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Meta-analysis of Shengyang Yiwei Decoction as The Main Intervention in The Treatment of Diarrhea-Predominant Irritable Bowel Syndrome

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Abstract: *OBJECTIVE: To investigate the efficacy and safety of Shengyang Yiwei Decoction as the main intervention in the treatment of diarrhea-predominant irritable bowel syndrome (IBS-D), and to provide evidence for its clinical application. METHODS: Randomized controlled trials (RCTs) of Shengyang Yiwei Decoction in The treatment of IBS-D were searched from CNKI, Wanfang database, PubMed, The Cochrane Library and VIP database from the establishment of these databases to June 10, 2020. The Cochrane risk bias tool in the Cochrane manual was used to evaluate the literature quality. Meta-analysis was performed using RevMan5.3 software. Results: A total of 16 RCTs were included, involving 1244 patients. Meta-analysis results showed that: Total effective rate (N =1204, OR=3.38, 95%CI [2.43, 4.71], P < 0.00001), abdominal pain score after treatment (n= 444, MD=-0.25, 95%CI [-0.31, -0.19], P < 0.00001), diarrhea score after treatment (n=292, MD=-0.99, 95%CI [-1.25, -0.73], P < 0.00001), abdominal distension score after treatment (n=284, MD=-0.42, 95%CI [-0.54, -0.30], P < 0.00001) and stool traits score after treatment (n=348, MD=-0.40, 95%CI [-0.50, -0.30], P < 0.00001) were better than the control group. Conclusion: The experimental group is superior to the control group in improving clinical diagnosis and treatment efficiency and symptom score.*

Keywords: *Shengyang Yiwei Decoction, Diarrhea-predominant irritable bowel syndrome, Meta analysis, Irritable bowel syndrome*

1. Introduction

Irritable bowel syndrome (IBS) is characterized by chronic, recurrent abdominal pain or discomfort, abnormal bowel movements and changes in bowel habits, and the lack of morphological and biochemical abnormalities [1] to explain the symptoms. According to the characteristics of stool, IBS is divided into four clinical types: IBS with diarrhea (IBS-D), IBS with constipation (IBS-C), IBS with a mixed pattern of constipation and diarrhea (IBS-M) and IBS with unshaped (IBS-U), IBS with diarrhea (IBS-D) is more common in China [2]. IBS is the result of the interaction of social, physiological and psychological factors, the prevention and treatment of such diseases need to consider a variety of factors. There are a variety of drugs for the treatment of IBS, all of which have good efficacy, but cannot be used for a long time due to contraindications or adverse reactions [3]. In recent years, TCM has shown unique advantages in the treatment of IBS. The application of TCM has improved the clinical symptoms of patients, improved the quality of life of patients and reduced the recurrence rate. Compared with western medicine, TCM has better treatment effect, less toxic side effects and better compliance of patients [4]. This study evaluated the effectiveness and safety of Shengyang Yiwei Decoction in the treatment of IBS-D by collecting the clinical observation of shengyang Yiwei Decoction or combined with other therapies, and provided evidence for its clinical application.

2. Literature and method

2.1 Criteria for inclusion and exclusion of literature

2.1.1 Inclusion criteria

① All randomized controlled trials with Shengyang Yiwei Decoction as the main intervention in the treatment of IBS-D. ② Subjects of the study were patients who were clearly diagnosed as diarrhea-

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predominant irritable bowel syndrome. ③ Intervention measures: Shengyang Yiwei decoction was mainly used in the experimental group (including Shengyang Yiwei Decoction, shengyang Yiwei decoction plus or minus, Shengyang Yiwei Decoction combined with other therapies); The control group was treated with western medicine or Chinese patent medicine. (4) Outcome indicators: overall clinical efficacy, evaluation of symptoms scores such as abdominal pain, abdominal distension, diarrhea and stool traits after intervention.

2.1.2 Exclusion criteria

①Non-IBS-D randomized controlled trials, such as clinical review, case reports, animal studies, etc. ② Other types of IBS were diagnosed, such as IBS-D,IBS-M and IBS-U; ③ Efficacy indicators did not meet the requirements of inclusion criteria,such as incomplete experimental data, or self-controlled or non-controlled studies.

