

Clinical efficacy of Duiyiwei capsule in treating gingivitis

A protocol of systematic review and meta-analysis

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Abstract

Background: This study will investigate the clinical efficacy of Duiyiwei capsule (DYWC) for the treatment of gingivitis.

Methods: Relevant studies will be searched in PUBMED, EMBASE, Cochrane Library, WANGFANG, VIP, CBM, and CNKI from inception to the March 31, 2020 without limitations of language and publication time. All potential randomized controlled trials on the clinical efficacy of DYWC for the treatment of gingivitis will be considered. Two authors will independently perform literature selection, data collection, and study quality assessment. Any disagreements will be solved by a third author through discussion. We will utilize RevMan 5.3 software for statistical analysis.

Results: This study will summarize present randomized controlled trials on the efficacy and safety of DYWC for the treatment of gingivitis.

Conclusion: The findings of this study will provide evidence to show whether DYWC is effective and safety for gingivitis. Systematic review registration: INPLASY202040199.

Abbreviations: CIs = confidence intervals, DYWC = Duiyiwei capsule.

Keywords: Duiyiwei capsule, efficacy, Gingivitis, safety

1. Introduction

Gingivitis is a common periodontal disease,^[1–3] which may affect about 55.7% in general population.^[4] It is characterized by gingiva changes without loss of periodontal attachment.^[5–7] Patients with this condition often experience bleeding on tooth brushing, gingival swelling, and redness.^[8,9] Although several managements are reported that can benefit gingivitis, the efficacy is limited.^[10–12]

Traditional Chinese medicine is widely used to treat a variety of diseases in China during the past time and present, and it has achieved satisfied efficacy. Recent studies reported that Duiyiwei

capsule (DYWC) can be utilized for the treatment of gingivitis.^[13–20] However, no systematic review was conducted in the past. Thus, this study aims to assess the efficacy and safety of DYWC for the treatment of gingivitis.

2. Methods

2.1. Study registration

This study has been registered on INPLASY202040199. It will be carried out under the guideline of Preferred Reporting Items for Systematic Reviews and Meta-analyses Protocols.^[21]

2.2. Inclusion criteria for study selection

2.2.1. Type of study. Only randomized controlled trials that assessed the efficacy and safety of DYWC for gingivitis will be included. We will exclude any other studies, such as animal studies, reviews, and nonclinical studies.

2.2.2. Type of patients. The patients, over 18 years, who were diagnosed with gingivitis will be included in this study. There are no limitations related to the race, gender, and nationality.

2.2.3. Type of interventions. Experimental interventions: All patients received DYWC as an interventional management, irrespective dosage, duration, and frequency.

Control interventions: All patients underwent any modalities as a comparison. However, we will exclude studies if they included studies involved any forms of DYWC.

2.2.4. Types of outcome measurements. The primary outcomes are gingival index, dental plaque index, and bleeding on probing.

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Data sharing not applicable to this article as no datasets were generated or analyzed during the current study.

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Table 1
Search strategy for PUBMED.

Number	Search terms
1	Gingivitis
2	Gingiva
3	Gum inflammation
4	Periodontal disease
5	Gum disease
6	Bacteria
7	Or 1–6
8	Chinese medicine
9	Herbal medicine
10	Duyiwei
11	Capsule
12	Formula
13	Or 8–12
14	Random
15	Randomly
16	Controlled trial
17	Randomized trial
18	Blind
19	Allocation
20	Control
21	Comparator
22	14 and 21
23	7 and 13 and 22

The secondary outcomes are gingival abrasion scores, bleeding scores, and adverse events.

2.3. Search methods for identification of studies

2.3.1. Electronic databases. This study will search relevant studies in PUBMED, EMBASE, Cochrane Library, WANG-FANG, VIP, CBM, and CNKI from inception to the March 31, 2020. There are no restrictions related to the language and publication time. We will include randomized controlled trials that assessed the efficacy of DYWC for the treatment of gingivitis. We will present detailed search strategy for PUBMED in Table 1. We also adapt similar detailed search strategy for other electronic databases.

