

Should acupuncture therapy be used for acute facial paralysis? A protocol of systematic review

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Protocol

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Abstract

Introduction Peripheral Facial paralysis (PFP) results in functional and social dysfunction, when it is under a severe condition at onset, long-term poor outcomes do occur. Different acupuncture method has been reported to be potentially effective for shortening the disease course and reduce the occurrence of sequelae when applying at an early stage. Neuroedema is a common pathological feature in the acute phase, many clinical studies have suggested its effect of reducing facial nerve edema. It is of value to estimate the effectiveness and safety of acupuncture treatment at the onset, and it is worthwhile to assess the most suitable acupuncture method for the acute period.

Methods and analysis We will include all the RCTs and quasi-RCTs on acupuncture therapy for PFP at its acute stage. Literature searching will be conducted until September 15th, 2020 from eight databases systematically. Two reviewers will screen the literature and extract the data independently. RevMan software and the Cochrane tool of Risk of Bias will be used to assess the methodological quality of RCTs. Forest plots and summary findings will be generated. If data permits, a meta-analysis will be conducted.

Ethics and dissemination Since this study will not involve clinical treatment of patients, ethics approval is not required. The result of this study will be submitted to a peer-reviewed journal for publication and as a proposal for clinical practice and further study on acupuncture treatment at the early stage of PFP.

Discussion This review will summarize the evidence on the different type of acupuncture therapy for acute bell's palsy and Ramsay-Hunt syndrome. We anticipate that it would be safe and effective when applying to the acute phase of PFP, and some specific suitable acupuncture methods would be found resulting from this review.

Trial registration number International Prospective Register for Systematic Reviews (PROSPERO) number CRD42020205127

Strength and Limitations of This Study

- This systematic review will not only pay attention to the effectiveness and safety when applying acupuncture therapy in the acute phase of peripheral facial paralysis (PFP), but pay more attention to synthesis the evidence and find out will the sequelae rate decrease with the intervention of acupuncture therapy, and which specific manipulation or method would play the best role in this acute PFP period.
- One limitation of this study is that, by pooling different acupuncture therapy such as manual acupuncture, electroacupuncture, moxibustion, bloodletting, or a combination of two or more methods, there would be a significant heterogeneity from intervention variety. This impact could only be mitigated through suitable subgroup analysis.
- Another limitation of this study is the blinding part. For patients who participate in the included studies, the blinding may implement well. But for the practitioners, blinding could be difficult. This

may affect the interpretation of results.

1. Introduction

Facial palsy results in functional and social dysfunction, which is related to the inability to control the muscles of facial expression[1–3]. In all types of facial paralysis, Bell's palsy is the most common acute disorder affecting a single nerve, and the cause is unknown. The condition affects 11–40 people per 100,000 in the population each year, most commonly in the age group 30–45[4]. Compared with Bell's palsy, facial palsy caused by Varicella Zoster Virus(VZV), which is best known as the Ramsay Hunt syndrome has a lower incidence but more severe symptoms at onset, and it is less likely to ensure full recovery[5]. Besides, a risk of 10% -18% of a common complication of Ramsay Hunt syndrome may develop, which is known as postherpetic neuralgia (PHN), a chronic pain condition[6].

Typically, facial paralysis is self-limited, but long-term poor outcomes do occur when it is under a severe condition at onset. Although the detailed pathological changes of the facial nerve in the infratemporal remains unclear[7], the swelling of facial nerve segments was identified in all patients through enhanced MRI[8]. Thus, the use of corticosteroids can help attenuate disease progression by decompressing the swelling caused by inflammation of the facial nerve canal[9], and the use of oral steroids within 72 hours of symptom onset is recommended[10]. When it comes to Ramsay Hunt syndromes, the inflammation is due to Varicella-Zoster Virus(VZV), so the anti-viral drugs such as famciclovir or acyclovir should be given to patients with a 7–10 days course[5], and an early combined acyclovir-corticosteroid therapy displays a better result exclusive usage of corticosteroid or antiviral therapy[9]. Moreover, over 80% of the patients who received antiviral therapy within 72 h from onset obtained good recovery.[11]. That is to say, a timely diagnosis and treatment are crucial, otherwise, sequelae such as round eye or synkinesis may appear over time[12, 13].

