# Treating Insomnia with Chinese Medicine A Synthesis of Clinical Experience (short version)

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# Preface

For us, Chinese medicine clinicians, the source of knowledge we value the most is also the hardest to obtain. Clinical experience. I can still remember the hours spent in the library at Beijing University of Chinese Medicine reading clinical cases from ancient and modern physicians. The evenings and weekends spent following experienced physicians in the clinic, sometimes until 10 PM, longing for clinical pearls that would help me become a better clinician.

As a postgraduate, I started to shift my attention to academic literature. I found hidden behind the randomised-controlled trial, the laboratory experiments and the epidemiological studies literally a forest of clinical experience reports (CERs), i.e. articles written by clinicians (sometimes their students) about the use of a technique, a formula, or the treatment of a disease. These CERs were not only a blessing for hungry learners, but also so easily accessible.

The skills and tools acquired during my doctoral studies at Western Sydney University allowed me to design a research strategy to collect, select and synthesise the information from that huge pool of clinical knowledge. After two years of long and strenuous labour and consultation with experts, the clinical experience synthesis, a systematic synthesis of clinical experience on a specific topic, was born.

This book is the first clinical experience synthesis. It aims at answering the basing question "how should we treat insomnia with Chinese medicine". The audience is students and clinicians who are using or willing to use Chinese medicine to treat insomnia. I strongly believe that any clinician, regardless of age, experience and school, will find something valuable in this work.

The first chapter is an overview of the treatment of insomnia with Chinese medicine. Chapter 2 to chapter 11 present different aspects of Chinese herbal medicine treatment of insomnia, with a focus on herbal decoctions and granules. Chapter 12 to chapter 14 present acupuncture and related

therapies for insomnia. Chapter 15 presents massage treatments for insomnia. Chapter 16 to chapter 18 present non-typical Chinese medicine therapies such as psychotherapy, *yangsheng* and integrative strategies. Finally, chapter 19 presents the methodology used to collect the knowledge presented in this work.

People who are not familiar with the treatment of insomnia with Chinese medicine may want to start with chapter 3 and chapter 13, which provide the global strategy to treat insomnia with Chinese herbal medicine and acupuncture. The content of these chapters is similar to what can be found in textbooks and provides direct guidance. More experienced clinicians may find chapter 4, chapter 6, chapter 7 and chapter 8 more valuable as they propose discussions on subjects that are usually not debated elsewhere. I added an introduction and a discussion at the beginning and end of each chapter, respectively. These sections do not represent the content of the CERs but rather help the reader to navigate through the different chapters of this book.

Compared to existing textbooks and guidelines on the subject, the main strength of this work is to *systematically* (without bias of school or approach) collect knowledge in a transparent manner that can be assessed or repeated. Compared to books and individual CERs, this book provides pooled clinical experience from hundreds of clinicians, showing trends and common knowledge rather than personal opinion.

In this book, patterns are presented with more flexibility and link than textbooks, which usually provide several patterns as individual blocks with associated signs and symptoms (SSs), herbs and acupuncture points. In this book, we show causal links between these patterns and present a hierarchy of formulas, SSs, herbs and acupoints. This is achieved with the sensibility (sen) value, which represents how widely the SS, herb or acupoint is cited, and the specificity (spe) value, which represents the strength of the association between the SS, herb or acupoint, and the associated pattern.

In this book, I describe also therapies that are not always present in textbooks and guidelines, despite being used in the clinic. These therapies include scalp acupuncture, cupping, herbal paste, herbal patches, food therapy, etc. Psychotherapy techniques (the ones used by Chinese medicine clinicians), *yangsheng* recommendations and integrative approaches are also rarely described elsewhere. The treatment of insomnia according to the main complaint and insomnia duration are rarely discussed thoroughly elsewhere. The specific methods of treatment adaptation according to the person, the season and the location are described here, whereas only global principles are available in current textbooks.

One of the main strengths of this book is to propose clinical notes. These notes are similar to the tips our mentors give us after a hard day of clinical work. They show highly-relevant clinical knowledge on topics such as how to adjust the dose, how to prevent and treat adverse reactions, diagnostic tips, specific acupuncture techniques, etc. This knowledge is rarely available elsewhere. For each of these clinical notes, I provide the citation number (the number of CERs in which this idea was proposed), which allows the reader to assess how consensual the idea is.

