Epigastric pain syndrome: what can traditional Chinese medicine do? A randomized controlled trial of Biling Weitong Granules

CONSORT statement: The authors have read the CONSORT Statement—checklist of items, and the manuscript was prepared and revised according to the CONSORT Statement—checklist of items.

Checklist of Items for Reporting Trials of Chinese Herbal Medicine Formulas*				
Section/Topic	**Item Number**	**Standard CONSORT Checklist Item**	**Extension for CHM Formulas**	**Reported on Page Number**
Title, abstract, and keywords	1a	Identification as a randomized trial in the title	Statement of whether the trial targets a TCM Pattern, a Western medicine–defined disease, or a Western medicine–defined disease with a specific TCM Pattern, if applicable	2
	1b	Structured summary of trial design, methods, results, and conclusions	Illustration of the name and form of the formula used, and the TCM Pattern applied, if applicable	2-3
	1c		Determination of appropriate keywords, including "Chinese herbal medicine formula" and "randomized controlled trial"	3
Introduction				
Background and objectives	2a	Scientific background and explanation of rationale	*Statement with biomedical science approaches and/or TCM approaches*	3-4
	2b	Specific objectives or hypotheses	Statement of whether the formula targets a Western medicine–defined disease, a	4

			TCM Pattern, or a Western medicine–defined disease with a specific TCM Pattern	
Methods				
Trial design	3a	Description of trial design (such as parallel, factorial), including allocation ratio		8-9
	3b	Important changes to methods after trial commencement (such as eligibility criteria), with reasons		/
Participants	4a	Eligibility criteria for participants	Statement of whether participants with a specific TCM Pattern were recruited, in terms of 1) diagnostic criteria and 2) inclusion and exclusion criteria. All criteria used should be universally recognized, or reference given to where detailed explanation can be found.	4-6
	4b	Settings and locations where the data were collected		8
Interventions	5	The interventions for each group with sufficient details to allow replication, including how and when they were actually administered	5c. For patent proprietary CHM formulas 1. Reference to publicly available materials, such as pharmacopeia, for the details about the composition, dosage, efficacy, safety, and quality control of the formula 2. Illustration of the details of the formula, namely 1) the proprietary product name (i.e., brand name), 2) name of	5c:7 5d:7-8

			manufacturer, 3) lot number, 4) production date and expiry date, 5) name and percentage of added materials, and 6) whether any additional quality control measures were conducted 3. Statement of whether the patent proprietary formula used in the trial is for a condition that is identical to the publicly available reference 5d. Control groups Placebo control 1. Name and amount of each ingredient 2. Description of the similarity of placebo with the intervention (e.g., color, smell, taste, appearance, packaging) 3. Quality control and safety assessment, if any 4. Administration route, regimen, and dosage 5. Production information: where, when, how, and by whom the placebo was produced	
Outcomes	6a	Completely defined, prespecified primary and secondary outcome measures, including how and when they were assessed	Illustration of outcome measures with Pattern in detail	10-11
	6b	Any changes to trial outcomes after the trial commenced, with reasons		/
Sample size	7a	How sample size was determined		11-12

	7b	When applicable, explanation of any interim analyses and stopping guidelines		9
Randomization				
Sequence generation	8a	Method used to generate the random allocation sequence		9
	8b	Type of randomization; details of any restriction (such as blocking and block size)		9
Allocation concealment mechanism	9	Mechanism used to implement the random allocation sequence (such as sequentially numbered containers), describing any steps taken to conceal the sequence until interventions were assigned		9-10
Implement	10	Who generated the random allocation sequence, who enrolled participants, and who assigned participants to interventions		/

Blinding	11a	If done, who was blinded after assignment to interventions (for example, participants, care providers, those assessing outcomes) and how		9-10
	11b	If relevant, description of the similarity of interventions		7-8
Statistical methods	12a	Statistical methods used to compare groups for primary and secondary outcomes		11-12
	12b	Methods for additional analyses, such as subgroup analyses and adjusted analyses		/
Results				
Participant flow (a diagram is strongly recommended)	13a	For each group, the numbers of participants who were randomly assigned, received intended treatment, and were analyzed for the primary outcome		Figure 2
	13b	For each group, losses and exclusions after		12

		randomization, together with reasons		
Recruitment	14a	Dates defining the periods of recruitment and follow-up		Figure 1
	14b	Why the trial ended or was stopped		12
Baseline data	15	A table showing baseline demographic and clinical characteristics for each group		Table 1 Table 2
Numbers analyzed	16	For each group, number of participants (denominator) included in each analysis and whether the analysis was by original assigned groups		Figure 2
Outcomes and estimation	17a	For each primary and secondary outcome, results for each group, and the estimated effect size and its precision (such as 95% confidence interval)		13-14
	17b	For binary outcomes, presentation of both		/

		absolute and relative effect sizes is recommended		
Ancillary analyses	18	Results of any other analyses performed, including subgroup analyses and adjusted analyses, distinguishing prespecified from exploratory		/
Harms	19	All important harms or unintended effects in each group		14
Discussion				
Limitations	20	Trial limitations; addressing sources of potential bias; imprecision; and, if relevant, multiplicity of analyses		15
Generalizability	21	Generalizability (external validity, applicability) of the trial findings	*Discussion of how the formula works on different TCM* Patterns *or diseases*	14-15
Interpretation	22	Interpretation consistent with results, balancing benefits and harms, and considering other relevant evidence	*Interpretation with TCM theory*	14-15
Other				

information				
Registration	23	Registration number and name of trial registry		1
Protocol	24	Where the full trial protocol can be accessed, if available		1
Funding	25	Sources of funding and other support (such as supply of drugs), role of funders		1