

## **Chemotherapy-Induced Diarrhea Evaluation Table 2023: Traditional Chinese Medicine**

## Systematic Review

Citation	Design/Method Sample/Setting	Variables and Intervention	Outcome Measures	Results/Analysis	Limitations	Quality and Nursing Implications
Chen G. (2018). Effects of Shenfu injection on chemotherapy- induced adverse effects and quality of life in patients with advanced non- small cell lung cancer: A systematic review and meta-analysis. <i>Journal of Cancer</i> <i>Research and</i> <i>Therapeutics</i> , <i>14</i> ,(Supplement), S549–S555. https://doi.org/10.4 <u>103/0973-</u> <u>1482.187299</u>	Design: Systematic review and meta-analysis Method: Preferred Reporting Items for Systematic Reviews and Meta-analyses (PRISMA). A search of Cochrane Library, PubMed®, Embase®, CNKI, Chinese Biomedical Database, VIP Chinese Science Journals Database, and Wanfang Database, and Wanfang Database for randomized controlled trials comparing chemotherapy alone to chemotherapy with Shenfu injection (SFI). Data extraction and quality assessment completed. Sample: Sixteen randomized controlled trials with a total of 948 participants with lung cancer Setting: Patients in active anticancer treatment with chemotherapy in the adjuvant setting for non- small cell lung cancer (NSCLC).	Independent Variable(s): Chemotherapy plus SFI 50 mg to 100 mg used at the start of chemotherapy Dependent Variable(s): World Health Organization (WHO) Hematologic Toxicity, Karnofsky Performance Status score, and grading of diarrhea Intervention: Shenfu is a product of Traditional Chinese Medicine (TCM) that contains ginseng and black aconite. Participants received injections of 50 mg to 100 mg at the start of chemotherapy.	Effects of SFI on chemotherapy- induced side effects for patients with NSCLC. Unclear symptom grading scale used. WHO Hematologic Toxicity Karnofsky Performance Status score	Five trials reported grades 3 and 4 chemotherapy- induced diarrhea results. SFI plus chemotherapy was associated with significantly lower risk of diarrhea when compared with chemotherapy alone (risk ratio (RR) 0.21, 95% CI [0.07, 0.63]).	Authors note risk of publication bias The meta-analysis for diarrhea outcome only includes 2 trials. Chemotherapy regimens varied in trials and included: cisplatin/vinorelbine, cisplatin/gemcitabine, and cisplatin/docetaxel Studies were classified as low-quality, with unclear risk of bias.	Studies were classified as low quality, with unclear risk of bias limiting the reliability of the results. Only 2 studies within the meta- analysis focused on the outcome of diarrhea. SFI had favorable results on diarrhea risk when administered with chemotherapy compared with chemotherapy alone.

McCulloch, M., Ly, H., Broffman, M., See, C., Clemons, J., & Chang, R. (2016). Chinese herbal medicine and fluorouracil- based chemotherapy for colorectal cancer: A quality-adjusted meta-analysis of randomized controlled trials. <i>Integrative Cancer</i> <i>Therapies</i> , <i>15</i> (3), 285–307. https://doi.org/10.1 177/153473541663 8738	<ul> <li>meta-analysis</li> <li>meta-analysis</li> <li>Method: Preferred</li> <li>Reporting Items for</li> <li>Systematic Reviews and</li> <li>Meta-analyses (PRISMA).</li> <li>Database search of</li> <li>TCMLARS, PubMed<sup>®</sup>, and</li> <li>Cochrane Library. Data</li> <li>extraction and quality</li> <li>assessment using</li> <li>Cochrane Risk of Bias</li> <li>criteria.</li> <li>Sample: For the 3 studies</li> <li>that qualified with low risk</li> <li>of bias, 268 patients. For</li> </ul>	Independent Variable(s): Chinese Herbal Medicine plus 5-FU chemotherapy versus 5-FU chemotherapy alone Dependent Variable(s): Diarrhea, neurological toxicity, white blood cell toxicity, white blood cell toxicity, platelet toxicity, vomiting, tumor response; survival; performance status Intervention: Use of Chinese Herbal Medicine plus 5-FU chemotherapy compared with 5-FU chemotherapy alone	WHO scale for diarrhea WHO scale for neurologic toxicity, WBC toxicity, platelet toxicity, and vomiting Tumor response— partial or complete Survival outcomes Karnofsky Performance Status score	Diarrhea was reduced by 57% in the intervention group though this was not statistically significant (RR = 0.43; 95% CI [0.19, 1.01]; p = 0.05; l <sup>2</sup> = 0%) Reduction of neurological toxicity was not statistically significant (p = 0.27). Reduction of platelet toxicity was not statistically significant (p = 0.64). Reduction of vomiting toxicity was not statistically significant (p = 0.64). There was a 66% reduction of WBC toxicity which was statistically significant (p < 0.01). Reduction in tumor response was not statistically significant (p = 0.38).	Only two studies were reported that had low risk of bias.	A subgroup analysis of studies with low risk of bias in this meta-analysis do not support the use of Chinese herbal medicine with 5-FU therapy among patients with CRC to decrease the toxicity of chemotherapy. Studies supporting the use of Chinese herbal medicine with 5-FU therapies among CRC patients, appear to have a high risk of bias and should be interpreted with caution.
