

Supplementary Table 1 Rome III diagnostic criteria and TCM syndrome diagnostic criteria for FD

Rome diagnostic criteria	III	Must include one or more of the following: (1) Postprandial fullness (2) Early satiety (3) Epigastric pain (4) Epigastric burning And there is no evidence of organic disease that can explain the above symptoms. The symptoms must have occurred for at least 6 months before diagnosis, and the above criteria must have been met in the past 3 months.
		If the main symptoms are met and the secondary symptoms are ≥ 3, the corresponding syndrome type can be diagnosed by referring to the tongue and pulse: (1) Liver-stomach disharmony syndrome: Main symptoms: epigastric and abdominal fullness or distending pain. Secondary symptoms: chest distress, sighing, poor appetite, nausea, vomiting, belching. Tongue and pulse: light red or red tongue body, white tongue coating, wiry pulse. (2) spleen-stomach damp-heat syndrome: Main symptoms: epigastric and abdominal fullness or distending pain. Secondary symptoms: poor appetite, bitter taste in the mouth, nausea, vomiting, heavy body with fatigue, scanty yellow urine. Tongue and pulse: red tongue body, yellow greasy coating, slippery pulse (3) Food stagnation syndrome: Main symptoms: epigastric and abdominal fullness or distending pain. Secondary symptoms: poor appetite, nausea, vomiting, acid regurgitation, burp, difficult bowel movement Tongue and pulse: light red or red tongue body, thick greasy coating, wiry-slippery pulse
TCM syndrome diagnostic criteria		

Supplementary Table 2 Quantitative Standard Scoring Scale for Grading Major Symptoms in Western Medicine

Symptom	Classification	Score
Postprandial Fullness	Asymptomatic	0
	Symptoms are mild and do not affect daily life	1
	Symptoms are more obvious, but have no significant impact on daily life	2
	Symptoms persist and significantly affect daily life	3
Early Satiety	Asymptomatic	0
	Symptoms are mild and do not affect daily life	1
	Symptoms are more obvious, but have no significant impact on daily life	2
	Symptoms persist and significantly affect daily life	3
Epigastric Burning	Asymptomatic	0
	Symptoms are mild and do not affect daily life	1
	Symptoms are more obvious, but have no significant impact on daily life	2
	Symptoms persist and significantly affect daily life	3

Supplementary Table 3 Research centers and Subgroups

Testing Center	City/province	Center code	High-dose group	Medium-dose group	Low-dose group	Placebo group	Total (cases)
West China Hospital, Sichuan University	Chengdu/ Sichuan	01	17	17	17	17	68
Affiliated Hospital of Chengdu University of Traditional Chinese Medicine	Chengdu/ Sichuan	02	14	14	14	14	56
First Affiliated Hospital of Hunan University of Traditional Chinese Medicine	Changsha/ Hunan	03	18	18	18	18	72
Xiangya Hospital, Central South University	Changsha/ Hunan	04	0	0	0	0	0
Affiliated Hospital of Jiangxi University of Traditional Chinese Medicine	Nanchang/ Jiangxi	05	0	0	0	0	0
First Affiliated Hospital of Tianjin University of Traditional Chinese Medicine	Tianjin	06	12	12	12	12	48

Second Affiliated Hospital of Tianjin	Tianjin	07	6	5	6	6	23
University of Traditional Chinese Medicine							
Total (cases)			67	66	67	67	267

Text S1 Standard Operating Procedure (SOP) for Gastric Emptying Function Testing
Standard Operating Procedure (SOP) for Gastric Emptying Rate Testing Using Nuclear Imaging

Gastric Emptying Test Using Nuclear Imaging: This method uses nuclear imaging to measure solid gastric emptying function, assessing gastric emptying rate and gastric half-emptying time 2 hours post-meal

. Observations and recordings are made once before medication administration and once 28 days after medication administration.

1. Discontinue medications affecting gastrointestinal motility 7 days prior to the examination.
2. Fast after consuming easily digestible foods by 7 PM the day before the examination.
3. On the day of the examination, at 7 AM (after fasting for at least 8 hours), consume a standard meal (one fried egg labeled with ^{99m}Tc sulfur colloid at $200\ \mu\text{Ci}$, 100g of bread, 20g of vegetable oil, 200ml of milk, totaling 500 calories), and finish eating within 5 minutes.
4. Nuclear gastric emptying examination: Use a γ camera (Picker DC-4, USA) connected to a computer. The patient lies in a supine position, and the radioactive activity in the gastric region is measured immediately after the meal, every 15 minutes for the first hour, and every 30 minutes for the second hour up to 2 hours. The data is stored in the computer and processed using specialized software.
5. Observation indicators:
 - ① Gastric emptying rate (GE) 2 hours postprandial = $(100 - \text{amount of radioactive nuclide retained in the stomach}) \times 100\%$;
 - ② Gastric half-emptying time ($T_{1/2}$) = the time required for 50% of the radioactive nuclide in the stomach to be excreted.