I would like to acknowledge the support and help of my dear fiancée Mingxian Jia, who has not only conducted some of the main processes (such as article screening) of the study but also used her valuable time to discuss how to resolve the countless issues that arose down the path and provided unconditional support to her focused partner. Thanks to my doctoral supervisors Xiaoshu Zhu, Alan Bensoussan and Catrina Tannous, who provided their time, expertise and support on each step of the process, with incredible patience and devotion. Thanks to my beloved mother Christine Buy and my sincere friends Emily Yang, Jordan Bencherif, Zhichao Yu, Christine Murray, Andrew Wong and all the others who provided valuable insights on how to improve this method to make it benefit more people.

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# Chapter 1 General Considerations in the Treatment of Insomnia with Chinese Medicine

This chapter explores the diagnostic and treatment models used in different modalities such as Chinese herbal medicine, acupuncture and massage. It presents also more global strategies used to treat insomnia such as what to do in case of absence of treatment response.

#### 1. Diagnostic approach

The two main models used by the clinicians are the pattern-differentiation model and the disease-differentiation model. In the former, the diagnosis is based on patterns of signs and symptoms and a specific treatment is given for each pattern. In the latter, one single formula is used in every case of insomnia. In both cases, the treatment can be modified according to specific signs and symptoms and also according to individual characteristics such as age, comorbidities, and constitution.

The pattern-differentiation model is preferred by clinicians who use herbal medicine whereas the disease-differentiation model is preferred by clinicians who use acupuncture or massage. Most clinicians use either one model or another, however the two models can be used simultaneously. For example, one clinician uses a disease approach with herbs that regulate the *yinyang* and calm the *shen* when there is not enough evidence for pattern differentiation. Another clinician uses generally a disease approach but changes to a pattern-specific treatment in case of blood stasis or food stagnation. The modification of the main formula in the disease approach according to the pattern is common and sometimes a disease-based treatment is added to the pattern-based formula. In the latter case, the purpose of the added disease-based treatment is generally to calm the *shen* and sometimes to improve *qi* circulation.

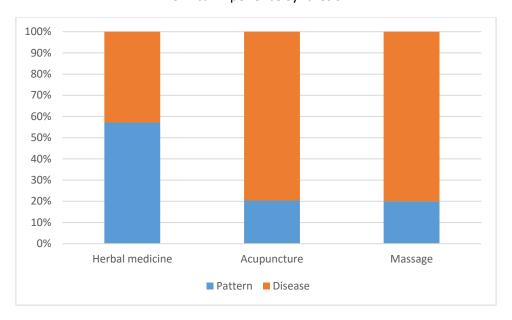


Figure 1-1. This figure shows the ratio of each therapeutic model according to the treatment modality

# 2. Clinical pathway

Some clinicians propose a stepped-care approach. This means that different therapeutic approaches can be used depending on the severity of the condition. In one 4-step model, cognitive-behavioural therapy is proposed as the first step, then non-pharmacological Chinese medicine methods such as acupuncture and massage are used as the second step, Chinese herbal medicine is used as the third step, and finally Western medicine used as the fourth step (1). Another clinician proposes a therapeutic course composed of acupuncture needling first, then moxibustion, fire needles or bloodletting according to the condition of the patient, and ear acupuncture or buried needle at the end of the treatment (1).

In case of **the absence of treatment response**, three approaches can be used in addition to a reassessment followed by appropriate treatment. These approaches are used regardless of the signs and symptoms of the patient. The first approach is the treatment of **blood stasis** with Xue Fu Zhu Yu Tang (4). The second approach is the treatment of **yang deficiency** with warm-tonifying herbs such as *huangqi*, *yinyanghuo*, *guizhi*, *fuzi* and *ganjiang* and oppressing-immersing herbs such as *wuweizi*,

cishi, longgu, muli or guijia (3). This approach is used especially when yin-nurturing and spirit-calming methods are ineffective (2) and can be used only when there is no significant sign of yangheat (1). The third approach is the treatment of **phlegm** with Wen Dan Tang (1).

