CONSORT 2025 Checklist

Section/topic	No	Item description	Reported on Page/Line	Reported on Section/Paragraph
Title and abstract				
Title and structured abstract	1a	Identification as a randomised trial	Title, Abstract	Abstract; Title: *A clinical study on the efficacy of rectal administration of Tongfu Qinghua decoction combined with external application of Ruyi Jinhuang powder in treating acute pancreatitis*
	1b	Structured summary of trial design, methods, results, and conclusions	Abstract	Abstract (Background, Objectives, Methods, Results, Conclusion)
Open science				
Trial registration	2	Name of trial registry, identifying number (with URL) and date of registration	Trial registration	NCT07712081
Protocol and statistical analysis plan	3	Where the trial protocol and statistical analysis plan can be accessed	Not mentioned	Not reported
Data sharing	4	Where and how the individual de-identified participant data (including data dictionary), statistical code and any other materials can be accessed	Data availability statement	Data availability statement: datasets available from the corresponding author on request
Funding and conflicts of interest				
	5a	Sources of funding and other support (eg, supply of drugs), and role of funders in the design, conduct, analysis and reporting of the trial	Funding	Funding: supported by Wenzhou Traditional Wenzhou Traditional Chinese Medicine (TCM) and Health Science Research Project (No.: Z2023005).
	5b	Financial and other conflicts of interest of the manuscript authors	Conflict of interest	Conflict of interest: authors declare no conflict of interest
Introduction				
Background and rationale	6	Scientific background and rationale	INTRODUCTION	INTRODUCTION: background of acute pancreatitis, limitations of Western medicine, rationale for Tongfu Qinghua decoction enema + Ruyi

				Jinhuang powder external application
Objectives	7	Specific objectives related to benefits and harms	INTRODUCTIO N (last paragraph)	INTRODUCTION: to investigate clinical efficacy and safety of combined therapy as adjunct to standard treatment for acute pancreatitis
Methods				
Patient and public involvement	8	Details of patient or public involvement in the design, conduct and reporting of the trial	Trial registration	NCT07712081
Trial design	9	Description of trial design including type of trial (eg, parallel group, crossover), allocation ratio, and framework (eg, superiority, equivalence, non-inferiority, exploratory)	MATERIALS AND METHODS > General information	MATERIALS AND METHODS: single-center, prospective, randomised controlled, parallel-group, Phase II trial; 1:1 allocation
Changes to trial protocol	10	Important changes to the trial after it commenced including any outcomes or analyses that were not prespecified, with reason	Not mentioned	Not reported
Trial setting	11	Settings (eg, community, hospital) and locations (eg, countries, sites) where the trial was conducted	MATERIALS AND METHODS > General information	MATERIALS AND METHODS: Third Affiliated Hospital of Wenzhou Medical University, Hepatobiliary Surgery and Gastroenterology Departments; October 2023–August 2025
Eligibility criteria	12a	Eligibility criteria for participants	Inclusion and exclusion criteria	Inclusion criteria: acute pancreatitis diagnosis, age 18–75 years, first onset, informed consent; Exclusion criteria: surgical indication, severe gastrointestinal disorders, organ dysfunction, pregnancy/lactation, mental illness, enema contraindications
	12b	If applicable, eligibility criteria for sites and for individuals delivering the interventions (eg, surgeons, physiotherapists)	Not mentioned	Not reported
Intervention and	13	Intervention and	Method	Method: Control = conventional

comparator		comparator with sufficient details to allow replication. If relevant, where additional materials describing the intervention and comparator (eg, intervention manual) can be accessed		Western medicine (fasting, decompression, fluid resuscitation, enzyme inhibition, anti-infection, analgesia); Observation = conventional Western + Tongfu Qinghua decoction enema (full prescription, 200 mL, 38–40℃, left lateral, 15–20 cm insertion, retain 30 min, once daily × 5 days) + Ruyi Jinhuang powder external application (paste, Shenque point, twice daily × 4 h)
Outcomes	14	Prespecified primary and secondary outcomes, including the specific measurement variable (eg, systolic blood pressure), analysis metric (eg, change from baseline, final value, time to event), method of aggregation (eg, median, proportion), and time point for each outcome	Observation indicators	Observation indicators: (1) hospital stay and symptom relief time; (2) serum amylase (AMY), urine amylase (UAMY); (3) C-reactive protein (CRP), procalcitonin (PCT); (4) overall clinical efficacy; (5) adverse reactions; (6) age-stratified subgroup analyses
Harms	15	How harms were defined and assessed (eg, systematically, non-systematically)	Observation indicators (5)	Observation indicators (5): passive reporting + active follow-up (treatment days 1/3/5, discharge, 7 days post-discharge); AE/SAE defined, recorded in eCRF, reported per hospital procedures
Sample size	16a	How sample size was determined, including all assumptions supporting the sample size calculation	General information	General information: PASS 20.0; control efficacy 60%, observation 85%; α=0.05, β=0.20; 47 per group + 6% loss → 50 per group, total 100
	16b	Explanation of any interim analyses and stopping guidelines	Not mentioned	Not reported
Randomisation:				
Sequence generation	17a	Who generated the random allocation sequence and the method used	General information	General information: two independent statisticians; SPSS 24.0 random number table
	17b	Type of randomisation and details of any restriction (eg,	General information	General information: simple randomisation; no stratification or blocking reported

