

# Acupuncture and vitamin B<sub>12</sub> injection for Bell's palsy: no high-quality evidence exists

Li-li Wang, Ling Guan\*, Peng-liang Hao, Jin-long Du, Meng-xue Zhang

Department of Acupuncture and Moxibustion, Chinese PLA General Hospital, Beijing, China

\*Correspondence to:  
Ling Guan, Ph.D.,  
guanling301@sina.com.

doi:10.4103/1673-5374.156987  
<http://www.nrronline.org/>

Accepted: 2015-02-09

## Abstract

**OBJECTIVE:** To assess the efficacy of acupuncture combined with vitamin B<sub>12</sub> acupoint injection versus acupuncture alone to reduce incomplete recovery in patients with Bell's palsy.

**DATA RETRIEVAL:** A computer-based online retrieval of Medline, Web of Science, CNKI, CBM databases until April 2014 was performed for relevant trials, using the key words "Bell's palsy or idiopathic facial palsy or facial palsy" and "acupuncture or vitamin B<sub>12</sub> or methylcobalamin".

**STUDY SELECTION:** All randomized controlled trials that compared acupuncture with acupuncture combined with vitamin B<sub>12</sub> in patients with Bell's palsy were included in the meta-analysis. The initial treatment lasted for at least 4 weeks. The outcomes of incomplete facial recovery were monitored. The scoring index varied and the definition of healing was consistent. The combined effect size was calculated by using relative risk (RR) with 95% confidence interval (CI) using the fixed effect model of Review Manager.

**MAIN OUTCOME MEASURES:** Incomplete recovery rates were chosen as the primary outcome.

**RESULTS:** Five studies involving 344 patients were included in the final analysis. Results showed that the incomplete recovery rate of Bell's palsy patients was 44.50% in the acupuncture combined with vitamin B<sub>12</sub> group but 62.57% in the acupuncture alone group. The major acupoints were *Taiyang* (EX-HN5), *Jiache* (ST6), *Dicang* (ST4) and *Sibai* (ST2). The combined effect size showed that acupuncture combined with vitamin B<sub>12</sub> was better than acupuncture alone for the treatment of Bell's palsy (RR = 0.71, 95% CI: 0.58–0.87; P = 0.001), this result held true when 8 patients lost to follow up in one study were included into the analyses (RR = 0.70, 95% CI: 0.58–0.86; P = 0.0005). In the subgroup analyses, the therapeutic effect in patients of the electroacupuncture subgroup was better than in the non-electroacupuncture subgroup (P = 0.024). There was no significant difference in the incomplete recovery rate by subgroup analysis on drug types and treatment period. Most of the included studies were moderate or low quality, and bias existed.

**CONCLUSION:** In patients with Bell's palsy, acupuncture combined with vitamin B<sub>12</sub> can reduce the risk of incomplete recovery compared with acupuncture alone in our meta-analysis. Because of study bias and methodological limitations, this conclusion is uncertain and the clinical application of acupuncture combined with vitamin B<sub>12</sub> requires further exploration.

**Key Words:** nerve regeneration; brain injury; facial palsy; Bell's palsy; comparison; methodological quality; therapy; fixed effect model; acupuncture; incomplete recovery; randomized controlled trials; electroacupuncture; NSFC grants; neural regeneration

**Funding:** This study was financially supported by a grant from the National Natural Science Foundation of China, No. 81273848.

Wang LL, Guan L, Hao PL, Du JL, Zhang MX (2015) Acupuncture and vitamin B<sub>12</sub> injection for Bell's palsy: no high-quality evidence exists. *Neural Regen Res* 10(5):808-813.