2.2 Literature retrieval strategy

All RCTs related to the treatment of IBS-D by Shengyang Yiwei Decoction were searched in CNKI, Wanfang Database, PubMed, The Cochrane Library, VIP database and other databases. The search period was since the establishment of the database to June 10, 2020. The search terms were: Irritable bowel Syndrome, Diarrhea-predominant Irritable Bowel syndrome, Shineyang Yiwei Decoction, and so on. The method of "subject words + free words" was used for retrieval, and all eligible randomized controlled experiments were collected.

2.3 Literature screening and data extraction

Two evaluators will screen the literature according to the inclusion and exclusion criteria respectively, and collect the data needed in the qualified literature. Finally, two evaluators will check the results, and if there is any disagreement, the third evaluator will participate in the discussion and decision.

2.4 Quality evaluation of literature

The assessment was based on the Cochrane Collaboration's risk bias assessment tool, including: ① Random sequence generation; ② Allocation concealment; ③ Blinding of participants and personnel; (4) Blinding of outcome assessment; (5) Incomplete outcome data; ⑥ Selective reporting; ⑦ Other bias. Each item is rated as "high risk", "unclear risk" and "low risk".

2.5 Statistical processing

Meta-analysis was performed using RevMan5.3 software provided by the Cochrane collaboration. Odds ratio (OR) and 95% confidence interval (CI) were used as the effect size for counting data, and mean difference (MD) and 95%CI were used as the effect size for continuous variable data. If the heterogeneity of each group was small ($P \geq 0.1$, $I^2 < 50\%$), the fixed-effect model was adopted. If the heterogeneity of each group was large ($P < 0.1$, $I^2 \geq 50\%$), the source of heterogeneity was analyzed first; if the cause of heterogeneity was not found, the random effect model was used. Funnel plot analysis was performed to determine whether there was potential publication bias.

3. Conclusion

3.1 Literature search results

See Figure 1 and Table 1. A total of 156 articles were retrieved from the literature, 48 duplicate documents were excluded, 67 articles were excluded from the reading titles and abstracts, and 16 articles [5,6,7,8,9,10,11,12,13,14,15,16,17,18,19,20]of the literature that met the requirements were finally included, with a total of 1244 patients.

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Table 1: Basic information of included literature

research	Sample size (n/male/female)		Age (years, x±s)		interventions		Course
	Experimental group	Control group	Experimental group	Control group	Experimental group	Control group	
Fan JianWei 2009	68/32/36	60/27/33	43.6±6.9	41.5±6.37	Shengyang Yiwei Decoction increase or decrease combined Shenque acupoint application therapy	Pivromamine+ Gluvisu or+ Domperidone + imodium	four weeks
Zou ShiChang 2009	52/35/26	30/17/13	39.8±10.8	40.2±9.8	Shengyang Yiwei Decoction increase or decrease	four weeks	four weeks
Fan JianWei 2011	40/23/17	40/22/18	42.6±6.28	41.8±6.37	Shengyang Yiwei Decoction increase or decrease	pinaverium bromide	four weeks
Ge YanLiang 2011	20	20	-		Shengyang Yiwei Decoction	Trimebutine + B.licheniformis	four weeks
Fan JianWei 2012	40	40	-		Shengyang Yiwei Decoction increase or decrease	pinaverium bromide	four weeks
Wang Cong 2012	48/19/29	44/20/24			Shengyang Yiwei Decoction increase or decrease + trimebutine maleate tablets	trimebutine maleate tablets	four weeks
Cao Yang 2014	31/13/17	31/14/16	39.67±8.98	40.43±9.68	Shengyang Yiwei Decoction increase or decrease	trimebutine maleate tablets	two weeks
Liu Qian 2015	80/38/42	80/36/44	39.69±16.70	42.57±12.17	Shengyang Yiwei Decoction increase or decrease	trimebutine maleate tablets + Bacillus coagulans tablets	four weeks
Liu Feng 2015	25/16/9	25/15/10	35.1±5.7	34.9±6.4	Shengyang Yiwei Decoction increase or decrease	Smecta	eight weeks
Yang Peng 2016	30	30	19±65		Shengyang Yiwei Decoction increase or decrease	Pinaverium bromide+ Montmorillonite powder	four weeks
Gong XuHeng 2016	20	20	43.5±5.3	46.2±4.7	Shengyang Yiwei Decoction Combined acupuncture treatment	otilonium bromide	four weeks
Shao YanFeng 2017	34	34	36±17		Shengyang Yiwei Decoction increase or decrease combined fluorine ton of merritusin	Pinaveriumbromide+Montmorillonite powder+bifidobacterium	four weeks
Huang XuDong 2017	52	52	-		Shengyang Yiwei Decoction increase or decrease	trimebutine maleate tablets	four weeks
Xie XiaoFeng 2017	39/22/17	39/21/18	35.06±9.25	34.36±9.65	Shengyang Yiwei Decoction increase or decrease combined Shenque acupoint application therap	Medilac-S	A month
Zhang XiYan 2018	30/17/13	30/14/16	-		Shengyang Yiwei Decoction increase or decrease	Bupiyichangwan	four weeks
Liang ZhiTao 2018	30	30	-		Shengyang Yiwei Decoction increase	trimebutine maleate tablets	two weeks