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Yang, J., Zhu, X.,	Design: Meta-analysis	Independent	QOL	QOL: Odds ratio (OR) =	Potential bias and	The methodology was valid.
Yuan, P., Liu, J.,	•	Variable(s): Traditional		2.79, 95% CI [1.87, 4.16];	exaggeration of the efficacy	Results of the study were
Wang, B., & Wang,	Method: Database search	Chinese medicine	KPS	p < 0.00001	of the treatment group as	reliable because of use of
G. (2020). Efficacy	China	(TCM)			not all trials elaborated how	meta-analysis of high quality
of traditional	National Knowledge	( - )	Efficacy	Clinical efficacy: OR =	they handled concealment	randomized controlled trials.
Chinese Medicine	Infrastructure (CNKI)	Dependent		2.88, 95% CI [2.32, 3.58];	and blinding	
combined with	database,	Variable(s):	ADRs	p < 0.00001	a	Although the articles report
chemotherapy in	Wanfang Database,	Quality of Life	/ 121 10	P 0.00001	Low sample sizes	that TCM combined with
patients with non-	PubMed <sup>®</sup> , Baidu Academic	(QOL), Karnofsky		KPS score: OR = 2.88,	Low campio cizeo	chemotherapy can improve
small cell lung	for randomized controlled	Performance Status		95% CI [1.79, 4.62]; p <	Studies were only	clinical efficacy, Karnofsky
cancer (NSCLC): A	trials comparing Traditional	(KPS), efficacy,		0.0001	conducted in China: which	Performance Status score, and
meta-analysis of	Chinese Medicine and	adverse drug reactions		0.0001	may make results non-	QOL, and reduce ADRs,
randomized clinical	chemotherapy with	(ADRs)		Diarrhea results were	generalizable and complex	descriptions of TCM
trials. Supportive	chemotherapy alone in	(ADI(3)		reported in 3 studies (n =	ingredients in intervention	interventions were not included
Care in Cancer,	patients with NSCLC from	Intervention: Yigi		168 in the intervention	not easily feasible.	and it is therefore uncertain
28(8), 3571–3579.	January 2005 to October	yangyin huatan jiedu		group and n = 159 in the	not easily leasible.	whether interventions would be
20(0), 3571–3579. https://doi.org/10.1	2019. Data extraction and	recipe, bufei xiaoji		control group): OR = 0.21,	Possible publication bias	feasible for the nursing/care
007/s00520-020-	quality assessment of	recipe, jianpi		95% CI [0.12, 0.37]; p <	Possible publication bias	team to offer.