Acupuncture was defined as inserting fine needles into specific locations in the body[14]. As an invasive treatment, injury is inevitable. Inflammation usually results from infection or tissue injury[15]. Thus, there are concerns that acupuncture therapy would have some side effects such as increasing the grade of facial nerve swelling and causing a delay in instituting steroid therapy[10]. In the acute phase of facial paralysis, facial nerve edema more or less exists, if a strong stimulation of acupuncture therapy is performed at that local area, side effects or aggravation would appear eventually. Acupuncture therapy is not a simple procedure by choosing some local points near the lesion, but a purposeful and targeted operation under the guidance of traditional Chinese medicine theory.

For acupoints, both horizontal and vertical levels should be considered. Specifically, it involves the locus and nature of the disease, as well as the different symptoms a disease reflected. Thus, we have different ways to select acupoints such as from the near part (of locus) or the distant part (of locus) based on syndrome differentiation or based on symptoms". These are choices from a "horizontal" perspective. On this basis, the depth of needling varies for each acupoint which is based on the depth of the disease locus. "skin" "veins" "flesh" "tendons" and "bones", which corresponds roughly to the concept of "pi" "mai"

"rou" "jin" and "gu", is a transition from the surface of the body to the deeper layers of the body, choosing the most appropriate depth to operate is about the "vertical" perspective. Just as a location is determined by latitude and longitude in a map, the exact location of the needle puncture can only be determined when both horizontal and vertical aspects are identified. Also, when necessary, time of the day, season, age, the structure of different people and other factors will be taken into account in the depth of needling. By combining all these factors, the selection of acupoints and the method of acupuncture manipulation have greater flexibility and consequent precision, similar to the precision medicine that modern medicine is beginning to approach[16]. According to the theory of traditional Chinese medicine, the evil qi in the acute phase of facial paralysis is still shallow and deepens inward as the condition progresses. As it is said in the classics of Chinese medicine, "*The shallow focus means the shallow acupuncture depth, and the deep focus means the deep acupuncture depth*". Therefore, during the acute phase of facial palsy, the clinical selection of acupuncture points is mainly from distal acupuncture points with local superficial acupuncture for treatment(Figure 1A-B), when the disease progresses to the recovery period, deep puncture and penetrating puncture are adopted (Fig. 2A-B). After understanding these characteristics of acupuncture, it is clear that the idea of acupuncture performed in early facial palsy could aggravate local edema is a limited understanding of acupuncture therapy, which is formed in the absence of relevant elements.

Traditional Chinese medicine believes that the main cause of facial paralysis is the emptiness of the meridian and the invasion of external evils. When the body is tired and the immune system is weakened, the wind pathogens would take advantage of the void. Or it could be caused by bad emotional conditions such as anxiety and tension. Among them, damp-heat of liver and gallbladder or hyperactivity of liver yang are the most common syndromes of Ramsay Hunt syndrome [17]. Bad emotions can be the trigger of this disease, and the potentially devastating disorder may result in extensive functional or psychosocial sequelae for patients which will enhance the depression in affected individuals [18, 19]. There is an old saying in Chinese medicine, *Righteousness is inside, evil cannot be done*. Acupuncture can regulate the qi and blood of the whole body to a balanced condition by tonifying qi, activating blood, dredging collaterals, etc. According to the patient's facial function damage, selecting different meridian points can purposely affect the facial meridians. Modern studies have also suggested that the occurrence of facial paralysis may be related to weakened immunity[13, 20]. Although the onset is regardless of age and gender, a North American study suggests that children have a higher incidence of Bell's palsy[21]. Acupuncture has a certain effect in the treatment of autoimmune diseases and neurological diseases, and can better regulate emotions[22–24], so it has the basis for lightening the causes of facial paralysis.

