



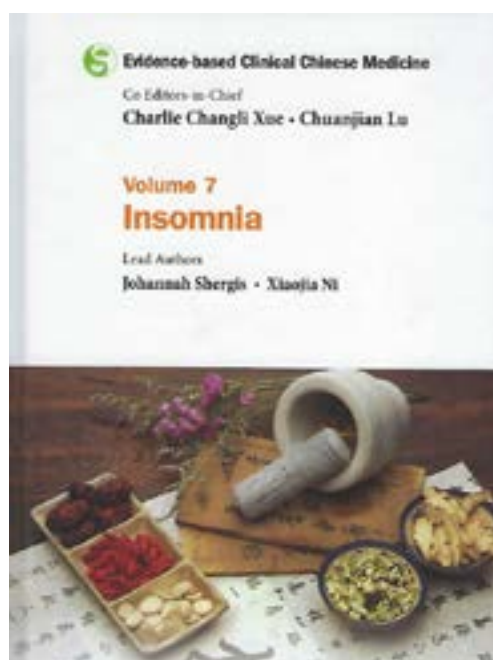
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was also no difference between CHM and BZDs (MD 13.20 minutes [-42.27, 68.67]) (H268). CHM combined with BZDs was not superior to BZDs alone (MD 32.80 minutes [-19.57, 85.17]) (H268).

Wake After Sleep Onset

In terms of the frequency of waking up after the onset of sleep measured by polysomnography, there was no difference between CHM and placebos in two studies (MD 0.58 times [-3.20, 4.37], $P = 50\%$) (H198, H268). There was also no difference between CHM and BZDs (MD 3.30 times [-2.62, 9.22]) (H268). The integrative use of CHM plus BZDs did not reduce the frequency of awakenings compared to BZDs alone (MD -0.35 times [-5.72, 5.02]) (H268).

Sleep Efficiency

In terms of sleep efficiency measured by polysomnography, there was no difference between CHM and placebo in two studies (MD 0.48% [-6.02, 6.99], $P = 36\%$) (H198, H268). There was also no difference between CHM and BZDs (MD 3.10% [-10.15, 16.35]) (H268). The integrative use of CHM plus BZDs did not improve sleep efficiency compared to BZDs alone (MD 6.90 [-4.59, 18.39]) (H268).

Depression and Anxiety Scales

Hamilton Rating Scale for Depression

The Hamilton Rating Scale for Depression (HAM-D) is measured on a scale of 0 to 50 and lower scores indicate a reduction in depressive symptoms. CHM did not show a greater effect than BZDs in terms of depression reduction measured with the HAM-D in two studies (MD -1.24 [-4.19, 1.71], $P = 80\%$) (H113, H31). CHM combined with pharmacotherapy was not superior to pharmacotherapy alone at reducing HAM-D scores in two studies (MD -0.75 [-1.63, 0.13], $P = 0\%$) (H212, H247). In individual studies, CHM was not

superior to BZDs (MD 0.50 [-2.77, 3.77]) (H247) or anti-depressant drugs (MD -0.85 [-1.77, 0.07]) (H212).

Hamilton Rating Scale for Anxiety

The Hamilton Rating Scale for Anxiety (HAMA) is measured on a scale of 0 to 56 and lower scores indicate a reduction in anxious symptoms. CHM was not superior to BZDs in terms of anxiety reduction measured with the HAMA in 11 studies (MD -0.76 [-1.61, 0.10], $I^2 = 70\%$) (H13, H29-H31, H131, H144, H147, H172, H173, H180, H191).

CHM combined with pharmacotherapy had a greater effect in improving anxiety than pharmacotherapy alone in five studies (MD -1.65 [-2.27, -1.04], $I^2 = 0\%$) (H212, H247, H249, H252, H253). In a subgroup comparing CHM plus BZDs to BZDs alone, integrative treatment was not found to be superior in three studies (MD -1.23 [-2.56, 0.10], $I^2 = 0\%$) (H247, H252, H253). One study compared CHM plus non-BZDs against non-BZDs alone and found no differences between the two groups (MD -1.94 [-4.60, 0.72]) (H249). However, a single study comparing CHM plus anti-depressants against anti-depressants alone showed an improvement in the integrative medicine group (MD -1.76 [-2.49, -1.03]) (H212).

Zung's Self-rating Depression Scale

Zung's Self-rating Depression Scale (SDS) assesses depression on a scale ranging from 20 to 80; lower scores indicate less depression symptoms. Participants treated with CHM had lower SDS scores compared to participants treated with BZDs in seven studies (MD -4.91 [-6.48, -3.34], $I^2 = 19\%$) (H39, H41, H63, H76, H98, H153, H268). One study was not included in the meta-analysis because it used a different scoring approach (H42), and one study showed that CHM was not superior to a placebo (MD 1.50 [-8.81, 11.81]) (H268).

Sleep quality and subjective sleep parameters

One study assessed sleep quality using the PSQI (H80). *Gui pi tang* improved sleep quality compared to BZDs (MD -1.80 [-2.72, -0.88]). Total sleep duration rated by participants was reported in another study and *Gui pi tang* was not found to be more effective than BZDs (MD 0.37 hours [-0.33, 1.07]) (H124).

Clinician-rated outcomes

Effective rate defined by the New Drug Guideline was assessed in three studies and *Gui pi tang* did not improve the effective rate compared to BZDs (RR 1.16 [0.97, 1.38], $P = 78\%$) (H70, H96, H97). However, the integrative use of *Gui pi tang* and BZDs was superior to BZDs alone in two studies (RR 1.33 [1.07, 1.64], $P = 0\%$) (H224, H227).

Tian wan bu xin dan 天王补心丹

Four studies evaluated *Tian wan bu xin dan* 天王补心丹 (H67, H71, H72, H177).

Sleep quality

In terms of sleep quality measured by the PSQI, *Tian wan bu xin dan* was superior to BZDs in two studies (MD -0.73 [-2.87, 1.42], $P = 88\%$) (H67, H72).

Clinician-rated outcomes

Tian wan bu xin dan was not found to be superior to BZDs in terms of the effective rate as defined by the New Drug Guideline in two studies (RR 1.23 [0.92, 1.64], $P = 61\%$) (H71, H72).

Table 5-9. GRADE: Wen dan tang 溫胆湯 vs. Benzodiazepine Drugs

Outcomes	No. of Participants (Studies)	Quality of the Evidence (GRADE)	Relative Effect (95% CI)	Anticipated Absolute Effects	
				Risk with BZDs	Risk Difference with Wen dan tang 溫胆湯
Sleep quality effective rate	492	⊕⊕⊕⊕	RR 1.17	766 per 1,000	130 more per 1,000
Mean treatment duration; 5 weeks	(6 RCTs)	LOW ^{1,2}	(1.06, 1.29)		(46 more to 222 more)
Sleep onset latency, total sleep duration, sleep efficiency, and wake after sleep onset: not reported					
Adverse events	355				
	(4 RCTs)				

*The risk in the intervention group (and its 95% confidence interval) is based on the assumed risk in the comparison group and the relative effect of the intervention (and its 95% CI).

Abbreviations: BZDs, benzodiazepine drugs; CI, Confidence Interval; PQM, Pittsburgh Sleep Quality Index; RR, Risk ratio; RCTs randomised controlled trials.

Notes

1. Insufficient blinding of personnel, participants, and outcome assessors.
2. The use of subjective outcome in place of the patient-important outcome of interest.

Study References

- Sleep quality: H17, H43, H67, H89, H104, H145.
- Adverse events: H89, H101, H140, H206.



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