<u>05433-w</u>	studies were done by dual	yishen recipe, yiqi		$0.00001, l^2 = 0\%$		
<u>05455-w</u>				0.00001, 1 = 0.000		
	investigators.	fuzheng recipe, yiwen				
	Sample: 20 RCTs	yang recipe, buqi jianpi xuan fei llitan		Leukopenia: OR = 0.21,		
				95% CI [0.12, 0.37]; p <		
	representing 1669 cases	recipe, ziyin runfei		0.0001		
	(N = 845 in the intervention	qingre san recipe,		Thursday to a transition OD		
	group and N = 824 in the	liqi huoxue huayu		Thrombocytopenia: OR =		
	control group). Sample of	huatan recipe, buqi		0.23, 95% CI [0.13, 0.40];		
	patients with NSCLC.	yangxue fuzheng		p < 0.00001		
	O attila an Ohima	pei recipe,				
	Setting: China			Hemoglobin reduction: OR		
	(unspecified care settings)			= 0.17, 95% CI [0.10,		
				0.30]; p < 0.00001		
				Myelosuppression: OR =		
				0.24, 95% CI [0.10, 0.58];		
				p < 0.001		
				Nausea and vomiting: OR		
				= 0.16, 95% CI [0.11,		
				0.22]; p < 0.00001		
				Liver damage: OR = 0.17,		
				95% CI [0.10, 0.27)]; p <		
				0.00001		
				Kida ayadama CD		
				Kidney damage: OR =		
				0.30, 95% CI [0.10, 0.90];		
				p = 0.03		

## **General Evidence**

Citation	Design/Method Sample/Setting	Variables and Intervention	Outcome Measures	Results/Analysis	Limitations	Quality and Nursing Implications
Xing, H., Zhang, L., Ma, J., Liu, Z., Song, C., & Liu, Y. (2018). <i>Fructus</i> <i>mume</i> extracts alleviate diarrhea in breast cancer patients receiving the combination therapy of lapatinib and capecitabine. <i>Frontiers in</i> <i>Pharmacology</i> , <i>9</i> , 516. https://doi.org/10.3 389/fphar.2018.005 16	Design: Randomized controlled trial Method: The intervention group received 100 mg of <i>Fructus mume</i> extract (EFM) daily for 6 weeks; the control group took placebo. Gastrointestinal (GI) symptoms and QOL outcomes were measured during the 6 weeks of intervention and for 4 weeks following the intervention. Sample: N = 208 (104 in the intervention group, 104 in the control group) Setting: China (unspecified)	Independent Variable(s): EFM Dependent Variable(s): Diarrhea and other GI symptoms, anxiety and depression, QOL Intervention: The intervention group received 100 mg of EFM daily for 6 weeks; the control group took placebo. GI and QOL outcomes were measured for during the 6 weeks of intervention and for 4 weeks following intervention.	Diarrhea: Measure of three fecal volumes and three fecal consistencies. Daily scores were calculated on all stools. GI symptoms, including abdominal pain, bloating, straining, mucus, incomplete evacuation, urgency, wind, hard stool, loose stool, frequency of motions, and nausea, were measured using a seven-point Likert- type scale. Overall QOL was measured using the SF-36 <sup>®</sup> questionnaire. Hospital Anxiety and Depression (HADS) score Components of the EFM were measured in different batches repeatedly and determined to be stable, thereby not affecting therapeutic results.	Baseline differences in GI symptoms were not statistically significant. Diarrhea symptoms in EFM group (12.97, SD = 6.62) compared with the control group (13.11, SD = 7.53) did not differ at baseline ( $p > 0.05$ ). After 6 weeks of therapy, diarrhea symptoms were reduced in the EFM group over the control group (8.47, SD = 4.62 vs. 14.29 SD = 8.15; $p < 0.001$ ). After an additional 4 weeks following treatment, diarrhea symptom scores were reduced in the EFM group compared with the control group (9.25, SD = 4.63 vs. 13.01, SD = 6.24; p < 0.001). There were no significant differences in QOL between the EFM and control groups at baseline ( $p > 0.05$ ). After 6 weeks of intervention and 4 weeks after intervention, the EFM group had significant improvement of quality of life and decrease in HADS scores compared with the control group ( $p <$ 0.05).	Authors explicitly stated that they did not include safety aspects such as dose intensity, rash, mucositis, and drug interactions in this work. Potential safety implications of the intervention are important to note when planning symptom management interventions. Although patients were randomized and a placebo control group was included, there was no discussion of blinding of participants or of the researchers, which is a potential source of bias. In addition, EFM batch differences were measured for this study, which may not be feasible in practice.	Methodology was sound; results reporting are interpreted with caution considering risk of bias and lack of potential safety implications, which may indicate selective reporting. More research is needed on the utility of EFM for treatment of lapatinib- and capecitabine-related diarrhea in patients with metastatic breast cancer. Diarrhea scoring measures were not fully described, leading to difficulty in interpretation and effect size.