In the setting of no treatment, 70% of the Bell's palsy patients fully recovered, 15% progress to non-flaccid FP and 15% recover with minor deficits. For people who are unable to restore by themselves, a potentially devastating disorder may result in functional, sensuous, and psychosocial sequelae on patients[19]. Modern medicine's understanding of this disease is to find out and treat it as soon as possible. Early diagnosis and the immediate initiation of treatment can improve the outcome. Besides,for children younger than 18 years old, the use of glucocorticoids or antiviral drugs is slightly restricted, and there are fewer clinical studies [25]. There is no age limit for acupuncture therapy, and many clinical studies have

found that the intervention of early acupuncture and moxibustion programs can shorten the course of facial paralysis, reduce complications, and sequelae[26–29]. Therefore, whether acupuncture therapy should be involved in the treatment of facial paralysis patients at onset is of great significance.

Four systematic reviews have assessed the safety and effectiveness of acupuncture applying in the acute phase of facial palsy[30–33], the findings showed a beneficial effect of acupuncture therapy at the onset of the facial palsy, but still illustrate some methodological limitations of included trials, varies from study design or comparisons. Two out of four systematic reviews only searched literature from Chinese databases, and use Jadad scoring criteria to score the quality of the literature[31, 32]. JIN *et al*[33] selected 11 studies, in which the control group's selection of points must involve facial points. And all of the systematic reviews only focused on the peripheral facial paralysis but did not include Hunter's facial paralysis. In addition, these studies are only general descriptions of the safety and effectiveness of acupuncture therapy and didn't specify the most suitable point selection or manipulation in the acute phase. Thus, although several systematic reviews are suggesting that the acupuncture treatment at onset is beneficial to the recovery of facial paralysis, there is still controversy. Recently, more clinical trials have been published, but little is known about whether there is a most suitable way to perform acupuncture in the acute phase.

The objective of this systematic review is to assess whether acupuncture should be used in the acute phase of peripheral facial paralysis and whether an early acupuncture intervention can shorten the recovery time of the facial function and reduce the formation of sequelae, and find out the most suitable therapy for FP in the acute phase.

2. Method

2.1. Protocol and registration

The protocol of this review follows the Preferred Reporting Items for Systematic Review and Meta-Analysis Protocols checklist (online supplemental file 1)[34], and was registered at PROSPERO international register of systematic reviews (No. CRD42020205127). And the method used for this protocol will be performed under the criteria of the Cochrane Handbook of Systematic Reviews of Interventions[35].

2.2. Inclusion criteria of studies

There is no restriction on publication language or types. When there are studies reported in different languages other than Chinese or English, we will ask professionals for help.

2.3. Type of studies

We will include all RCTs and quasi-RCTs of acupuncture for peripheral facial palsy. If there is a cross-over trial, we will only use the first phase data and outcomes when analyzing.

2.4. Type of participants

Participants who are in the acute phase of peripheral facial paralysis such as bell's palsy or Ramsay Hunt syndromes will be included. No limitation of gender and age and race will be applied.

2.5. Type of intervention

Acupuncture therapy including manual acupuncture, electroacupuncture, moxibustion, bloodletting, and fire needle around acupoints will be eligible, there will be no limitation of acupuncture points, stimulation techniques, stimulation methods, the depth of needle insertion, needle retention time, stimulation frequency, and so on. If there is a co-therapy with acupuncture, it is necessary to be consistent with the control group.

2.6. Type of control

No treatment, placebo, or conventional treatment such as antiviral therapy, nutritional nerve therapy will be eligible. If both groups involve acupuncture, it is acceptable for the control group not to undergo acupuncture in the acute phase. Or if the control group applies a different acupuncture method from no matter techniques or depth, will all be eligible.

2.7. Type of outcome

The primary outcomes of this review will be the recovery rate of facial function, how long it takes to restore facial function and the odds of sequelae occurring. (use House-Brackman scales, Facial Nerve Grading 2.0 and other related scales). Secondary outcomes will be psychological well-being and quality of life. (use Facial Disability Index scale (FDI), World Health Organization Quality of Life Scale-Brief Form Questionnaire (WHOQOL-BREF)).

3. Patient And Public Involvement

No patient involved in the design, conduct parts of the research. Four of our outpatients permitted us to use their photos during acupuncture treatment as a more intuitive explanation of different kinds of acupuncture manipulation.

