INPLASY PROTOCOL

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Review Stage at time of this submission: **The review has not yet started.**

Conflicts of interest:
None.

Clinical efficacy of Duyiwei capsule in treating gingivitis: a protocol of systematic review and meta-analysis

Liu, HY[1]; Fan, JH[2]; Lin, N[3]; Zhao, ZX[4].

Review question / Objective: **Is Duyiwei capsule (DYWC) effective for the treatment of gingivitis?**
Condition being studied: **Duyiwei capsule; gingivitis.**
Information sources: **Electronic databases - This study will search relevant studies in PUBMED, EMBASE, Cochrane Library, WANGFANG, 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 RCTs 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. Searching other resources - Other resources of relevant studies will also be identified, including websites of clinical trial registry, dissertations, conference papers, and reference lists of relevant literature.**

INPLASY registration number: This protocol was registered with the International Platform of Registered Systematic Review and Meta-Analysis Protocols (INPLASY) on 27 April 2020 and was last updated on 27 April 2020 (registration number INPLASY202040199).

INTRODUCTION

Review question / Objective: **Is Duyiwei capsule (DYWC) effective for the treatment of gingivitis?**

Condition being studied: **Duyiwei capsule; gingivitis.**

METHODS

Participant or population: **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.**

Intervention: All patients received DYWC as an interventional management, irrespective dosage, duration and frequency.

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

Study designs to be included: Only randomized controlled trials (RCTs) that assessed the efficacy and safety of DYWC for gingivitis will be included.

Eligibility criteria: Only RCTs 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 non-clinical studies.

Information sources: Electronic databases - This study will search relevant studies in PUBMED, EMBASE, Cochrane Library, WANGFANG, 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 RCTs 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. Searching other resources - Other resources of relevant studies will also be identified, including websites of clinical trial registry, dissertations, conference papers, and reference lists of relevant literature.

Main outcome(s): The primary outcomes are gingival index, dental plaque index, and bleeding on probing. The secondary outcomes are gingival abrasion scores, bleeding scores, and adverse events.

Data management: Two authors will independently extract data using a standardized data extraction form. If there are different disagreements between two authors, we will invite a third author to settle them down through consultation. The extracted data includes publication information (e.g. title, first author, and publication year), patients' characteristics (e.g. age, gender, and eligibility criteria), trial setting, trial methods, details of treatment and comparison (e.g. 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.

Quality assessment / Risk of bias analysis: 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 three degrees: low risk of bias, unclear risk of bias, and high risk of bias. If we identify any disagreements between two authors, we will resolve them by discussion with the help of a third author.

Strategy of data synthesis: This study will analyze data using RevMan 5.3 software. If minor heterogeneity is identified across two 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.

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.

Sensibility analysis: A sensitivity analysis will be performed to examine the stability of study findings by eliminating low quality studies.

Country(ies) involved: China.

Keywords: Gingivitis; Duyiwei capsule; efficacy; safety.