recovery of facial grading** with exercises with waiting list control Absolute results not reported Facial grading measured by Sunnybrook scale (0 to 100 points), fully recovered facial function = Sunnybrook score of 100 points	Mean difference 20.40 95% CI 8.76 to 32.04	○○○	exercises
[26] Systematic review	34 people with chronic Bell's palsy Data from 1 RCT	**Recovery on the FDI social domain (0 to 100)** with exercises with waiting list control Absolute results not reported Improvement in social and physical aspects of facial disability were measured using the FDI questionnaire The FDI uses a 100-point scale, with a higher score indicating less handicap and less impairment	Mean difference 14.50 95% CI 4.85 to 24.15	○○○	exercises
[26] Systematic review	34 people with chronic Bell's palsy Data from 1 RCT	**Recovery on the FDI physical domain** with exercises with waiting list control Absolute results not reported Improvement in social and physical aspects of facial disability were measured using the FDI questionnaire The FDI uses a 100-point scale, with a higher score indicating less handicap and less impairment	Mean difference +10.30 95% CI –1.37 to +21.97	⟷	Not significant
[26] Systematic review	145 people; uncertain duration of Bell's palsy Data from 1 RCT	**Proportion of people with incomplete recovery , 3 months** 6/85 (7%) with exercises 7/60 (12%) with waiting list control	RR 0.61 95% CI 0.21 to 1.17	⟷	Not significant

Presence of sequelae

Facial re-training compared with waiting list control Facial re-training exercises may be more effective than waiting list control at reducing the risk of motor synkinesis (low-quality evidence).

Ref (type)	Population	Outcome, Interventions	Results and statistical analysis	Effect size	Favours
Presence of sequelae					
[26] Systematic review	145 people with chronic Bell's palsy Data from 1 RCT	**Motor synkinesis** 4/85 (5%) with exercises 12/60 (20%) with waiting list control	RR 0.24 95% CI 0.08 to 0.69	●●○	exercises

No data from the following reference on this outcome. [25]

Time to recovery

Facial re-training compared with conventional treatment Facial re-training exercises may be more effective than conventional treatment at reducing the mean time to beginning and completion of recovery (low-quality evidence).

Ref (type)	Population	Outcome, Interventions	Results and statistical analysis	Effect size	Favours
Time to recovery					
[26] Systematic review	90 people with uncertain duration of Bell's palsy Data from 1 RCT	**Mean time to beginning of recovery (weeks)** with exercises with conventional treatment Absolute results not reported	Mean difference –0.59 weeks 95% CI –1.01 to –0.17 weeks	○○○	exercises
[26] Systematic review	90 people with uncertain duration of Bell's palsy Data from 1 RCT	**Mean time to complete recovery (weeks)** with exercises with conventional treatment Absolute results not reported	Mean difference –0.91 weeks 95% CI –1.49 to –0.34 weeks P = 0.01	○○○	exercises

No data from the following reference on this outcome. [25]

Adverse effects

No data from the following reference on this outcome. [25] [26]

Further information on studies

[25] The authors of the review concluded that, because of lack of evidence, it was not possible to conclude if physiotherapy was effective for the treatment of Bell's palsy.

Comment: **Clinical guide:**
There is limited evidence that physical facial re-training, such as mime therapy, can improve both the function and quality of life of people with long-standing facial nerve palsies. Optimal outcomes are likely to be achieved in a multidisciplinary clinic setting, which would facilitate coordination of medical, surgical, physical, and psychological services.

GLOSSARY

Hemifacial spasm is a generalised involuntary mass contracture of the facial muscles.

Neuropraxia is reversible nerve dysfunction without the degeneration or loss of nerve axons.

Ramsay Hunt syndrome is characterised by acute facial paralysis with herpetic (herpes zoster virus) blisters of the skin of the ear canal or tongue. Other symptoms may include vertigo, ipsilateral hearing loss, and tinnitus.

Wallerian degeneration describes the sequelae of axonal injury and subsequent removal of axonal and myelin debris by Schwann cells and invading macrophages.

High-quality evidence Further research is very unlikely to change our confidence in the estimate of effect.

Low-quality evidence Further research is very likely to have an important impact on our confidence in the estimate of effect and is likely to change the estimate.

Moderate-quality evidence Further research is likely to have an important impact on our confidence in the estimate of effect and may change the estimate.

SUBSTANTIVE CHANGES

Corticosteroids plus antiviral treatment: New evidence added. [18] Evidence re-evaluated, categorisation changed from likely to be beneficial to unknown effectiveness.