Text S2 Data Management

1. Establishment of the Database

The original source of data was the medical record. Outpatient cases were required to have a separate research medical record for proper archiving. The case report form (CRF) was derived from the medical record and completed by the investigator. Each enrolled subject was required to have a completed research medical record and CRF. After all CRFs were reviewed by the clinical monitor, the first copies were submitted to the designated biostatistics unit for data entry and management, while the research medical records were retained at the research site for future reference.

Data entry and management were carried out by data administrators from the statistical unit. To ensure data accuracy, two data administrators were assigned to independently enter and verify the data. In the event of any queries arising from the CRFs, the data administrators completed a data query form and forwarded it to the investigator via the clinical monitor. Investigators were required to respond to the queries and return the form as promptly as possible. The data administrators then modified, confirmed, and entered the data according to the investigators' responses. Additional query forms were issued when further clarification was needed.

Once the blind review was completed and the accuracy of the database was confirmed, the clinical research leader, the sponsor, and the statistical analyst jointly locked the database. No changes to the data were permitted after the database was locked.

2. Unblinding and Data Processing

After data entry and database locking, the first unblinding was performed by the sponsor and the designated researcher responsible for maintaining the blinding codes. The database was then handed over to the statistical analyst for statistical analysis in accordance with the pre-specified statistical analysis plan. Following the completion of statistical analysis, the second unblinding was conducted by the sponsor and the clinical research leader. Finally, the statistical

analyst prepared the statistical analysis report, which was provided to the principal investigator for drafting the final clinical study report.

Supplementary Table 4 Analysis of adverse events in the two groups (SS)																					
SOC(PT)		High-dose group				Medium-dose group				Low-dose group				Placebo group				P			
																		value			
		N	n (%)	Mild	Moderate	Severe	N	n (%)	Mild	Moderate	Severe	N	n (%)	Mild	Moderate	Severe	N		n (%)	Mild	Moderate
All		45	5.97	4	0	0	14	6.06	4	0	0	0	0	0	0	6	7.46	4	0	1	P=0.122
Various tests		2	2.99	2	0	0	0	0	0	0	0	0	0	0	0	1	1.49	1	0	0	P=0.6208
Positive urine red blood cells		1	1.49	1	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	P=1.0000
Decreased blood glucose		1	1.49	1	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	P=1.0000
Decreased platelet count		0	0.00	0	0	0	0	0	0	0	0	0	0	0	0	1	1.49	1	0	0	P=1.0000

SOC(PT)	High-dose group				Medium-dose group				Low-dose group				Placebo group				P value				
	N	n (%)	Mild	Moderate	Severe	N	n (%)	Mild	Moderate	Severe	N	n (%)	Mild	Moderate	Severe						
Respiratory, thoracic, and mediastinal diseases	1	1(49)	1	0	0	5	3(55)	3	0	0	0	0(00)	0	0	0	1	1(49)	1	0	0	P=0.2301
Chronic bronchitis	1	1(49)	1	0	0	0	0(00)	0	0	0	0	0(00)	0	0	0	0	0(00)	0	0	0	P=1.0000
Cough	0	0(00)	0	0	0	3	3(55)	3	0	0	0	0(00)	0	0	0	1	1(49)	1	0	0	P=0.0590
Oropharyngeal pain	0	0(00)	0	0	0	2	2(03)	2	0	0	0	0(00)	0	0	0	0	0(00)	0	0	0	P=0.0604

																			P		
SOC(PT)	High-dose group				Medium-dose group				Low-dose group				Placebo group				value				
	N	n (%)	Mild	Moderate	Severe	N	n (%)	Mild	Moderate	Severe	N	n (%)	Mild	Moderate	Severe	N		n (%)	Mild	Moderate	Severe
Skin and subcutaneous diseases		1(1.49)	1	0	0		0(0.00)	0	0	0		0(0.00)	0	0	0		0(0.00)	0	0	0	P=1.000
	Acne	1(1.49)	1	0	0		0(0.00)	0	0	0		0(0.00)	0	0	0		0(0.00)	0	0	0	P=1.000
Systemic diseases and reactions at the administration site		1(1.49)	1	0	0		2(3.03)	2	0	0		0(0.00)	0	0	0		0(0.00)	0	0	0	P=0.1979
		1(1.49)	1	0	0		2(3.03)	2	0	0		0(0.00)	0	0	0		0(0.00)	0	0	0	P=0.1979

