

# Effectiveness of Auricular Acupuncture in Treating Depressive Disorders: a Systematic Review Protocol

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## Protocol

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# Abstract

**Background:** Depression is a chronic condition of high prevalence in the world population and associated with functional disability and compromises the physical health of affected individuals. According to Traditional Chinese Medicine (TCM), depression is associated with disability, there is not enough energy for positive feelings or associated with stagnation, when there is energy, but the flow of energy and emotions is blocked. Deficiency is also associated with excess in manic depression or irregularity in depression associated with anxiety. Auricular acupuncture, also known as auriculotherapy, it is part of a set of techniques based on TCM. For this, the auricular pavilion is related to 12 meridians, stimulating points in the ear and restoring the balance between blood and Qi (energy or vital force).

**Methods:** This is a systematic review protocol for clinical trials prepared in accordance with the guidelines of the protocol Preferred Reporting Items for Systematic Reviews and Meta-analysis (PRISMA-P). Studies in which participants have any depressive disorder, diagnosed through standardized criteria such as the Diagnostic and Statistical Manual of Mental Disorders (DSM), the International Classification of Diseases (ICD) and other diagnostic criteria used internationally will be included. There will be no restrictions on age, gender, ethnicity, education or economic status. Studies will be accepted that have as experimental intervention any type of auricular acupuncture (using needles, seeds, magnetic stones, lasers, ultrasound, bleeding or electrical treatment). The control interventions that will be considered for the studies will be conventional medical treatment for each depressive disorder, no treatment, placebo and other active therapies.

**Discussion:** Auricular acupuncture can be a potential alternative complementary treatment, it is low cost and has minimal side effects presented until now. With this review we hope to complete gaps in the knowledge of auricular acupuncture, promoting an updated and comprehensive synthesis of research on this topic.

**Record of systematic review:** In accordance with the guidelines, our systematic review protocol was registered with the International Prospective Registry of systematic reviews (PROSPERO) on 10/27/2020 (registration number CRD42020211302).

## Background

Depression is a chronic condition of high prevalence in the world population and associated with functional incapacitation and compromises the physical health of affected individuals. The World Health Organization assumes that depression will be the second largest cause of disability in 2030 <sup>[1, 2]</sup>. According to the American Psychiatric Association (APA) depression affects about one in 15 adults (6.7%) per year. Added to that, one in every 6 people (16.6%) will suffer from depression at some point in their life.

Thus, depression is a common and serious illness that affects negatively how the individual feels, thinks and acts, it causes feelings of sadness and/or loss of interest in activities and happens at any time, but

on average it appears for the first time at the end of adolescence until mid-20 years old [3]. Symptoms can vary from mild to severe and must last at least 2 weeks for a diagnosis to be possible. It can affect any individual, even one who seems to live in relatively ideal circumstances [4].

Among the types of depression found in the literature are major depressive disorder, melancholy, dysthymia, postpartum depression, psychotic depression, seasonal affective disorder, bipolar disorder, among others [1, 2]. The drugs commonly used for the treatment of these disorders are selective serotonin-recepting inhibitors (SSRIS) and serotonin-norepinephrine reuptake inhibitors (IRSNs), second generation antidepressants, they have greater safety in relation to most older drugs, the first generation antidepressants [5].

The combination of psychological treatment with antidepressants can be more effective than each therapy used separately. Price [6] performed an overview and showed that cognitive-behavioral therapy and interpersonal psychotherapy improve symptoms in mild to moderate depression when used in initial treatment. It is not known whether problem solving therapy, cognitive-behavioral therapy and relapse prevention programs are effective in reducing the risk of relapse after recovery, and care systems can increase the chances of effective treatment for depression.

According to Traditional Chinese Medicine depression is associated with deficiency, there is not enough energy for positive feelings or associated with stagnation, when there is energy, but the flow of this and of emotions is blocked. Disability is also associated with excess in manic depression, or with irregularity in depression associated with anxiety. So, what can make the energy flow normally again, that the balance is stabilized, can bring a solution to these problems [7, 8].

The World Health Organization (WHO) encourages the use of Traditional Medicine/Complementary/Alternative Medicine in health systems in an integrated manner with the techniques of modern Western medicine. Traditional Chinese Medicine (TCM) is a complex medical system that integrally and dynamically approaches the health-disease process in human beings and can be used in isolation or integrated with other therapeutic resources [9].

For TCM, the auricular pavilion relates to 12 meridians, stimulating points in the ear and restoring the balance between the blood and Qi (energy or life force). The Qi flows in the body through channels that pass through specific points connected to each organ, so in cases of imbalance of the Qi, such points can be stimulated, which changes the flow of energy and regains the individual's health by restoring the body's balance. There are several forms of stimulation, besides needles, seeds, magnetic stones, lasers, ultrasound, bleeding, electrical treatment and manual pressure can also be used [10, 11].