## Introduction

Bell's palsy (or idiopathic facial palsy) is an acute and idiopathic paralysis of the facial nerve, resulting in unilateral weakness or paralysis of the face. It is a common disorder that occurs in 20–30 per 100,000 in the general population (Rowlands et al., 2002), with 1 in 60 people being affected during their lifetime (Holland et al., 2004). The prognosis is favorable as 71% of untreated patients completely recover and 84% have complete or near normal recovery within 6 months (Peitersen, 1982, 2002). The remainder had sequelae, such as moderate to severe paresis, facial contracture, hemifacial spasm or synkinesis (Holland et al., 2004).

The aetiology is still unknown, but infection by herpes

simplex virus is a likely cause. A previous study showed that herpes simplex virus genes were isolated from the geniculate ganglia (Murakami et al., 1996). Inflammation of the facial nerve in the temporal bone followed by swelling and the immune demyelination might be involved in the pathogenesis of Bell's palsy (Fisch et al., 1972; Schwaber et al., 1990; Rioridan, 2001; Burmeister et al., 2011).

The treatment for Bell's palsy is preventing the sequelae. Therapeutic methods are varied, such as corticosteroids, antiviral, vitamins, acupoint injection, acupuncture and surgical decompression (Chen, 2009); however, the effectiveness of these methods remains controversial. Acupuncture has been used in clinical practice for thousands of years in China

and has been proven an effective method for Bell's palsy (Li et al., 2004; Liang et al., 2006). A previous Cochrane Systematic Review did not make any conclusion about the efficacy of acupuncture for Bell's palsy because of the poor quality of the included studies (He et al., 2008). The mechanism of action of acupuncture is to regulate the concentration of 5-hydroxytryptamine and acetylcholine to increase blood flow volume and thereby relieve edema (Wei, 2006).

Vitamin B<sub>12</sub> is currently used in the clinic for peripheral nerve damage (Sun et al., 2012). A randomized trial suggested that patients treated with vitamin B<sub>12</sub>, alone or combined with steroids, recovered faster than those treated with steroids alone (Jalaludin, 1995). Furthermore, vitamin B<sub>12</sub> used by acupoint injection is better than other methods in Bell's palsy (Luo et al., 2009). Previous randomized controlled trials were completed recently, showing that combination with vitamin B<sub>12</sub> was better than acupuncture alone (Chen et al., 2009; Lan, 2012; Shi et al., 2013). However, whether adding vitamin B<sub>12</sub> to acupuncture can improve clinical efficacy compared with acupuncture alone in clinical practice is unclear. Previous meta-analysis researched the use of vitamin B<sub>12</sub>, but the efficacy of the drug was low. Therefore, we collected and analyzed previously published studies on the outcome of patients with Bell's palsy who were treated with acupuncture alone or with vitamin B<sub>12</sub>, in an attempt to evaluate the efficacy of the combination method. The number of incomplete recovery patients was extracted as the outcome index.

## Materials and Methods

### Literature retrieval

We searched the Medline, Web of Science, Chinese Biomedical Literature Database (CBM) and Chinese National Knowledge Infrastructure (CNKI) database until April 1<sup>st</sup>, 2014, for relevant trials published in English and Chinese. In addition, we searched the references of the relevant articles for further appropriate articles. Medical Subject Headings, sub-headings and free text words were used as the search terms, including "Bell's palsy, idiopathic facial paralysis, facial paralysis, acupuncture, vitamin B<sub>12</sub>, and methylcobalamin". We used the following search terms: (Bell's palsy or idiopathic facial palsy or facial paralysis) and (acupuncture or vitamin B<sub>12</sub> or methylcobalamin), limited to randomized controlled trials. Gray literature such as conference proceedings was not included in the search field. All the studies were screened by title or abstract for those requiring further retrieval and then these studies were independently reviewed for eligibility by two investigators.

### Inclusion and exclusion criteria

#### Inclusion criteria

(1) Patients with Bell's palsy or idiopathic facial palsy; (2) patients treated by acupuncture combined with vitamin B<sub>12</sub>; (3) patients treated by acupuncture alone as the control group; (4) studies reporting the outcomes of incomplete facial recovery, no matter the scoring system; and (5) a follow-up time of at least 4 weeks from initial treatment.