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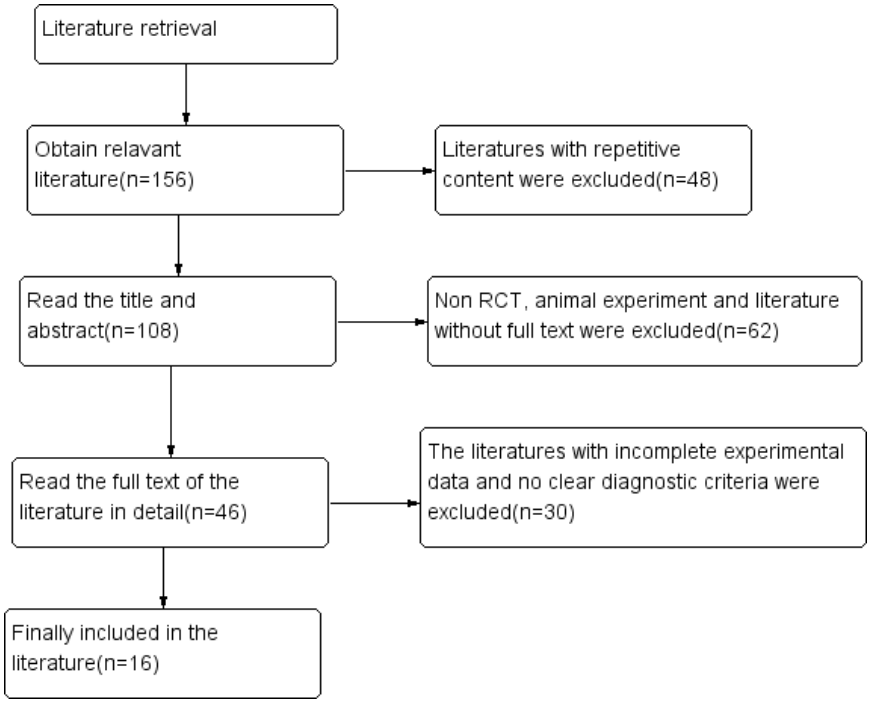

Figure 1: Literature Retrieval Flowchart

3.2 The basic information of the literature and the quality evaluation of the included research methodology

A total of 1244 patients were included in the 16 RCT literatures, involving 639 patients in the experimental group and 605 patients in the control group. The basic information of the included studies is shown in Table 1. Among them, random number table method was used in 4 studies, draw lots was used in 1 study, single-double order was used in 1 study, and random method was not mentioned in the other 10 studies. None of the studies specifically mentioned blindness; None of the studies clearly demonstrated the use of allocation hiding; Withdrawal and loss of follow-up were mentioned in three studies; Three studies may have selective reporting results; It is not clear whether there is any other bias. The bias risk assessment results of the included studies are shown in Figure 2 and Figure 3.