With technological advances, clinical trials are increasingly showing evidence about the detailed mechanisms of auricular acupuncture in the treatment of diseases. Because it is non-invasive, simple to implement, easy to learn and with minimal side effects, in addition to being performed independently, ear acupuncture can be used as an alternative approach or to assist in the management of symptoms of

various diseases [10, 12]. Moura et al [13], carried out a systematic review that demonstrated that ear acupuncture showed 80% positive results in patients with chronic low back pain. Ruela et al [14], assessed pain reduction in patients undergoing cancer treatment, and he observed a significant reduction in pain.

Summarizing the clinical evidence of this therapy for depressive disorders will allow healthcare professionals to use this simple non-pharmacological approach based on evidence-based medicine [10, 12]. Therefore, the objective of this study is to investigate, analyze and unite existing clinical trials in the literature on ear acupuncture in the treatment of depressive disorders, in search of new scientific evidence that can help in the treatment of these patients.

## Methods

Study design:

This is a systematic review protocol for clinical trials prepared in accordance with the guidelines of the protocol Preferred Reporting Items for Systematic Reviews and Meta-analysis (PRISMA-P) [15]. The PRISMA-P checklist is included as an additional file (see additional file 1).

Study registration

In accordance with the guidelines, our systematic review protocol was registered with the International Prospective Registry of systematic reviews (PROSPERO) on 10/27/2020 (registration number CRD42020211302).

Available at: [https://www.crd.york.ac.uk/prospero/display\\_record.php?ID=CRD42020211302](https://www.crd.york.ac.uk/prospero/display_record.php?ID=CRD42020211302)

### Eligibility Criteria

Types of studies:

Randomized and non-randomized clinical trials will be included. Observational trials, systematic reviews and meta-analysis will be excluded, but the studies used in them will be analyzed.

However, controlled studies comparing different methods of auricular acupuncture will be excluded because these studies cannot produce and demonstrate the net effect of auricular acupuncture.

Types of participants:

Studies in which participants have any depressive disorder, diagnosed through standardized criteria such as the Diagnostic and Statistical Manual of Mental Disorders (DSM), the International Classification of Diseases (ICD) and other diagnostic criteria used internationally will be included. There will be no restrictions on age, gender, ethnicity, education or economic status.

Types of intervention/comparison:

Auricular acupuncture aims at establishing the balance of energy flow (Qi). The Qi flows in the body through channels that pass through specific points connected to each organ, so in cases of imbalance of the Qi, such points can be stimulated, which changes the flow of energy and regains the individual's health by restoring the body's balance. The stimulation can be from a needle, is the technique most used today, but can also be used seeds and magnets, and several other techniques.

Studies will be accepted that have as experimental intervention any type of auricular acupuncture (using needles, seeds, magnetic stones, lasers, ultrasound, bleeding or electrical treatment).

The control interventions that will be considered for the studies will be conventional medical treatment for each depressive disorder, no treatment, placebo and other active therapies.

### **Types of outcome measures**

Primary results:

It is expected to observe a change in the level and symptoms of depression from the beginning to the end of treatment, being analyzed by qualified and validated forms of depression, such as the Beck-II inventory, Hamilton evaluation scale and Zung Depression Self-assessment scale.

Secondary results:

Evaluation of the change in quality of life or adverse reactions with the intervention.

Research methods to identify the studies:

Databases used will be: Pubmed Medline (see additional file 2), Scielo, Lilacs, Scopus, Web of Science and Embase. The search will not have restriction of language and period of publication. Unpublished studies will not be analyzed.

The keywords used will be auricular acupuncture (auriculotherapy, acupuncture therapy, among other synonyms) and the types of depressive disorders (major depressive disorder, bipolar disorder, postpartum depression (peripartum), seasonal affective disorder, psychotic depression, persistent depressive disorder (dysthymia), pre-menstrual dysphoric disorder, situational depression and atypical depression). The ENTREE TERM referring to these terms will be analyzed for the Embase and the DECS and their MESH terms will be used in the other databases.

The reference list of all included studies will be checked in order to identify potentially relevant studies.

### **Data collection and analysis**

Selection of studies:

Two reviewers (KNS and MRJS) will independently review literature titles and abstracts mainly to exclude articles that do not meet the inclusion criteria, and then make an additional judgment on whether articles

that may meet the inclusion criteria can be included. The disagreement of the two reviewers to include or exclude an article will be determined by a third reviewer (LPL). The entire process will be conducted in the Rayyan<sup>[16]</sup> application, a specific application<sup>[17]</sup> to assist researchers in producing reviews.

#### Data extraction and management:

As well as the selection of articles, evaluators will independently extract (KNS and MRJS) data from the articles included in the study. The contents extracted include details of the intervention and comparator used, measured results and results according to the STRICTA p checklist (Revised standards for reporting interventions in acupuncture clinics)<sup>[17]</sup>. The details will be organized in excel tables. For articles published only in summary or articles where important information is missing, we will seek complete information on methods and results by contacting the authors. Disagreement on data extraction will be determined by a third reviewer (LPL).

#### Bias risk assessment:

The risk of bias in each study will be assessed by 2 independent reviewers (KNS and MRJS) using the Cochrane Rev Man "risk of bias tool" which analyzes 7 domains: random sequence generation, concealment of allocation, blinding of participants and staff, blinding of result evaluation, incomplete result data, selective result reports and other biases. The bias risk for each item will be classified as "low risk of bias", clear risk of bias or "high risk of bias". Any disagreement will be resolved through the third reviewer (LPL).