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N. Julian Holland
Consultant Otolaryngologist, Head and Neck Surgeon
Waitemata District Health Board
Auckland
New Zealand

Jonathan M. Bernstein
Fellow, Head and Neck Surgical Oncology
University Health Network
Toronto
Canada

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Disclaimer

GRADE **Evaluation of interventions for Bell's palsy.**

Important outcomes			Presence of sequelae, Recovery of motor function, Time to recovery						
Studies (Participants)	**Outcome**	**Comparison**	**Type of evidence**	**Quality**	**Consistency**	**Directness**	**Effect size**	**GRADE**	**Comment**
What are the effects of drug treatments for Bell's palsy in adults and children?									
10 (1507) [10] [11] [12] [13]	Recovery of motor function	Corticosteroids versus placebo or no specific treatment	4	–1	0	0	0	Moderate	Quality point deducted for the inclusion of some single-blinded studies in the meta-analysis
at least 3 (at least 901) [10] [11] [12] [13]	Presence of sequelae	Corticosteroids versus placebo or no specific treatment	4	–2	0	0	0	Low	Quality points deducted for incomplete reporting of results and the inclusion of some single-blinded studies in the meta-analysis
1 (829) [13]	Time to recovery	Corticosteroids versus placebo or no specific treatment	4	0	0	0	0	High	
5 (1228) [15]	Recovery of motor function	Antiviral agents versus placebo	4	–1	0	0	0	Moderate	Quality point deducted for the inclusion of single-blinded studies in the meta-analysis
2 (at least 99) [11] [15]	Presence of sequelae	Antiviral agents versus placebo	4	–2	0	0	0	Low	Quality points deducted for unclear reporting of number of people in analysis and incomplete reporting of results
3 (768) [15]	Recovery of motor function	Antiviral agents versus corticosteroids	4	0	0	0	0	High	
7 (1987) [15]	Recovery of motor function	Corticosteroids plus antiviral treatment versus placebo/no treatment	4	–1	0	0	0	Moderate	Quality point deducted for the inclusion of some single-blinded studies in the meta-analysis
9 (1504) [11] [15] [17] [18]	Recovery of motor function	Corticosteroids plus antiviral treatment versus corticosteroids alone	4	–1	–1	0	0	Low	Quality point deducted for the inclusion of open-label studies in the meta-analysis; consistency point deducted for conflicting results depending on analysis undertaken
1 (99) [15]	Presence of sequelae	Corticosteroids plus antiviral treatment versus corticosteroids alone	4	–1	0	–1	0	Low	Quality point deducted for sparse data; directness point deducted for small number of events
2 (660) [11]	Recovery of motor function	Corticosteroids plus antiviral treatment versus antiviral treatment alone	4	0	0	0	0	High	
1 (79) [23]	Recovery of motor function	Hyperbaric oxygen versus corticosteroids	4	–2	0	0	0	Low	Quality points deducted for sparse data and incomplete reporting of results
1 (79) [23]	Time to recovery	Hyperbaric oxygen versus corticosteroids	4	–2	0	0	0	Low	Quality points deducted for sparse data and incomplete reporting of results
What are the effects of physical treatments for Bell's palsy in adults and children?									

Important outcomes	Presence of sequelae, Recovery of motor function, Time to recovery								
Studies (Participants)	Outcome	Comparison	Type of evidence	Quality	Consistency	Directness	Effect size	GRADE	Comment
2 (82) [25] [26]	Recovery of motor function	Facial re-training versus waiting list control	4	–2	0	0	0	Low	Quality points deducted for sparse data and incomplete reporting of results
1 (145) [26]	Presence of sequelae	Facial re-training versus waiting list control	4	–2	0	0	0	Low	Quality points deducted for sparse data and methodological weaknesses
1 (90) [26]	Time to recovery	Facial re-training versus waiting list control	4	–2	0	0	0	Low	Quality points deducted for sparse data and incomplete reporting of results

We initially allocate 4 points to evidence from RCTs, and 2 points to evidence from observational studies. To attain the final GRADE score for a given comparison, points are deducted or added from this initial score based on preset criteria relating to the categories of quality, directness, consistency, and effect size. Quality: based on issues affecting methodological rigour (e.g., incomplete reporting of results, quasi-randomisation, sparse data [<200 people in the analysis]). Consistency: based on similarity of results across studies. Directness: based on generalisability of population or outcomes. Effect size: based on magnitude of effect as measured by statistics such as relative risk, odds ratio, or hazard ratio.