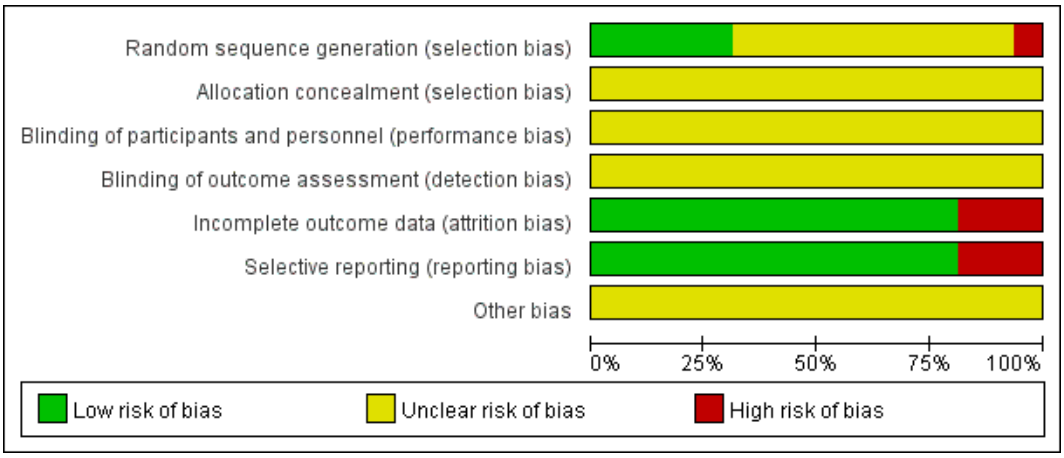

Figure 2: Bias risk percentage chart

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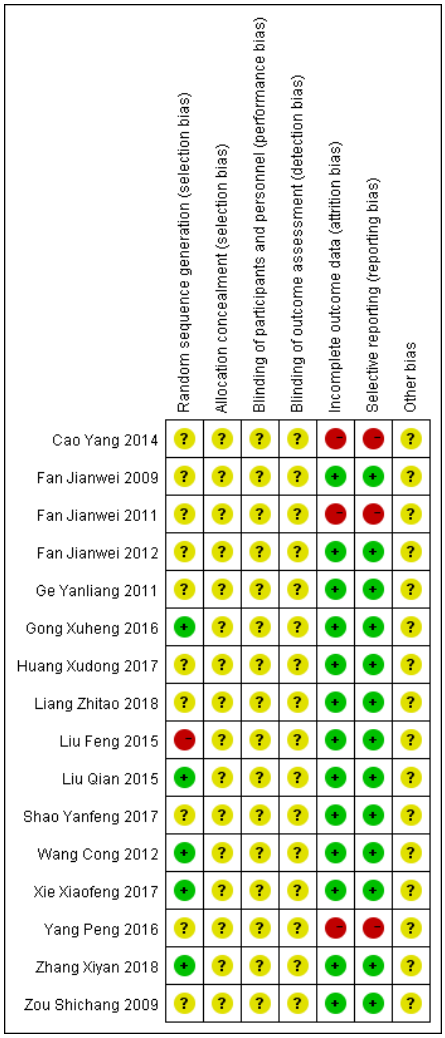

Figure 3: A summary of bias risk

3.3 Meta analysis results

3.3.1 The total effective rate of clinical efficacy

As shown in figure 4.A total of 15[5,6,7,9,10,11,12,13,14,15,16,17,18,19,20] studies were included, heterogeneity test analysis showed (P = 0.95, I^2 = 0%), the fixed effects model is adopted. Meta-analysis results showed that the difference was statistically significant (OR=3.38, 95%CI [2.43, 4.71], P < 0.00001), suggesting that the experimental group is superior to the control group in the total effective rate of clinical efficacy.

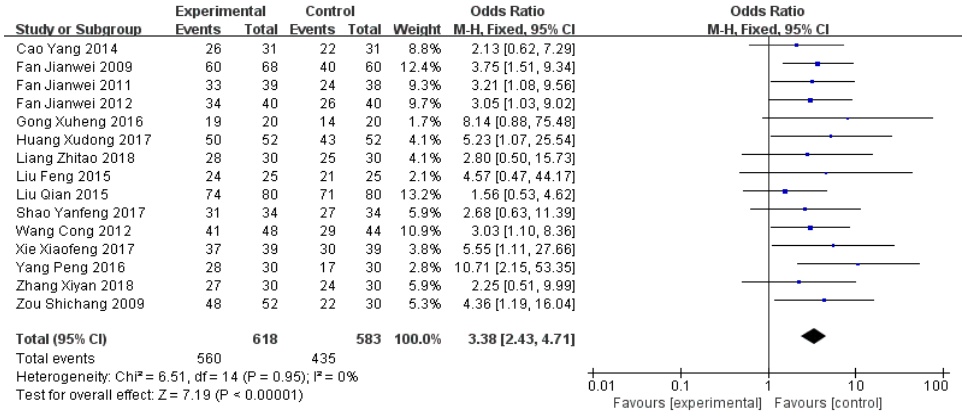

Figure 4: Total effective rate of clinical efficacy

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3.3.2 Abdominal pain score

As shown in figure 5. A total of 7[7,8,10,11,13,19,20] studies were included, and the heterogeneity test analysis showed (P=0.64, I2=0%), so the fixed-effect model was adopted. Meta-analysis results showed that the difference was statistically significant (MD=-0.25, 95%CI [-0.31, -0.19], P < 0.00001), suggesting that the experimental group was superior to the control group in the improvement of abdominal pain.