# Chapter 2 Pattern-Based Treatment of Insomnia with Chinese Herbal Medicine

This chapter is the pillar of the chapters on Chinese herbal medicine. It presents the typical patterns (the ones in which there is a clear direction in terms of treatment) of insomnia with the causal relationsip between them, the associated population, SSs, formulas, and individual herbs.

Modification methods and clinical notes are also presented.

# 1. General findings

#### 1.1. Causes and mechanism

Only causes and mechanisms cited at least six times were included in Figure 2-1. A total of eight different mechanisms and ten causes were included in the final model. These eight main mechanisms are

- Liver Stagnation
- Blood stasis
- Phlegm-heat
- Liver blood deficiency
- Liver fire
- Spleen deficiency
- Heart-spleen deficiency
- Kidney *yin* deficiency and
- Heart fire

According to the clinicians, the primary causes of insomnia are

Emotions

- Excessive thinking
- Excessive diet
- Alcohol intake
- Constitution
- Overstrain
- Severe or long-term diseases
- Aging and
- Excessive sexual life.

The most extensively cited cause is "emotions", with 122 citations, and the most extensively cited mechanism is "liver stagnation", with 114 citations.

Some causes can provoke different mechanisms, for example, emotions causing either liver stagnation, liver blood deficiency, liver fire or heart fire. Some mechanisms can have different causes, for example, kidney *yin* deficiency can be caused by constitution, severe or long-term disease, aging, excessive sexual life and overstrain. Complex causal relationships, sometimes bidirectional, were identified between the above causes and mechanisms or between two mechanisms.

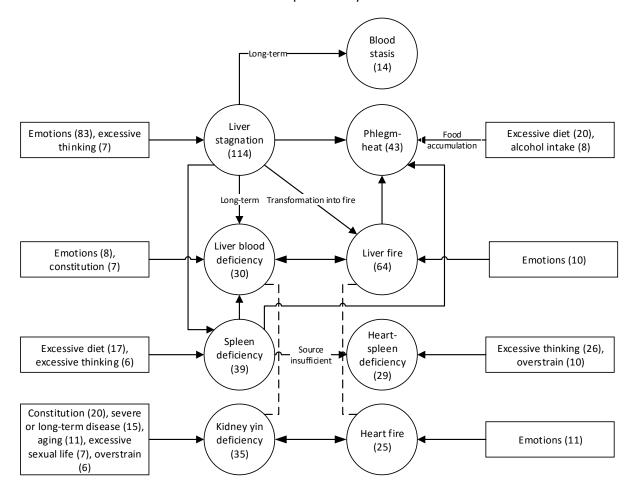


Figure 2-1. Flowchart of the causes and mechanisms leading to insomnia described by the authors in the context of Chinese herbal medicine treatment with a pattern approach. Causes are presented in rectangles and mechanisms are presented in squares. Arrows show a causality relationship and dot lines show some proximity between two mechanisms. The text inlaid on the arrow represents additional descriptions of the causality relationship by the author. Causes have been placed on both sides of the flowchart to allow better readability of the chart.

Three main "systems" of causes and mechanisms can be identified.

In the first system liver stagnation caused by excessive emotions is the primary mechanism, leading to four secondary mechanisms, i.e. liver fire, phlegm heat, blood stasis and liver blood deficiency.

Emotions, overthinking and excessive diet can also create or aggravate phlegm heat, liver fire and liver blood deficiency.

In the second system kidney *yin* deficiency and heart fire are intertwined. The primary causes of these are different, kidney *yin* deficiency being caused by consumption through aging, diseases, and overstrain, and heart fire being caused by excessive emotions. Ultimately, these two mechanisms aggravate each other and form a cluster. This system is connected to the "liver stagnation" system via liver blood deficiency and liver fire.

In the third system heart spleen deficiency is caused directly or indirectly through spleen deficiency by excessive diet, excessive thinking or overstrain. This system is relatively independent but can be connected to the "liver stagnation" system by liver stagnation causing spleen deficiency.

It is important to understand that these "mechanisms" are different from "patterns" represented in this study by clusters of formulas. Mechanisms were expressed directly by the authors of the CERs whereas patterns were identified through computerised cluster analysis. In order to differentiate them, we capitalised the patterns but not the mechanisms. Some patterns may be associated with two or more mechanisms (e.g., Yin Deficiency with Effulgent Fire associated primarily with kidney *yin* deficiency, liver blood deficiency and heart fire) while some mechanisms and patterns overlap (e.g., heart-spleen deficiency and Heart-Spleen Deficiency).