#### Exclusion criteria

(1) Review, meta-analysis, or case report studies; (2) studies of pediatric populations or pregnant women; (3) studies with other treatments or sequelae; (4) facial paralysis for other reasons; (5) inadequate outcome data; and (6) non-random controlled trials.

#### Data extraction

Two independent reviewers extracted the following information from all studies: (1) publication year; (2) sample size; (3) mean age; (4) type of treatment in each group; (5) study design; (6) time to treatment; (7) length of follow-up; (8) the number of completely recovered patients in each group; and (9) mean recovery time in each group. If the study had more than 2 groups, only the data of the acupuncture combined with vitamin B<sub>12</sub> and acupuncture alone groups were extracted. Disagreements regarding data extraction were resolved by consensus. If there were missing data that were not clearly expressed in the publication, the authors were contacted to provide more detailed information.

#### Quality assessment

The methodological quality of all studies was assessed by two independent investigators. Criteria for quality assessment were based on recommendations from the Cochrane criteria guidelines (Julian et al., 2011), which includes 7 fields: (1) adequate sequence generation; (2) allocation concealment; (3) blinding of participants and personnel; (4) blinding of outcome assessment; (5) incomplete outcome data; (6) selective reporting; and (7) other bias.

#### Main outcome measurements

The primary outcome was the proportion of patients with incomplete recovery defined as a House-Brackmann grade of  $\geq 2$  or an equivalent score using an alternative scoring system (Alberston et al., 2006; Sullivan et al., 2007).

#### Statistical analysis

Review Manager Version 5.2 software (Nordic Cochrane Center, Copenhagen, Denmark) was used for the statistical analysis. We calculated a pooled outcome using relative risk (RR) with 95% confidence interval (CI). Heterogeneity of RRs was assessed using Cochran's Q test and I<sup>2</sup>. If heterogeneity was not present, RRs were pooled using the fixed effects model. Otherwise, a random effects model was used to incorporate heterogeneity among studies. Subgroup analysis was applied to investigate heterogeneous resources. We used the analysis of variance (F test) to explore the interaction between subgroups. Contour enhanced funnel plots were used to detect publication bias due to small study effects (Jonathan et al., 2011).

## Results

### Data retrieval

A flow diagram of study selection is shown in **Figure 1**. Three hundred and eighty-four studies were identified from the database searches. Of these, 26 met the eligible criteria

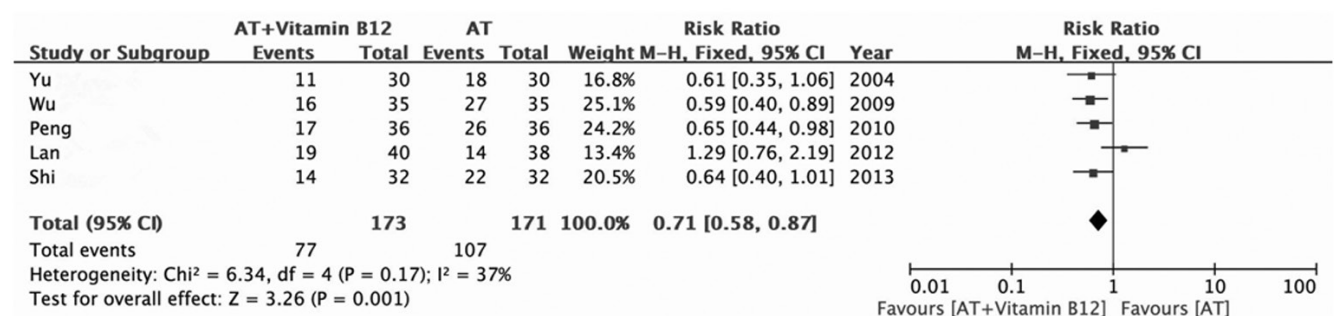
**Table 1** Baseline characteristics of included studies