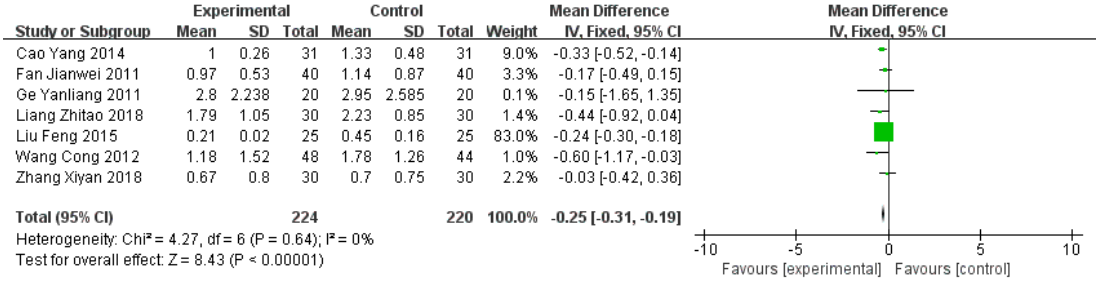

Figure 5: Abdominal pain score forest plot

3.3.3 Diarrhea score

As shown in figure 6. A total of 4[10,11,18,20] studies were included, and the heterogeneity test analysis showed (P=0.45, I2=0%), so the fixed-effect model was adopted. Meta-analysis results showed that the difference was statistically significant (MD=-0.99, 95%CI [-1.25, -0.73], P < 0.00001), suggesting that the experimental group was better than the control group in improving diarrhea.

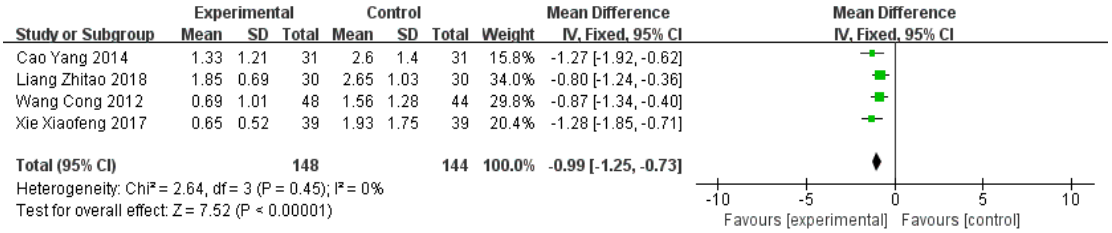

Figure 6: Diarrhea score forest plot

3.3.4 Abdominal distention score

As shown in figure 7. A total of 4[6,10,13,19] studies were included, and the heterogeneity test analysis showed (P=0.45, I2=0%), so the fixed-effect model was adopted. Meta-analysis results showed that the difference was statistically significant (MD=-0.42, 95%CI [-0.54, -0.30], P < 0.00001), suggesting that the experimental group was better than the control group in improving abdominal distention.

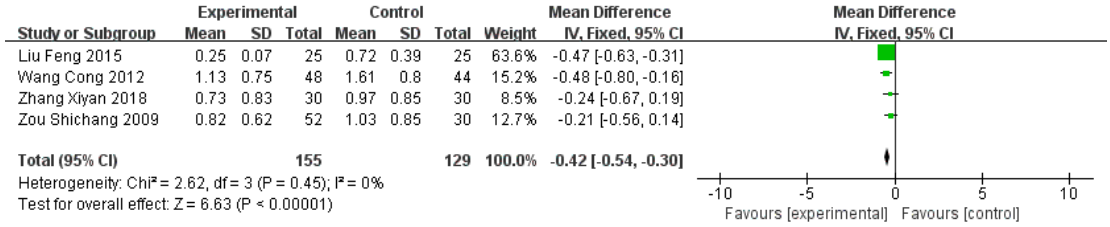

Figure 7: Abdominal distention score forest plot

3.3.5 Stool traits score

As shown in figure 8. A total of 4[12,13,18,19] studies were included, and the heterogeneity test analysis showed (P=0.50, I2=0%), so the fixed-effect model was adopted. Meta-analysis results showed that the difference was statistically significant (MD=-0.40, 95%CI [-0.50, -0.30], P < 0.00001), suggesting that the experimental group was better than the control group in improving stool traits.