4. Search Strategy

Eight major English and Chinese electronic databases will be searched: PubMed Embase Cochrane Library Web of Science CNKI (China National Knowledge Infrastructure) VIP (China Science Technology Journal Database) Wanfang Database Sino-Med Database (including China Biology Medicine disc (CBM)). Search dates: from their inception to September 15th, 2020. LC will apply several strategy exercises in different electronic databases to adjust the sensitivity and specificity. (online supplemental file 2, the detailed search strategy in Pubmed).

5. Selection Of Studies

We will choose software such as EndNote and NoteExpress to manage studies searching from different databases. Two reviewers (XLL and YY) will respectively screen the title and abstracts according to the

predefined criteria. Then full-text phases of the review will also be done by these two authors. If there are any disagreements, a third reviewer will join in and resolve them after discussion (Fig. 3).

6. Data Extraction

Two reviewers (XLL and SQM) will extract the data independently from the included RCTs

and quasi-RCTs by using EXCEL. The following information will be included: (1) Basic information of research: authors, year, title, diseases, corresponding author, contact details, reviewer's ID, time of extraction. (2) Study designs: type of study, sample size, method of random number generation and allocation concealment, blinding, incomplete outcome data, selective reporting. (3) Patient characteristics: inclusion and exclusion criteria, age, gender, diagnostic criteria, severity, race, institution, baseline comparability. (4) Intervention group: type/form of acupuncture therapy, acupuncture points, manipulation, frequency, course of treatment. (5) Control group: control treatment, operation, frequency, course of treatment. (6) Outcomes: effectiveness outcome, safety outcome, efficiency. The discrepancies will be resolved by a third reviewer through consensus.

7. Quality Assessment

Two reviewers (SHD and SQM) will evaluate the quality of the selected studies independently according to the Cochrane Collaboration's tool[35] for randomized control trials. The following characteristics will be assessed: sequence generation (selection bias), allocation concealment (selection bias), blinding of participants and personnel (performance bias), blinding of outcome assessment (detection bias), incomplete outcome data (attrition bias), selective reporting (reporting bias), and other sources of bias. These questions will be assessed by Review Manager 5.3.

8. Data Synthesis And Analysis

If studies are judged to be homogeneous, we will perform a meta-analysis. We will pool the data using risk ratio or odds ratio with 95% confidence interval (CI) for dichotomous outcomes, as for continuous outcomes, we will use standard mean difference or mean difference with 95% CI. The clinical heterogeneity will be assessed according to the characteristics of the included studies and participants, details of the intervention or control, types of outcome measurements will also be analyzed. The I^2 statistic will be used to assess the heterogeneity. According to the Cochrane handbook, when I^2 is between 0%-40%, 30%-60%, 50%-90%, 75%-100%, the heterogeneity will be regarded as not important, moderate, substantial, and considerable. We will use the random-effects model to conduct the meta-analysis unless the I^2 statistic is 75%. When there is substantial heterogeneity, we will try to investigate possible causes from clinical perspectives. Subgroup and sensitivity analysis will be conducted. Forest plots will show the results of the meta-analysis, and if there are more than 10 included studies, funnel plots will be used to identify publication bias.

9. Subgroup Analysis

For facial paralysis, there are different severity and TCM syndrome; for intervention, there are different types of acupuncture therapy; and there are different types of the control group. These all can lead to heterogeneity. To explore the treatment effects respectively, we plan to conduct subgroup analysis for different severity, syndromes, acupuncture techniques (such as manuacupuncture, electroacupuncture, a combination of a different method, different stimulate of acupoint, different acupoint selection, different depth of needling), control group and other possible factors.

10. Sensitivity Analysis

For the main outcome with important positive significance, when the literature conditions are met, the random method is compared according to the methodological quality of the literature. Clear/unclear, double-blind use or not; when the combined results are in a critical state and the heterogeneity is small, compare results of random effects model and fixed effects model. If necessary, leave each study out to assess the weight of the research.