2.3.2. Searching other resources. Other resources of relevant studies will be identified, including websites of clinical trial registry, dissertations, conference papers, and reference lists of relevant literatures.

2.4. Data collection and analysis

2.4.1. Study selection. Two authors will independently examine the titles and abstracts of all retrieved literatures, and will exclude all duplicated and irrelevant studies. Then, full papers of potential studies are carefully read against all inclusion criteria. We will list reasons of all excluded studies and will present them in a table. If conflicts occur between 2 authors, a third author will be invited to solve them by discussion. The process of study selection is showed in a Preferred Reporting Items for Systematic Reviews and Meta-analyses Protocols flow chart.

2.4.2. Data extraction and management. Two authors will independently extract data using a standardized data extraction form. If there are different views between 2 authors, we will invite a third author to settle them down through consultation. The extracted data includes publication information (eg, title,

first author, and publication year), patients' characteristics (eg, age, gender, and eligibility criteria), trial setting, trial methods, details of treatment and comparison (eg, delivery methods, dosage, and frequency), primary and secondary outcomes, results, findings, and other essential information. If unclear or missing data is examined, we will contact primary authors to achieve it.

2.4.3. Assessment of risk of bias. Two authors will independently examine the risk of bias for all trials using Cochrane risk of bias. We will check it on 7 different levels, and will divide it into 3 degrees: low risk of bias, unclear risk of bias, and high risk of bias. If we identify any disagreements between 2 authors, we will resolve them by discussion with the help of a third author.

2.4.4. Detection of treatment effect. We will detect treatment effect of dichotomous data as risk ratio and 95% confidence intervals, and will estimate treatment effect of continuous data as mean difference or standardized mean difference and 95% confidence intervals.

2.4.5. Assessment of heterogeneity. Statistical heterogeneity will be identified by I^2 statistics. $I^2 \leq 50\%$ means minor heterogeneity, and a fixed-effects model will be implemented, while $I^2 > 50\%$ suggests major heterogeneity, and a random-effects model will be utilized.

2.4.6. Subgroup analysis. A subgroup analysis will be conducted to explore the major heterogeneity based on the variations in study and patient characteristics, treatments, controls, and outcomes.

2.4.7. Sensitivity analysis. A sensitivity analysis will be performed to examine the satiability of study findings by eliminating low quality studies.

2.4.8. Publication bias. If there are adequate studies (normally over 10 trials), we will investigate the publication bias using Funnel plot and Egger regression test.^[22]

2.4.9. Data synthesis. This study will analyze data using RevMan 5.3 software. If minor heterogeneity is identified across 2 or more eligible studies on same outcomes, meta-analysis will be carried out based on the sufficient similarity in study and patient characteristics, details of interventions and controls, and outcome measurements. Otherwise, if major heterogeneity is investigated, a subgroup analysis and meta-regression test will be undertaken to explore the possible reasons of obvious heterogeneity. In addition, a narrative description will be used to report study results.

2.5. Dissemination and ethics

This study will not require ethical document, because this study will not use individual data. This study is expected to be published in a peer-reviewed journal.

3. Discussion

A number of previous studies have reported the clinical efficacy of DYWC for the treatment of gingivitis.^[13–20] However, there is no similar systematic review exploring this subject. This systematic review will be conducted to critically examine the literature on the treatment of gingivitis. Specifically, we will assess the efficacy and safety of DYWC for gingivitis. Findings from this study may

supply the generation of clinical recommendations for clinician treating patients with gingivitis. Its results may also help inform future research in this field.

Author contributions

Conceptualization: Hai-ying Liu, Zhi-xuan Zhao.

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Formal analysis: Hai-ying Liu.

Investigation: Zhi-xuan Zhao.

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