Xu, M., Wang, Y., Wang,	·						
<ul> <li>(2021). Adjuvant traditional Chinese in patients were handwised pils and pairs traditional Chinese medicines in patients rescue has possible (S). Cardiac function, complex functio</li></ul>	Xu, M., Wang, Y.,	Design: Randomized	•	,	Scores of symptom	Small sample	Results of the study were
Concomiant tradinoration tradinorational Chinese medicines in Chinese medicines in Chinese medicines in Component theraptional Chinese medicines in Chinese medicine (TCM) or to pacitizativity stratumal alone.Dependent multicon, complete blocd ocurit, head has a hari toss nausea a sheriar, insomna, loss of apette somning, loss nausea, sheriar, insomna, loss of apette somningWere besterial group somning, loss of apette somning, loss nausea, sheriar, insomna, loss of apette somning ingredents: Porial complementary ares (GLICA) 273Were besterial group somning, group and 40 in theraptes in Chinese multicoma group) average e60.5 (SD= 6) yearsDepending with the control group (p = 0,003).for symptom dimensions cores was 17,112,013,111,112,		controlled trial	Variable(s): TCM				
treatment with traditional Chinese medicines in patients receiving chemotherapy (r HER2-positive HER2-positive HER2-positive HER2-positive controlide that <i>Complementary</i> <i>chemotherapy</i> (r HER2-positive HER2-posi				•	,		,
traditional Chinese medicines in patients receiving hereficies (CRM) or to pacificate/fusturements incs. HER2-positive breast cancer. A plot rational chinese medicine (TCM) or to pacificate/fusturements of pain, diarrhes, hari loss, nausea/asthenia, insomnia, loss of appetite, working theraptication accores with receiving medicine for the second practice action of the second provide action action action action provide action action provide action action pre			•			for symptom outcomes	
medicines in patients receiving patients receiving address in the constraint of the total constraint of the total constraint of the constraint							
patients receiving chemotherapy to theread cancer: A pilot randomized control group and 40 in intervention group.       medicine (TCM) or 10 pain, diarrhea, hai toss, nausea, asthenia, insomnia, loss of pain, diarrhea, hai toss, nausea, asthenia, insomnia, loss of appetite, control group and 40 in intervention group.       material function, symptom dimensions accore appetite, vomiting       Diarrhea in the experimental group versus 21:19 (SD = 3:12).       Feasibility concerns with multicomponents of the TCM components of the TCM components of the TCM insomnia, loss of appetite, vomiting         101373.       Sample: N = 80 (40 in intervention group) average age 05. (SD- 6.6) years       Intervention: to containing roup) average age 05. (SD- 6.6) years       Intervention: to containing roup) appetite, vomiting       The left ventricular global logicularia strain was better in the experimental group (-18.01, SD = 0.64) vs. +62.22 SD = 0.52; P < 0.01).       The left ventricular global logicularia strain was better in the experimental group (-18.01, SD = 0.64) vs. +62.22 SD = 0.52; P < 0.01).       The left ventricular global logicularia strain was better in the experimental group (-18.01, SD = 0.64) vs. +62.22 SD = 0.52; P < 0.01).       The left ventricular global logicularia strain was better in the experimental group (-18.01, SD = 0.64) vs. +62.22 SD = 0.52; P < 0.01).       The intervention global columns are and based to prove the strain the control group (-18.01, SD = 0.64) vs. +62.22 SD = 0.52; P < 0.01).       The intervention global columns are and based to contain the control group (-18.01, SD = 0.64) vs. +62.22 SD = 0.52; P < 0.01).       The intervention global columns are solaram My returned to contain group was prove for the scheet solaram My returned to contain (-10; group contain the control group fact cheet to sola	-			,			populations.
chemotherapy for hER2-positive breast cancer. A plot randomizes controlled trial.aclitizativanab alone.seditaxe/trastuzumab alone.meditaxe/trastuzumab of pain, dinfree, hair loss, nausea, astheni loss, nausea, astheni loss of appetite, vomitinginsomnia, loss of appetite, vomitinginsomnia, loss of<				,	chemotherapy (P < 0.01).		
<ul> <li>HER2-positivé breast cancer: A pilot randomized complementary l'acrage age 60 5 (SD= 016) (zeros 2011)</li> <li>Sample: N = 80 (d û in controli group and 40 in interventioning oroup).</li> <li>Sample: N = 80 (d û in controli group and 40 in interventioning oroup).</li> <li>Bergie: N = 80 (d û in controli group and 40 in interventioning oroup).</li> <li>Bergie: N = 80 (d û in controli group and 40 in interventioning oroup).</li> <li>Bergie: N = 80 (d û in controli group and 40 in interventioning oroup).</li> <li>Bergie: N = 80 (d û in controli group and 40 in interventioning oroup).</li> <li>Bergie: N = 80 (d û in controli group and 40 in interventioning oroup).</li> <li>Bergie: N = 80 (d û in controli group and 40 in ingredients: Poria containing the following ingredients: Poria containing the control group after the reperimentain product the re</li></ul>			,	· · · · · ·			