Study	Average age <i>n</i> (year)	Type of treatment		Study design	Time to treatment	Follow-up time	Results (number of incomplete recovery, intervention/control)	Recovery time
		Intervention	Control					
Yu (2004)	60 42	Acupuncture once a day × 28 days, Vitamin B <sub>12</sub> 500 µg/day × 20 days ( <i>n</i> = 30)	Acupuncture ( <i>n</i> = 30)	RCT	8–15 days	28 days	11/18 patients incompletely recovered (HB grade ≥ II)	Intervention: 17 days Control: 23 days
Wu (2009)	70 38	Electroacupuncture once a day × 40 days, methylcobalamin 500 µg/day × 16 days ( <i>n</i> = 35)	Electroacupuncture ( <i>n</i> = 35)	RCT	78.6 days	49 days	16/27 patients incompletely recovered (HB grade ≥ II)	Intervention: 28.32 days Control: 37.88 days
Peng (2010)	72 44	Electroacupuncture once a day × 24 days, methylcobalamin 500 µg/day × 24 days ( <i>n</i> = 36)	Electroacupuncture ( <i>n</i> = 36)	RCT	6.9 days	28 days	17/26 patients incompletely recovered (HB grade ≥ II)	Within 28 days
Lan (2012)	78 48	Acupuncture once 2 days × 40 days, methylcobalamin 500 µg/2 days × 40 days ( <i>n</i> = 40)	Acupuncture ( <i>n</i> = 38)	RCT	2.4 months	40 days	19/38 patients incompletely recovered (non-specific)	Within 40 days
Shi (2013)	64 38	Electroacupuncture once a day × 30 days, methylcobalamin 500 µg/day × 15 days ( <i>n</i> = 32)	Electroacupuncture ( <i>n</i> = 32)	RCT	3.6 days	36 days	14/22 patients incompletely recovered (HB grade ≥ II)	Within 36 days

RCT: Randomized controlled trials; HB: House-Brackmann.

**Table 2** The assessment of methodological quality of included studies

Study	Adequate sequence generation	Allocation concealment	Blinding of participants and personnel	Blinding of outcome assessment	Incomplete outcome data	Selective reporting	Other bias
Yu (2004)	Yes	No	No	Unclear	No	No	Yes (poorly described statistical methods and conflicts)
Wu (2009)	Yes	No	No	Unclear	Yes	No	Yes (conflicts of interest)
Peng (2010)	Unclear	No	No	Unclear	No	Yes	No
Lan (2012)	Yes	Yes	Yes	Unclear	No	Yes	Yes (poorly described statistical methods and conflicts of interest)
Shi (2013)	Yes	No	No	Unclear	No	No	Yes (poorly described statistical methods)