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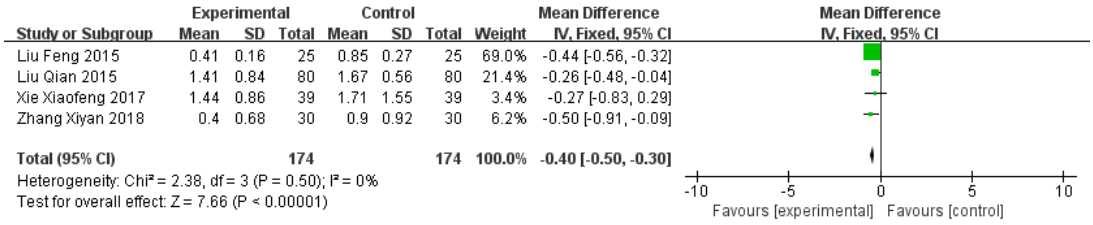

Figure 8: Stool traits score forest plot

3.3.6 Reporting bias analysis

As shown in figure 9. Participants included 15[5,6,7,9,10,11,12,13,14,15,16,17,18,19,20] study, clinical curative effect the outcome indexes for publication bias analysis, graphical distribution of symmetry, suggest there is a publication bias, may be related to the research into the literature of fewer samples, quality is low.

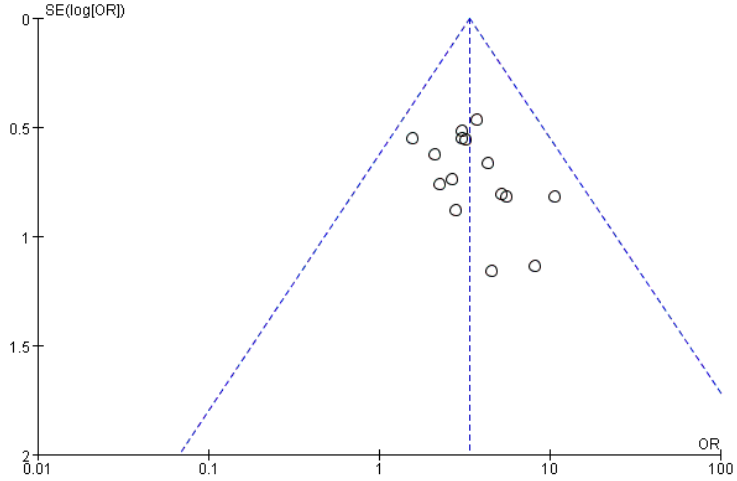

Figure 9: Funnel polt of clinical efficacy

4. Discussion

At present, the pathogenesis of IBS is not clear, but some studies suggest that the disease is related to genetic factors, dietary factors, gastrointestinal motility abnormalities, visceral hypersensitivity, brain-intestinal axis regulation abnormalities, intestinal infection and immune factors, psychological factors and intestinal microbiota [21]. When western medicine treats IBS-D, antidiarrheal drugs and drugs regulating intestinal flora are mainly used for symptomatic treatment, and the treatment method is single and easy to relapse. Starting from the overall concept of TCM, according to the different symptoms and signs of different patients, through TCM syndrome differentiation, individualized treatment, so as to achieve the effect of treating both symptoms and root causes, regulating Yin and Yang.

This study results from the study, said the experimental group's treatment efficiency is significantly higher than the control group, experimental group patients the symptoms score was significantly decreased, the integral and significantly lower than control group in all kinds of symptoms, shows that with Shengyang Yiwei decoction as the main intervention treatment of IBS-D can obviously improve the patients' clinical symptoms, improve quality of life. However, due to the small number of studies included in this study, and the small sample size and low quality of some included studies, in order to prove its clinical superiority, more randomized controlled trials with large sample size and high quality should be included in order to add strong evidence that TCM can better guide clinical practice.

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