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Research paper

Chinese herbal formula for postprandial distress syndrome: Study protocol of a double-blinded, randomized, placebo-controlled trial

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ABSTRACT

Introduction: Functional dyspepsia is one of the typical functional gastrointestinal disorders and can be further categorized into postprandial distress syndrome and epigastric pain syndrome. The clinical response to conventional medicine treatment is unsatisfactory so that a majority of the population will seek help from Traditional Chinese Medicine. In clinical practice JianPi'I, derived from a classical TCM formula Xiangshaliujunzi decoction, appears to have a satisfactory effect on functional dyspepsia. Therefore, in order to further verify the benefit of JianPi'I, we designed a strict clinical trial to evaluate the safety and efficacy of JianPi'I in postprandial distress syndrome patients.

Methods: This is a 10-week, multicenter, randomized, double-blinded, placebo-controlled trial. Eligible 144 patients will randomly be assigned to JianPi'I or placebo. The primary outcome is the change in the postprandial discomfort severity scale from baseline to treatment endpoint. The secondary outcomes include the changes in the clinical global impression scale, Traditional Chinese Medicine symptoms scores, MOS 36-Item Short-Form Health Survey and gastric emptying from baseline to treatment endpoint.

Discussion: The main ingredients of JianPi'I contain *Radix Codonopsis* (Dangshen), *Rhizoma Atractylodis Macrocephalae* (Baizhu), *Poria* (Fuling), *Fructus Amomi* (Sharen), *Radix Glycyrrhizae* (Gancao), *Radix Aucklandiae* (Muxiang), *Pericarpium Citri Reticulatae* (Chenpi), and *Rhizoma Pinelliae* (Banxia), which are expected to alleviate symptoms of postprandial distress syndrome. This randomized placebo-controlled trial will comprehensively examine the efficacy and safety of JianPi'I in postprandial distress syndrome patients, and aim to provide a new treatment option for clinical practice in postprandial distress syndrome management.

1. Introduction

Functional gastrointestinal disorders (FGIDs) are a series of diseases characterized by various gastrointestinal symptoms but with no structural lesions. Functional dyspepsia (FD) is one of the typical FGIDs [1–4]. According to the Rome III criteria [5], FD is defined as the presence of symptoms originated from the gastroduodenal region such as postprandial fullness, early satiation, epigastric pain or burning and can be further classified into two subtypes: postprandial distress syndrome (PDS) and epigastric pain syndrome (EPS), which are characterized by postprandial fullness and early satiation, and epigastric pain and burning, respectively [6,7]. FD is not life-threatening, however, it would seriously affect the quality of life (QoL) of patients and result in high disease burden [8–10]. Owing to the difference of demographic factors, the incidence of FD ranges from 18% to 45% [11–14],

Abbreviations: AE, adverse event; CCK, cholecystokinin; CGI, clinical global impression; CGI-I, clinical global impression-improvement; CGI-S, clinical global impression-severity; ChiCTR, Chinese clinical trial registry; CONSORT, consolidated standards of reporting trial; CRC, clinical research coordinator; CRF, case report form; CRO, contract research organization; ECG, electrocardiogram; EPS, epigastric pain syndrome; FD, functional dyspepsia; FGID, functional gastrointestinal disorder; GCP, good clinical practice; GMP, Good manufacturing practice; PDS, postprandial distress syndrome; PDSS, postprandial discomfort severity scale; PPI, proton pump inhibitor; QoL, quality of life; SF-36, MOS 36-Item Short-Form Health Survey; SPIRIT, standard protocol items; SS, symptoms scores; TCM, Traditional Chinese medicine; VIP, vasoactive intestinal polypeptide.

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and FD accounts for approximate 40% of the total gastroenterology outpatient consultations globally [15,16].

At present, the etiology and pathogenesis of FD are not fully understood yet. It is commonly accepted that pathophysiological factors including gastric hypersensitivity, gastric receptive relaxation function, and delayed gastric emptying, *Helicobacter pylori* infection, and psychosocial factors are associated with FD [17–21]. Conventional treatment for FD generally includes proton pump inhibitors (PPIs), prokinetic agents, anti-*Helicobacter pylori* drugs, anxiolytic and antidepressant drugs, and mucosal protective agents; however, the response is not satisfied [22,23]. Therefore, many patients would seek help from complementary and alternative therapy [24], especially in China and East Asia.