#### Measures of effect on treatment:

If the results are continuous, the data will be expressed with mean difference (MD) or standard difference (SMD) with 95% CI. And in the case of dichotomous results, data will be expressed as the relative risk (RR) with 95% CI.

#### Dealing with missing data:

Regarding missing data, it will be analyzed why the data are missing. Whenever possible, the authors will be contacted to request any inappropriate and missing data from the included studies. If it is not possible to obtain missing data, a case analysis will be performed, only on known data. And we will address the potential impact of missing data on the results of the review in the bias study.

#### Evaluation of heterogeneity:

The evaluation of heterogeneity will be conducted by the Review Manager (V.5.4). Chi-square test and forest value  $I^2$  to detect non-overlap ping CIs and investigating  $x^2$  (with P value > 0.10 indicating no heterogeneity), The  $I^2$  value is classified into 4 levels: little or no heterogeneity (0% -40%), moderate heterogeneity (30% -60%), substantial heterogeneity (50% -90%) and considerable heterogeneity (75% -100%). We will use a cutoff point of 50% for significant heterogeneity among the studies included. If  $I^2 >$

50%, a significant heterogeneity between trials will be considered and a meta-analysis will not be performed.

If the data found does not fit the quantitative analysis, the qualitative description will be performed. If the meta-analysis is adequate, according to the data of good performance in homogeneity, it will be applied to conduct a quantitative analysis.

Evaluation of report bias:

If the number of studies included in the review is more than 10, funnel graphs will be generated to analyze the possible presence of report biases and effects of small studies.

Data synthesis:

According to the heterogeneity of the interventions of the studies, the grouping of the studies that fit in the necessary criteria for the accomplishment of the meta-analysis will be made. If it is not possible, only a descriptive review of the studies that meet the inclusion criteria will be performed. The results will be considered statistically significant when  $p$  is greater than 0.05.

Subgroup analysis:

We intend to perform subgroup analysis if we identify substantial heterogeneity. The following factors will be analyzed: different types of depression, techniques used in auricular acupuncture and whether the studies are randomized or not.

Sensitivity analysis:

In order to ensure the robustness of the results, the sensitive analysis will be performed to remove the impact of low quality studies, if after the heterogeneity exists after the subgroup analysis. Thus the meta-analysis will be performed again after the elimination of the studies of inferior qualities. The two meta-analyses will be compared in order to make the decision on the effective elimination of low quality studies, according to the sample size, to forced evidence and missing data.

Classifying the quality of evidence:

The quality of the evidence will be evaluated by the Classification of Evaluation, Development and Evaluation of Recommendations (GRADE), this classification evaluates the quality of evidence based on 5 factors: limitations of the study, consistency of the effect, imprecision action bias, indirect and publication. The evaluation is categorized into 4 levels: high, moderate, low and very low quality.

## **Discussion**

Due to the increased incidence of depressive disorders in the world population and consequently the increased need for the use of antidepressant drugs, it is interesting for health professionals and patients

that there is an effective complementary treatment for the treatment of these various types of depressive disorders.

Auricular acupuncture can be a potential alternative complementary treatment, it is low cost and has minimal side effects, presented until now.

With this review, we hope to complete gaps in the knowledge of auricular acupuncture, promoting an updated and comprehensive synthesis of research on this topic. In the case of inconclusive and limited evidence, this review intends to indicate paths for future research.

## Abbreviations

**APA-** American Psychiatric Association;

**CI-** Confidence interval;

**CID-** International classification of diseases;

**DMS-** Diagnostic and Statistical Manual of Mental Disorders;

**GRADE-** Classification of Evaluation, Development and Evaluation of Recommendations;

**ISRSS-** Selective Serotonin Reception Inhibitors;

**IRSNS-** Inhibitors of serotonin-noraepinephrine recaptation;

**MD-** Average difference;

**TCM-** Traditional Chinese Medicine;

**WHO-** World Health Organization;

**PRISMA-P-** Preferred Reporting Items for Systematic review and Meta-Analysis Protocols;

**PROSPERO-**International Prospective Register of Systematic Reviews;

**SMD-** Standard average difference;

**RR-** Relative Risk;

**STRICTA-** Revised norms for reporting interventions in clinics Acupuncture testing.

## Declarations

**Ethical approval and consent to participate:**

Not applicable for this section.

**Consent for publication:**

Not applicable for this section.

**Availability of data and materials:**

Not applicable for this section.

**Competitive interests:**

The authors declare that they have no conflicting interests.

**Financing:**

Not applicable for this section.

**Authors' contributions:**

KNS prepared the research question and wrote the review protocol. GCB and LPL - contributed to the adjustment of the research question, reviewed methods and the draft of the document in terms of intellectual content. All authors read and approved the final version of the manuscript.

**Recognition:**

I thank all employees for their assistance and support throughout the protocol process and continuing with the systematic review.

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## Supplementary Files

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