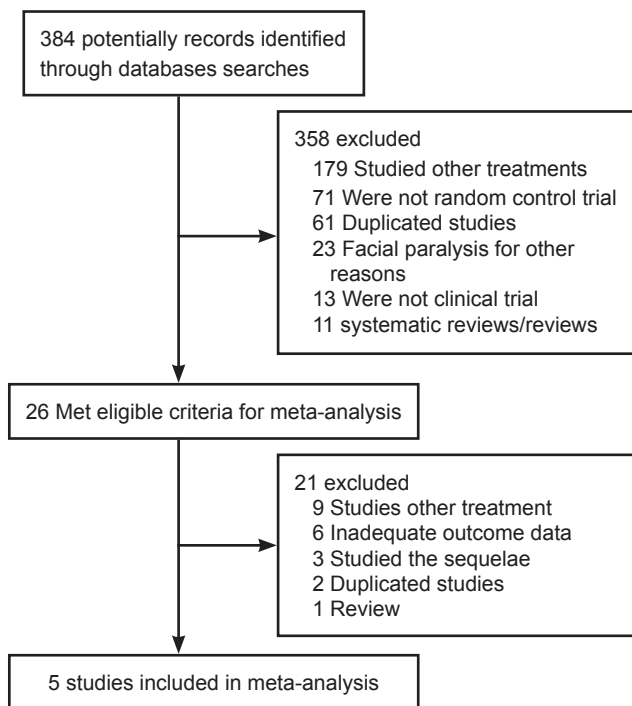


**Figure 2** Incomplete recovery rate in Bell's palsy patients following acupuncture alone or combined with vitamin B<sub>12</sub> treatment. Acupuncture combined with vitamin B<sub>12</sub> (incomplete recovery rate) was better than acupuncture alone.

**Table 3 Subgroup analysis of incomplete recovery after treatment with acupuncture and vitamin B<sub>12</sub>**

	Subgroup	Studies	Treatment (incomplete recovery cases/ total cases)	Control (incomplete recovery cases/ total cases)	RR (95%CI)	P value <sup>a</sup>	P value between subgroup <sup>b</sup>
Stage	Acute stage	Peng et al. (2010), Shi (2013)	31/68	48/68	0.65 (0.48–0.87)	0.93	0.470
	Non-acute stage	Yu et al. (2004), Wu et al. (2009), Lan (2012)	46/105	59/103	0.77 (0.58–1.01)	0.05	
Therapy	Electroacupuncture	Wu et al. (2009), Peng et al. (2010), Shi et al. (2013)	47/103	75/103	0.63 (0.49,0.80)	0.94	0.024
	Non-electroacupuncture	Yu et al. (2004), Lan (2012)	30/70	32/68	0.91 (0.63,1.33)	0.06	
Drug	Vitamin B <sub>12</sub>	Yu et al. (2004)	11/30	18/30	0.61 (0.35,1.06)	0	0.057
	Methylcobalamin	Wu et al. (2009), Peng et al. (2010), Lan (2012), Shi et al. (2013)	66/143	89/141	0.73 (0.59,0.91)	0.11	

<sup>a</sup>Based on the  $I^2$ ; <sup>b</sup>Based on the  $F$ -test.

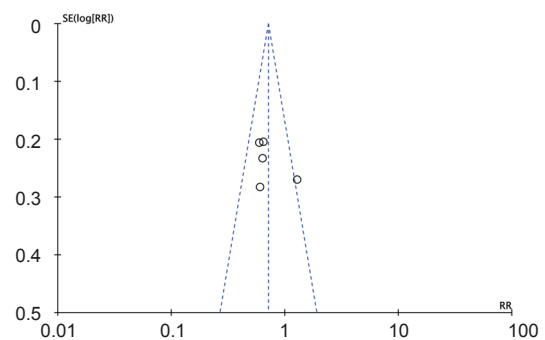
**Figure 1 Flow chart of literature screening.**

A total of 384 potential studies were identified from the database searches. Of these, 26 met the eligible criteria for meta-analysis. Among 26 studies, 21 records were excluded according to the inclusion and exclusion criteria, and 5 studies were included in the final analysis.

for meta-analysis. Among 26 studies, 12 records studied other treatments or sequelae, 6 records had inadequate basic or outcome data, and 3 records were duplicated studies or reviews. Only 5 studies were included in the final analysis. The characteristics of the included studies are demonstrated in **Table 1**. There were 344 patients for analysis, including 173 in the combination group and 171 in the acupuncture group.