#### 1.2. Overview of patterns

Seven patterns were identified through cluster analysis and labeled "Yin Deficiency with Effulgent Fire", "Liver-Spleen Disharmony", "Phlegm-Heat", "Heart and Spleen Deficiency", "Liver Fire", "Liver Stagnation" and "Blood Stasis" (Table 2-1).

Pattern ID	Label	Abbreviation	Most common formula	Number of formulas
1	"Yin Deficiency with Effulgent Fire"	Yin-Def-Fire	Suan Zao Ren Tang	122

2	"Liver-Spleen Disharmony"	L-S Dis	Chai Hu Jia Long Gu Mu Li Tang	45
3	"Phlegm-Heat"	Phlegm-Heat	Wen Dan Tang	75
4	"Heart and Spleen Deficiency"	H-S Def	Gui Pi Tang	45
5	"Liver Fire"	Liver Fire	Long Dan Xie Gan Tang	20
6	"Liver Stagnation"	Liver Stag	Dan Zhi Xiao Yao San	55
7	"Blood Stasis"	Blood Stasis	Xue Fu Zhu Yu Tang	26

Table 2-1. Seven patterns identified through cluster analysis

Generally speaking, patterns vary in terms of acceptation, diversity and consistency.

For example, "Yin-Def-Fire", with 122 formulas, is widely recognised by clinicians as a pattern of insomnia. Liver Fire and Blood Stasis are much less recognised, with 20 and 26 formulas, respectively.

H-S Def is almost exclusively associated with Gui Pi Tang, showing this formula is relatively isolated while Yin-Def-Fire has many major formulas, i.e. Suan Zao Ren Tang, Huang Lian E Jiao Tang, Zhi Zi Chi Tang and Shen Qi Wan, showing that these formulas are close enough to be clustered together.

The herbs and SSs of Phlegm-Heat pattern have a relatively high sensitivity and specificity levels, showing a strong inner consistency, while the ones of L-S Dis pattern have low sensitivity and specificity levels, showing that this pattern is relatively vague and lacks of a strong definition.

The difference between the present categorisation of pattern and other possible categorisations of patterns that were pre-selected is the number of clusters related to "Yin Deficiency with Effulgent Fire", ranging from one (in the present categorisation) and a maximum of four (labeled "Non-Communication Between Heart and Kidney", "Heart Blood Deficiency", "Liver Blood Deficiency" and "Kidney Deficiency"). Another variation is the formulas included in the "Liver-Spleen Disharmony" pattern, which included Huang Lian E Jiao Tang and Zhu Sha An Shen Wan in some categorisations.

#### 1.3. Overview of formulas

Among the 438 formulas for which the name of the formula was expressed by the author, 189 different formulas were cited (Figure 2-2). The most commonly cited formulas were Gui Pi Tang (30), Suan Zao Ren Tang (22), Wen Dan Tang (21), Xue Fu Zhu Yu Tang (21), Huang Lian Wen Dan Tang (20), Huang Lian E Jiao Tang (19), Dan Zhi Xiao Yao San (18), Long Dan Xie Gan Tang (16), Chai Hu Shu Gan San (13) and Chai Hu Jia Long Gu Mu Li Tang (10). The ten most cited formulas accounted for 43% of all the formulas.



Figure 2-2. Word cloud of the names of the formulas expressed by the authors. The size of the words depends on the number of citations and the colour depends on the pattern the formula belongs to.

Blue = Yin-Def-Fire, purple = L-S Dis, orange = Phlegm-Heat, yellow = H-S Def, red = Liver Fire, green = Liver Stag, brown = Blood Stasis. Formulas that were removed during the cluster analysis are shown in black.

#### 1.4. Pattern differentiation

The key signs and symptoms allowing for pattern differentiation are presented in figure 2-3. This model is able to predict patterns with an overall correct prediction rate of 55.4%. Some patterns are more easily identified through SSs than others. The correct prediction rate is 82.0% for "Yin Deficiency with Effulgent Fire", 0.0% for "Liver-Spleen Disharmony", 57.3% for "Phlegm-Heat",

46.7% for "Spleen and Heart Deficiency", 65.0% for "Liver Fire", 38.2% for "Liver Stagnation" and 65.4% for "Blood Stasis". This decision tree is based on 304 patterns for which at least one sign or symptom was described.