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Practice, 43, 101373.       average age 60.5 (SD= 6.9) years       TCM regimen constitutioning the following ingredients: Poria coos, 10 g; atractylodes, 10 g; ginger pinella, 10 g;       The left ventricular global longitudinal strain was better in the experimental group (-18.01, SD = 0.64 vs16.22, SD = 0.52; p < 0.01).       promise in improving myelosuppression, hepatic and renal function, as well as symptom dimensions of pain, darrhea, and hair loss.         Setting: Inpatient postmastectomy       atractylodes, 10 g; ginger pinella, 10 g; zedoary, 10 g; orange fruit, 10 g; criadix curcume aramaticae, 10 g; solumin lyrate, 10 g; chicken gizzard membrane, 10 g; licorice root, 10 g; and centiped, 10 g.       The reduction in white blood cells was more significant in the control group (5.04 x 10 <sup>9</sup> /L, SD = 2.32 x 10 <sup>9</sup> /L) than in the intervention group (2.57 x 10 <sup>9</sup> /L, SD = 2.11 x 10 <sup>9</sup> /L; p <0.01).		<b>U</b>	Intervention		0 1 (1		
101373. https://doi.org/10.1       6.6) years       containing the following indicidant strain was       The left ventricular global longitudinal strain was       myelosuppression, hepatic and renaf function, as well as symptom dimensions of pain, diarbea, and hair loss.         373       Setting: Inpatient postmastectomy       for paint of the following intraction of the postmastectomy       The left ventricular global longitudinal strain was better in the experimental group (-18.01, SD = 0.62, p < 0.01).       myelosuppression, hepatic and renaf function, as well as symptom dimensions of pain, diarbea, and hair loss.         373       Setting: Inpatient postmastectomy       for paint function, as well as symptom dimensions of pain, diarbea, and hair loss.         373       Thunberg fittillary bulb, 10 g; radix curcumae aromaticae, 10 g; zedoary, 10 g; orange fruit, 10 g; drad; tangerine peel, 10 g; solanum lyrate, 10 g; chicken gizzard membrane, 10 g; lurdie carapace, 10 g; licorice root, 10 g; and centipede, 10 g. solanum lyrate, 10 g; chicken gizzard medicine in 50 milliliers twice daily for 6 months. Adjustments were made based on patient's reaction to treatment.       Hepatic function in white bioled Chinese herbal medicine in 50 milliliers twice daily for 6 months. Adjustments were made based on patient's reaction to treatment.       No significant differences in renal function were observed between the two       No significant differences in renal function were observed between the two					0.003).		
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373       Setting: Inpatient postmastectomy       atractylodes, 10 g; ginger pinellia, 10 g;       group (-18.01, SD = 0.64)       diarrhea, and hair loss.         Thunberg fitillary bulb, 10 g; radix curcumae aromaticae, 10 g;       Thurucurcumae aromaticae, 10 g;       The reduction in white blood cells was more significant in the control group (5.04 x 10 <sup>9</sup> /L, SD = 2.31 x 10 <sup>9</sup> /L, SD = 2.11 x 10 <sup>9</sup> /L; p < 0.01).							
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Scutellaria, 10 g; zedoary, 10 g; orange fruit, 10 g; dried tangerine peel, 10 g; solanum lyrate, 10 g; chicken gizzard membrane, 10 g; turtle crapace, 10 g; loorde centipede, 10 g.significant in the control group (5.04 x 10%/L, SD = 2.32 x 10%/L) than in the intervention group (2.57 x 10%/L, SD = 2.11 x 10%/L; p < 0.01).Hepatic function in the experimental group was boiled Chinese herbal medicine in 50 milliters twice daily for 6 months. Adjustments were made based on patient's reaction to treatment.Hepatic function in the experimental group was better than that in control group after chemotherapy measured by serum glutamic-oxaloacetic transaminase ratio and bilirubin levels (p < 0.01).			aromaticae, 10 g;				
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solanum lyrate, 10 g; chicken gizzard membrane, 10 g; turtle carapace, 10 g; licorice root, 10 g; and centipede, 10 g.10°/L, SD = 2.11 x 10°/L; p < 0.01).Hepatic function in the experimental group was better than that in control group after chemotherapy measured by serum glutamic-oxaloacetic transaminase and serum glutamic-pyruvic transaminase ratio and bilirubin levels (p < 0.01).							
10 g; chicken gizzard membrane, 10 g; turtle carapace, 10 g; licorice root, 10 g, and centipede, 10 g. Participants took the boiled Chinese herbal medicine in 50 milliliters twice daily for 6 months. Adjustments were made based on patient's reaction to treatment.Hepatic function in the experimental group was better than that in control group after chemotherapy measured by serum glutamic-pyruvic transaminase and serum glutamic-pyruvic10 g; chicken gizzard medicine in 50 milliliters twice daily for 6 months. Adjustments were made based on patient's reaction to treatment.Hepatic function in the experimental group was better than that in control group after chemotherapy measured by serum glutamic-pyruvic transaminase and serum glutamic-pyruvicNo significant differences in renal function were observed between the twoNo significant differences in renal function were observed between the two					intervention group (2.57 x		
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