Based on Traditional Chinese Medicine (TCM) theory, PDS can be categorized as "distention and fullness" which the most related organ is "spleen". A previous study has already demonstrated that the syndrome of "spleen deficiency and qi stagnation" was the most common syndrome type in FD patients [25]. Based on these concepts, the herbal preparation JianPi'I, derived from a classical TCM formula Xiangshaliujunzi decoction, was designed and utilized in treating FD patients with "spleen deficiency and qi stagnation" syndrome. In this trial, a randomized, double-blinded, and placebo-controlled clinical trial was designed to evaluate the safety and efficacy of JianPi'I on PDS patients. The results of this study may provide explicit and powerful evidence for the therapeutic effect of herbal preparation on PDS.

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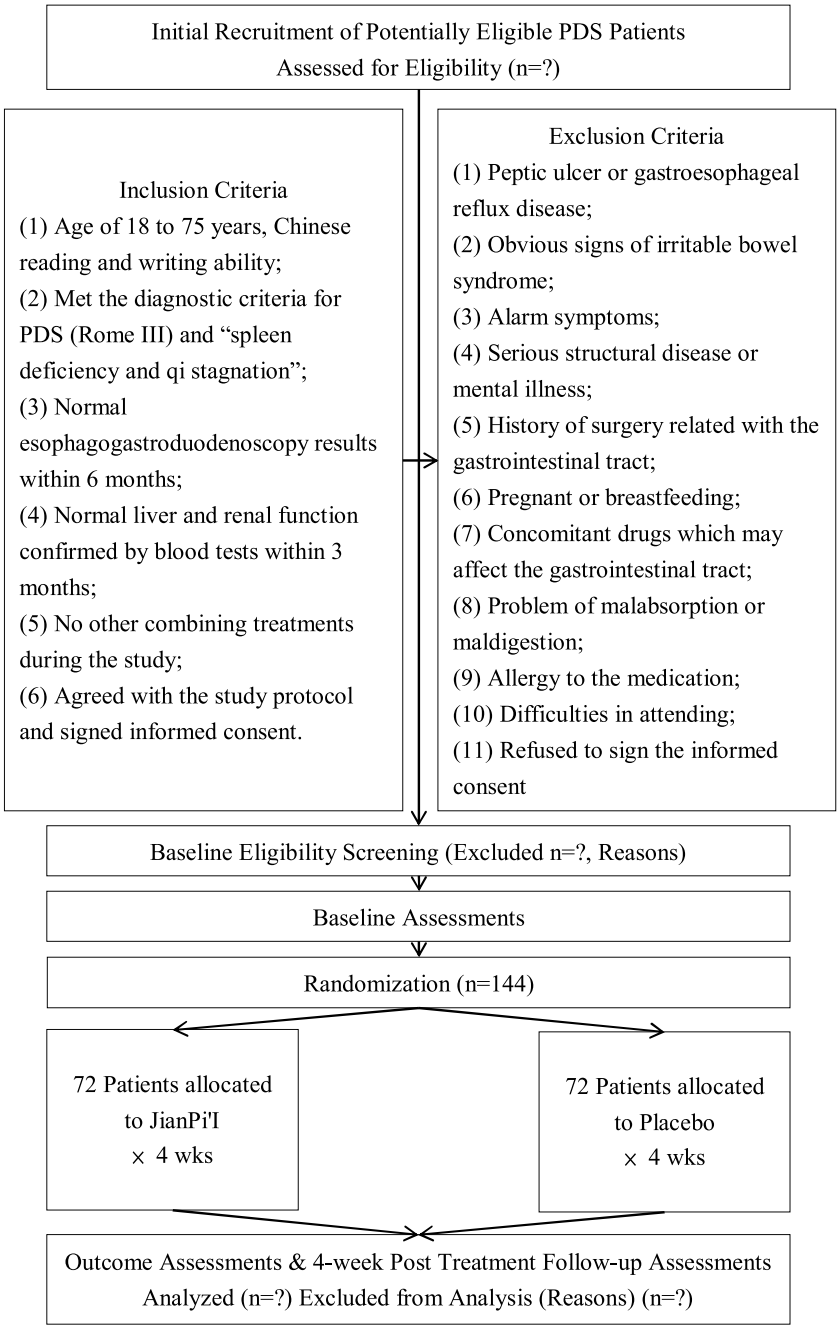

Fig. 1. Participant flowchart.