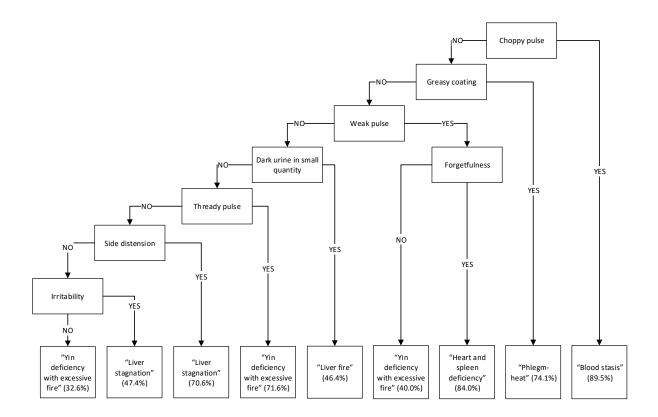


Figure 2-3. Decision tree of the signs and symptoms allowing for differentiation of patterns. The percentage of cases belonging to the pattern are shown in brackets.

## 2. Typical patterns

### 2.1. Yin Deficiency with Effulgent Fire

#### 2.1.1. Yin-Def-Fire population characteristics and sign/symptoms

This pattern is commonly observed in older adults (4), white collar workers (2). This pattern is also associated with persistent insomnia (2).

The SSs indicating Yin-Def-Fire are represented in Figure 2-4.



Figure 2-4. Signs and symptoms associated with the Yin-Def-Fire pattern. The font is darker for SSs with a high specificity level and bigger for SSs with a high sensitivity level.

#### The ten most common SSs of Yin-Def-Fire are

- 1. Agitation (63% sen, 40% spe)
- 2. Fine pulse (59% sen, 51% spe)
- 3. Palpitations (39% sen, 42% spe)
- 4. Red tongue (36% sen, 35% spe)
- 5. Wiry pulse (35% sen, 30% spe)
- 6. Rapid pulse (33% sen, 33% spe)
- 7. Pale tongue (32% sen, 36% spe)
- 8. Frequent dreams (31% sen, 27% spe)
- 9. Dry mouth (25% sen, 48% spe) and
- 10. Fatigue (25% sen, 31% spe)

Five high specificity SSs were identified:

- 1. Hot flushes (6% sen, 100% spe)
- 2. Blurred vision (4% sen, 100% spe)
- 3. Pale nails (3% sen, 100% spe)
- 4. Faint pulse (2% sen, 100% spe) and
- 5. Dull nails (2% sen, 100% spe).

#### 2.1.2. Prescriptions for Yin-Def-Fire

The herbs used for Yin-Def-Fire are represented in Figure 2-5.



Figure 2-5. Herbs used for the Yin-Def-Fire pattern. The font is darker for herbs with a high specificity level and bigger for herbs with a high sensitivity level.

The seven most common herbs for Yin-Def-Fire are reported in Table 2-2.

Herb (sen, spe)	Mean dose (min- max)	Туре	Notes
Suanzaoren (50%, 43%)	27.0g (15-90)g	Stir-fried (7)	<ol> <li>Use high doses (6), up to 180g (1)</li> <li>It is an important herb in the treatment of empty agitation with sleeplessness (1)</li> <li>Use it stir-fried for liver blood deficiency and raw for liver heat (1)</li> <li>Not appropriate when the fur is slimy (1)</li> </ol>

-			
			5. Its sour taste is used to tonify the liver (1)
Fuling (49%, 31%)	15.5g (9-20)g	Red (1), from Yunnan (1)	In case of severe insomnia or all-night insomnia, use fushen instead of fuling (1)
<i>Zhimu</i> (38%, 90%)	12.7g (9-20)g		
Huanglian (34%, 53%)	9.2g (5-15)g		
Gancao (34%, 17%)	7.0g (3-15)g	Prepared (12), raw (2)	Its sweet taste is used to relax the liver (1)
Chuanxiong (32%, 47%)	10.4g (3-20)g		<ol> <li>As the liver is a hard organ it relies on yin-blood for nutrition. Don't use too much of chuanxiong to prevent it from aggravating the dryness and heat (1)</li> <li>Its pungent taste is used to tonify the liver (1)</li> </ol>
Baishao (30%, 33%)	11.6g (6-15)g	Raw (2)	

Table 2-2. Information on the core herbs of the Yin-Def-Fire pattern

The formula is modified according to seven different situations (Table 2-3).