11. Quality of the Evidence

Summary of Findings (SoF) table will be generated by the GRADEpro Guideline

Development Tool (GDT). The SoF tables will show the overall quality of the body of evidence. Whether to upgrade or downgrade the level of the evidence will according to the Grading of Recommendations, Assessment, Development, and Evaluation (GRADE) criteria[36].

12. Discussion

Although acupuncture therapy has been widely recognized all over the world, and its curative effect on many diseases is evitable, how to choose the most suitable acupuncture therapy for different disease conditions has not been recognized by the public or even practitioners. Traditional Chinese medicine believes when facing facial paralysis, the sooner the treatment the better just like the conclusion drawn by western medicine. But there are doubts about whether acupuncture, can be performed in the acute phase of peripheral facial paralysis. This is not only related to the research quality of the original literature but also related to the failure to differentiate the complex acupuncture treatments.

Until now, there have been many clinical studies on acupuncture treatment, and all show effectiveness and safety. A few systematic reviews have concluded that acupuncture is effective at the onset of facial paralysis through the research of these clinical trials. However, previous studies limited the diseases in idiopathic facial paralysis or Hunter facial paralysis respectively, but the specific acupuncture therapies and manipulation were ignored. What's more, the clinical conclusions were not detailed enough to be a reference for clinical practitioners.

In this study, different facial paralysis in the acute phase will all be pooled. There were no restrictions on acupuncture therapy, and no restrictions on the specific treatment of the control group, these are for finding the most suitable acupuncture methods for acute facial paralysis. By doing this, the heterogeneity between various studies will be increased, which seems to be a defect. But currently, with there is more and more research about applying treatment in its acute phase of facial paralysis, we can review as many different acupuncture therapies as possible, and through appropriate subgroup analysis, more accurate conclusions will be drawn. Due to the particularity of acupuncture therapy, the practitioner cannot perform blinding, so we plan to slightly relax the standard for the quality evaluation of this part. But the blinding of outcome assessment will be conducted.

Declarations

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Contributors

LC conceptualized and designed the study. After that, LC organized the team for a further review study. LC drafted and revised the protocol with contributions from XLL, SQM, WG, YY. JPZ gave clinical suggestions. XLL and YY will undertake study selection, XLL and SQM will extract the data from studies, SHD and SQM will assess the quality of the studies. VG and XDZ will undertake evidence quality with GRADE. LC will do the analysis, interpretation, and reporting work. All authors have read and approved the manuscript of the version of this protocol.

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Declaration of competing interest

The authors declare that they are known to have no financial and personal interests which could influence the results of this paper.

Ethics and Dissemination

Ethical approval is not required. This systematic review will summarise the evidence of existing studies, and all the data used will be anonymous with no concerns regarding privacy. The results of this study will be disseminated through a peer-reviewed journal for publication.

Provenance and peer review

Not commissioned; externally peer reviewed.

Supplemental material

This contents are supplied by the authors.

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Figures

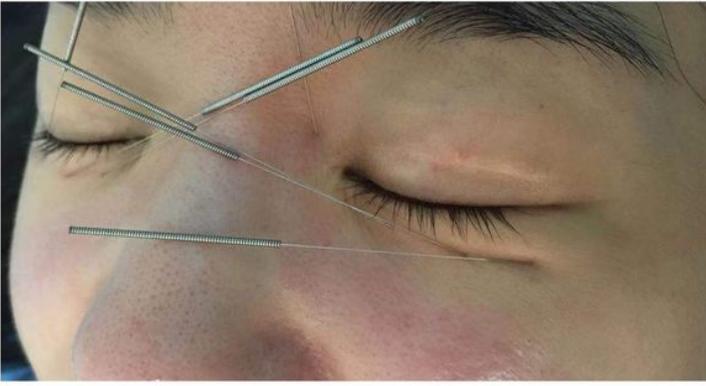


Figure 1

(A) (B) Shallow and Superficial. When manipulating the shallow needling method, the needle just penetrates through the skin, and the insertion depth is 0.1-0.2cm.