### Methodological quality evaluation

Among the 5 included studies, 4 studies adopted mecobal-

**Figure 3 Funnel plot of the 5 included studies.**

The distribution of 5 studies was not symmetrical, indicating publication bias.

amin and one study adopted vitamin B<sub>12</sub>. The 5 studies had various frequencies for the administration of drugs: 2 studies administered drugs once every other day (Lan, 2012; Shi et al., 2013), 2 studies administered drugs once a day or once every 2 days, while the remaining study administered drugs both once a day and once every other day (Yu et al., 2004). Bell's palsy has different path-stages: acute stage (1–7 days after onset of disease), resting stage (8–20 days after onset of disease) and restoration stage (21–90 days after onset of disease). Among the 5 studies, 2 studies (Peng et al., 2010; Shi et al., 2013) studied patients in the acute stage, 2 studies (Wu et al., 2009; Lan, 2012) in the restoration stage and one study (Yu et al., 2004) in the resting stage. Only one study had 3 groups (Yu et al., 2004): acupuncture alone, acupuncture combined with vitamin B<sub>12</sub> (acupoint injection) and acupuncture combined with vitamin B<sub>12</sub> (intramuscular injection). The adverse events of acupoint injection were observed by Shi et al. (2013) and Yu et al. (2004). The major acupoints were *Taiyang* (EX-HN5), *Jiache* (ST6), *Dicang* (ST4) and *Sibai* (ST2). There were 8 patients lost to follow up in the study by Wu et al. (2009). Most of the studies were moderate or low quality. The methodological qualities of all studies are shown in **Table 2**.

The pooled estimate of incomplete recovery of patients



with Bell's palsy who received acupuncture combined with vitamin B<sub>12</sub> acupoint injection or acupuncture alone is shown in **Figure 2**. The total proportion of patients with incomplete recovery was 53.49% (184/344) of all patients. The respective proportion of patients with recovery was 44.50% (77/173) in the acupuncture combined with vitamin B<sub>12</sub> group and was 62.57% (107/171) in the acupuncture alone group. The *RR* of the 4 studies listed showed a favorable response to the combination treatment (Yu et al., 2004; Wu et al., 2009; Peng et al., 2010; Shi et al., 2013). However, 3 studies had a *CI* that was greater than 1 (Yu et al., 2004; Lan, 2012; Shi et al., 2013).

### Meta-analysis

#### *The outcome of effect size*

The meta-analysis was performed using the fixed-effect model. Acupuncture combined with vitamin B<sub>12</sub> was shown to have significantly better efficacy than acupuncture alone in patients with Bell's palsy (*RR* = 0.71, 95%*CI*: 0.58–0.87; *P* = 0.001). The *I*<sup>2</sup> of the fixed model was 37%, indicating that there was unimportant heterogeneity between the studies. This result held true when the 8 patients lost to follow up were included in the analyses (*RR* = 0.70, 95%*CI*: 0.58–0.86; *P* = 0.0005).

#### *Subgroup analysis*

Subgroup analysis results showed that there were significant interaction differences (*P* = 0.024) between the patients with electroacupuncture (*RR* = 0.63, 95%*CI*: 0.49–0.80; *P* = 0.001) and non-electroacupuncture subgroups (*RR* = 0.91, 95%*CI*: 0.63–1.33; *P* = 0.63). However, in the other two subgroups analyses, the difference was not statistically significant (**Table 3**).

### Analysis of publication bias

A funnel plot indicated that there was evidence of publication bias based on visual inspection (**Figure 3**). The funnel plot was not symmetrical, suggesting publication bias.

### Discussion

These meta-analysis results indicated that the incomplete recovery rate of acupuncture combined with vitamin B<sub>12</sub> acupoint injection was significantly better than acupuncture alone. The pooled *RR* of treatment effects was 0.71 (95%*CI*: 0.58–0.87, *P* = 0.001), suggesting that 29% of Bell's palsy patients who received acupuncture combined with vitamin B<sub>12</sub> were more significantly likely to achieve complete recovery when compared with those who received acupuncture alone.