SOC(PT)	High-dose group				Medium-dose group				Low-dose group				Placebo group				P value				
	N	n (%)	Mild	Moderate	Severe	N	n (%)	Mild	Moderate	Severe	N	n (%)	Mild	Moderate	Severe						
Fatigue	1	1(49)	1	0	0	0	0(00)	0	0	0	0	0(00)	0	0	0	0	0(00)	0	0	0	P=1.000
Fever	0	0(00)	0	0	0	1	1(52)	1	0	0	0	0(00)	0	0	0	0	0(00)	0	0	0	P=0.2472
Pain	0	0(00)	0	0	0	1	1(52)	1	0	0	0	0(00)	0	0	0	0	0(00)	0	0	0	P=0.2472
Infections and infestations	0	0(00)	0	0	0	1	1(52)	1	0	0	0	0(00)	0	0	0	1	1(49)	1	0	0	P=0.6208
Rhinitis	0	0(00)	0	0	0	0	0(00)	0	0	0	0	0(00)	0	0	0	1	1(49)	1	0	0	P=1.000

SOC(PT)	High-dose group				Medium-dose group				Low-dose group				Placebo group				P value				
	N	n (%)	Mild	Moderate	Severe	N	n (%)	Mild	Moderate	Severe	N	n (%)	Mild	Moderate	Severe						
Upper																					
respiratory		0(0.					1(1.					0(0.				0(0.			P=0.2		
tract infection	0	00)	0	0	0	1	52)	1	0	0	0	00)	0	0	0	0	00)	0	0	0	472
Various																					
surgical																					
procedures																					
and medical		0(0.					0(0.					0(0.				1(1.			P=1.0		
interventions	0	00)	0	0	0	0	00)	0	0	0	0	00)	0	0	0	1	49)	1	0	0	000
Circumcision		0(0.					0(0.					0(0.				1(1.			P=1.0		
	0	00)	0	0	0	0	00)	0	0	0	0	00)	0	0	0	1	49)	1	0	0	000

																			P		
SOC(PT)	High-dose group				Medium-dose group				Low-dose group				Placebo group				value				
	N	n (%)	Mild	Moderate	Severe	N	n (%)	Mild	Moderate	Severe	N	n (%)	Mild	Moderate	Severe	N		n (%)	Mild	Moderate	Severe
Endocrine																					
system		0(0.					1(1.					0(0.					0(0.			P=0.2	
diseases	0	00)	0	0	0	1	52)	1	0	0	0	00)	0	0	0	0	00)	0	0	0	472
Thyroid		0(0.					1(1.					0(0.					0(0.			P=0.2	
swelling	0	00)	0	0	0	1	52)	1	0	0	0	00)	0	0	0	0	00)	0	0	0	472
Gastrointesti																					
nal system		0(0.					0(0.					0(0.					1(1.			P=1.0	
diseases	0	00)	0	0	0	0	00)	0	0	0	0	00)	0	0	0	2	49)	0	0	1	000
Reflux		0(0.					0(0.					0(0.					1(1.			P=1.0	
	0	00)	0	0	0	0	00)	0	0	0	0	00)	0	0	0	1	49)	0	0	1	000
Upper																					
abdominal		0(0.					0(0.					0(0.					1(1.			P=1.0	
pain	0	00)	0	0	0	0	00)	0	0	0	0	00)	0	0	0	1	49)	0	0	1	000

SOC(PT)	High-dose group				Medium-dose group				Low-dose group				Placebo group				P value	
	N	n (%)	Mild	Moderate	Severe	N	n (%)	Mild	Moderate	Severe	N	n (%)	Mild	Moderate	Severe			
Blood and lymphatic system diseases		0(0.00)	0	0	0	1(1.52)	1	0	0	0(0.00)	0	0	0	0(0.00)	0	0	0	P=0.2472
Lymphadenitis		0(0.00)	0	0	0	1(1.52)	1	0	0	0(0.00)	0	0	0	0(0.00)	0	0	0	P=0.2472

SOC: System Organ Class; PT: Preferred Term.