Figure 2

(A) (B) Deep and Penetrated. When manipulating the deep or penetrated method, the insertion may through different tissue levels, or from one acupoint to another acupoint. Insertion depth depending on the lesion level or the level that we aim to achieve.

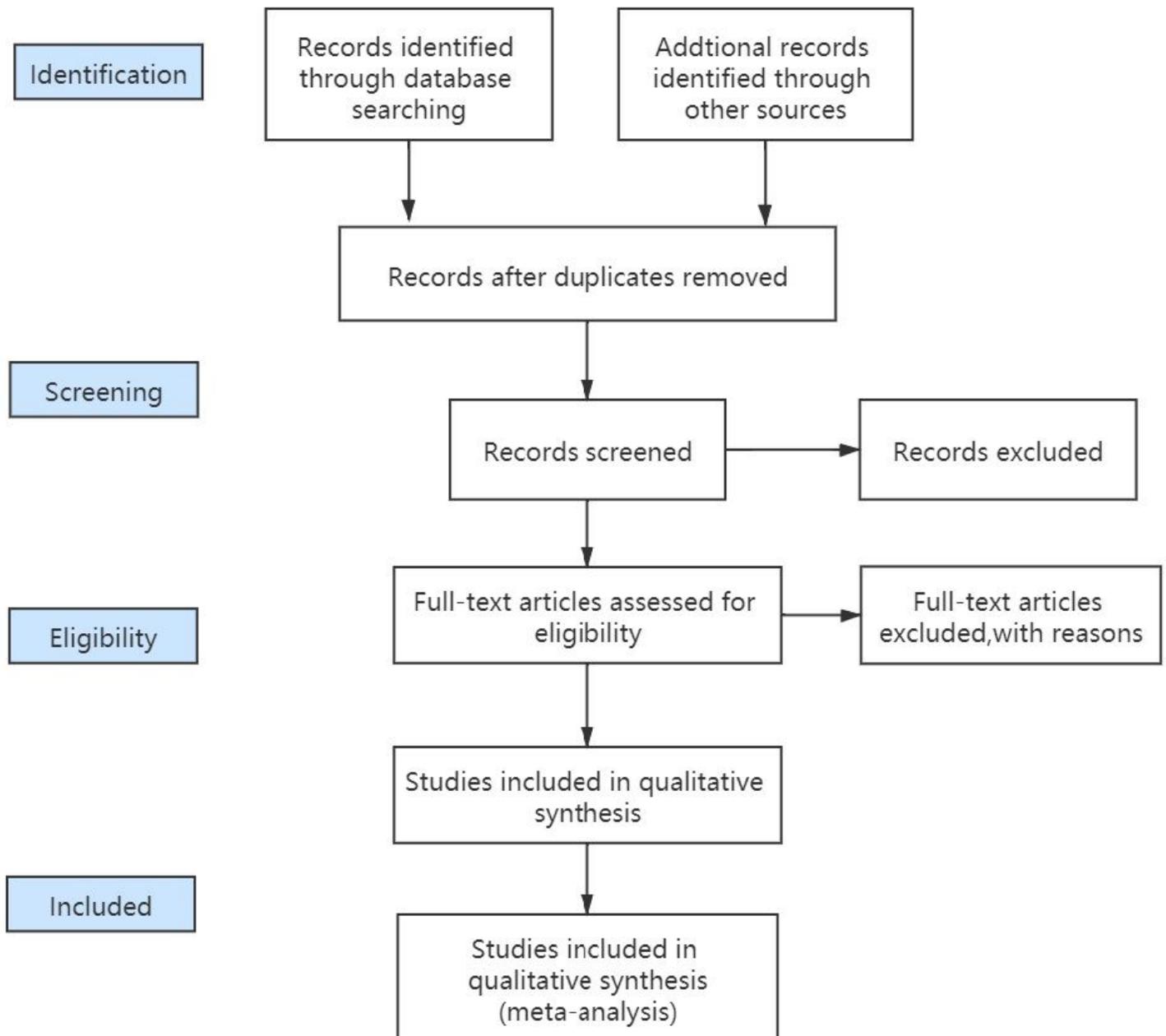


Figure 3

Flow chart of literature selection.

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