A multi-center randomized controlled trial indicated that the efficacy of acupuncture-moxibustion alone had better efficacy than acupuncture-moxibustion plus oral medicine containing vitamin B<sub>12</sub>, vitamin B<sub>1</sub>, or prednisone medicine. The proportion of complete recovery of the two groups was 41% and 31%, respectively, and the difference was statistically significant. However, the current meta-analysis showed a possible incremental benefit of adding vitamin B<sub>12</sub> to acupuncture treatment and a synergistic effect when they were

given in combination. The reasons for these differences with other studies difference might be that vitamin B<sub>12</sub> was added to acupuncture by acupoint-injection in our meta-analysis. Animal experiments showed that acupoint injection was better than intramuscular injection and oral administration when measuring the drug effect time (Tian, 2011).

In the subgroup analysis, patients with electroacupuncture achieved significantly greater benefit than those with non-electroacupuncture (*P* = 0.024). These findings were consistent with the previous trial outcomes of Liu et al. (2006) and Sun (2003). Previous trials comparing the effect of vitamin B<sub>12</sub> and methylcobalamin showed that the benefit of methylcobalamin was greater than the benefit of vitamin B<sub>12</sub> in patients with Bell's palsy. However, in our analyses the test for interaction was not statistically significant and the effect of vitamin B<sub>12</sub> for Bell's palsy was indeterminate. Only one study used vitamin B<sub>12</sub> and the number of patients was small, therefore the conclusion is not definitive. If more studies that used vitamin B<sub>12</sub> were included, a more powerful analysis would be achieved.

There was no significant difference in the efficacy of acupuncture and vitamin B<sub>12</sub> on incomplete recovery when patients treated within 7 days vs. those treated later. Peng et al. (2010) included patients with acute and non-acute stages of disease. However, the mean course of all patients was 6.9 days; therefore these were included in the acute stage subgroup. Therefore, the power of this meta-analysis was weak. If the information of all patients was available, the study might have had a more convincing conclusion.

This meta-analysis has limitations. First, the meta-analysis included a small number of studies and the total number of patients was small. Furthermore, this meta-analysis only included studies in which vitamin B<sub>12</sub> was administered by acupoint injection; those studies with vitamin B<sub>12</sub> administered by oral and intramuscular injection were excluded. Therefore, the results are only relevant to treatment with acupoint injection. Second, the methodological quality of all studies was moderate to low. Sequence generation of every study was adequate, but only one used allocation concealment and blinding of participants and personnel in the random process. None of the studies assessed the outcome as a blind study. Thus, the subjective factors of patients, doctors and assessor may have exaggerated the effect of vitamin B<sub>12</sub>. Third, the necessary raw data were unavailable to us for the subgroup analyses, thus the meta-analysis cannot provide a convincing suggestion regarding the time factors of treatment of Bell's palsy.

Many previous studies have shown that a virus infection might be the leading cause of Bell's palsy, by mechanisms including the swelling and immune demyelination of the facial nerve. The protective mechanism of vitamin B<sub>12</sub> might be to maintain the metabolism of myelin, so it can increase the recovery time of facial nerve function in Bell's palsy patients.

In summary, the effect of acupuncture combined with vitamin B<sub>12</sub> for Bell's palsy treatment was uncertain. Despite the positive outcome, the clinical effect is unclear. Therefore, a prospective double-blind study that uses a strict design is required.

**Acknowledgments:** We would like to thank Bin Huang and Cheng-xin Li from the Chinese PLA General Hospital in China for their direction about the design of the study and the controversy of data extraction.

**Author contributions:** LLW designed the protocol, performed data collection, analyzed the data and wrote the paper. LG designed the protocol, obtained funding and critical revision. JLD collected the data. PLH and MXZ screened and extracted the data. All authors approved the final version of the manuscript.

**Conflicts of interest:** The funnel plot showed that publication bias existed in the five studies. All of the studies were published in China, most of the studies chose vitamin B<sub>12</sub> from the same company and some studies did not have the fund financial resources. So it may have other bias such as selective reporting and conflicts of interest, both of these induced the outcome be exaggerated.

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