		stratification, blocking and block size)		
Allocation concealment mechanism	18	Mechanism used to implement the random allocation sequence (eg, central computer/telephone; sequentially numbered, opaque, sealed containers), describing any steps to conceal the sequence until interventions were assigned	General information	General information: sequentially numbered, opaque, sealed envelopes; opened sequentially after informed consent
Implementation	19	Whether the personnel who enrolled and those who assigned participants to the interventions had access to the random allocation sequence	General information	General information: investigator opened envelopes; sequence concealed
Blinding	20a	Who was blinded after assignment to interventions (eg, participants, care providers, outcome assessors, data analysts)	Outcome assessment implementation and bias control	Outcome assessment: outcome assessors not fully blinded
	20b	If blinded, how blinding was achieved and description of the similarity of interventions	Outcome assessment implementation and bias control	Outcome assessment: non-blinded due to intervention nature; no sham intervention
Statistical methods	21a	Statistical methods used to compare groups for primary and secondary outcomes, including harms	Statistical analysis	Statistical analysis: independent samples t-test, paired t-test, χ^2 test, Fisher's exact test; $P<0.05$ significant
	21b	Definition of who is included in each analysis (eg, all randomised participants), and in which group	Statistical analysis	Statistical analysis: all randomised participants analysed in assigned group
	21c	How missing data were handled in the analysis	Not mentioned	Not reported
	21d	Methods for any additional analyses (eg,	Observation indicators (6);	Observation indicators (6): prespecified age-stratified subgroups (18–40, 41–60,

		subgroup and sensitivity analyses), distinguishing prespecified from post hoc	Results	61–75 years)
Results				
Participant flow, including flow diagram	22a	For each group, the numbers of participants who were randomly assigned, received intended intervention, and were analysed for the primary outcome	General information; Results	General information: 100 randomised (50 control, 50 observation); Results: all received assigned intervention and analysed
	22b	Losses and exclusions after randomisation, together with reasons	Not mentioned	No losses/exclusions reported
Recruitment	23a	Dates defining the periods of recruitment and follow-up for outcomes of benefits and harms	General information	General information: recruitment October 2023–August 2025
	23b	If relevant, why the trial ended or was stopped	Not mentioned	Completed as planned
Intervention and comparator delivery	24a	Intervention and comparator as they were actually administered (eg, where appropriate, who delivered the intervention/comparator, how participants adhered, whether they were delivered as intended (fidelity))	Method; Results	Method: 5-day treatment course; Results: all participants completed assigned treatment
	24b	Concomitant care received during the trial for each group	Method	Method: identical routine symptomatic treatment for both groups
Baseline data	25	A table showing baseline demographic and clinical characteristics for each group	Table 1	Table 1: gender, age, disease course, aetiology, comorbidities, long-term medication
Numbers analysed, outcomes and estimation	26	For each primary and secondary outcome, by group: ● the number of participants included in the analysis ● the number of participants with available data at the	Tables 2–5	Table 2: hospital stay and symptom relief time; Table 3: AMY/UAMY; Table 4: CRP/PCT; Table 5: overall efficacy; P-values reported

		outcome time point ● result for each group, and the estimated effect size and its precision (such as 95% confidence interval) ● for binary outcomes, presentation of both absolute and relative effect size		
Harms	27	All harms or unintended events in each group	Table 6	Table 6: gastrointestinal discomfort, rash; control 2/50, observation 3/50; *P*=0.582
Ancillary analyses	28	Any other analyses performed, including subgroup and sensitivity analyses, distinguishing pre-specified from post hoc	Tables 7–11	Tables 7–11: prespecified age-subgroup analyses of efficacy and adverse reactions
Discussion				
Interpretation	29	Interpretation consistent with results, balancing benefits and harms, and considering other relevant evidence	DISCUSSION	DISCUSSION: combined therapy accelerates symptom relief and gastrointestinal recovery, improves pancreatic and inflammatory markers, safe overall; elderly subgroup shows biochemical benefit but less clinical improvement
Limitations	30	Trial limitations, addressing sources of potential bias, imprecision, generalisability, and, if relevant, multiplicity of analyses	DISCUSSION (last paragraph)	DISCUSSION: single-center, relatively small sample size, no long-term follow-up, no oxidative stress/intestinal barrier/gut microbiota markers, non-blinded design