Pattern	Main signs/symptoms	Main added herbs
Yin deficiency (5)	Dry mouth (4), agitation (3)	Shengdi (8), maidong (7), wuweizi (5)
Fire (6)	Agitation (7)	Zhizi (5), huanglian (4)
	Palpitations (5), severe insomnia (3), frequent panic (3), frequent dreams (3)	Longgu (7), muli (4), yejiaoteng (4)
Qi deficiency (6)	Fatigue (4), shortness of breath (4)	Huangqi (6)
Blood deficiency (4)	Palpitations (2)	Danggui (4)
	Constipation (3) with dry stools (2) and abdominal bloating (2)	Zhishi (3), houpo (2), dahuang (2)
Stagnation (2)		Yujin (3), xiangfu (2)

Table 2-3. Modification according to symptoms or pattern for the Yin-Def-Fire pattern.

#### 2.1.3. Clinical pearls for Yin-Def-Fire

The authors expressed twenty recommendations regarding the Yin-Def-Fire pattern, including:

1. "This type is frequently observed in the clinic".

- 2. This type is relatively easy to treat if the diagnosis is precise. (1)
- 3. These patients usually present signs of autonomous system impairment such as fast heart rate, thin body and having difficulty staying calm. (1)
- 4. "Fire-descending herbs such as *huangbai* and *zhimu* are excessively bitter, cold and water-draining, their coldness can damage the stomach. (...) Use instead *zhuye* and *zhizi* which are fragrant and cool, they open the orifice of the heart and move down heart fire".
- 5. "As older and chronic patients often have spleen-stomach disharmony, add in the formula herbs that waken the spleen and open the stomach such as *sharen* or *zhiqiao*, so you can tonify without stagnation and nurture without accumulating; you can also use *jiao sanxian* to strengthen the spleen and harmonise the stomach".
- 6. "Need to add appropriately *qi*-regulating herbs in order to keep the three burners free and herbs that warm and strengthen the spleen-stomach".
- 7. Yang immersing herbs such as *longgu*, *muli*, *guijia*, *biejia* or *shijueming* have to be combined to *yin* nurturing herbs (2). They have to be used raw and in high doses (1).
- 8. As you know that the condition of the liver will affect the spleen, use *fushen*, *lianzi* and *shanyao* to prevent the weakening of the spleen. (1)
- 9. Animal products such as *ejiao*, *ziheche*, *guijia* or *biejia* can be used in case of severe *yin*-blood deficiency. (1)
- 10. Huang Lian E Jiao Tang is bitter, cold and slimy, so it cannot be used for a long period. It can be replaced by Liu Wei Di Huang Wan after improvement. (1)
- 11. "Avoid too many rich (*zini* 滋腻) *yin*-nurturing herbs because it would be like trying to fight fire with firewood".

- 12. Combine *yin*-nurturing herbs such as *zhimu*, *hanliancao* or *baihe* to fire-draining herbs, otherwise you will not be able to drain the fire. (1)
- 13. "Food therapy is important. Light food, easy to digest and full of nutrient [is recommended] to help the production of *qi* and blood".
- 14. You should not treat this type of patient with medication only; they must be trained psychologically to improve their adaptation capacities.
- 15. "Zhi Zi Chi Tang and Suan Zao Ren Tang can be both used to treat empty agitation with insomnia. However, 'vexation in the heart' is present only in Zhi Zi Chi Tang syndrome".
- 16. "When using this formula [Suan Zao Ren Tang] (...) the time of administration is 1h before dinner and 2h before bedtime".
- 17. Bitter taste in mouth and dark urine are enough to indicate the use of Bai He Zhi Mu Tang. (1)
- 18. "When using this formula [Zhu Ling Tang] (...) use the original dose for each herb; do not use it if the patient is sweating".
- 19. "This formula [Ban Xia Shu Mi Tang] is too simple and has to be combined with other classic formula".
- 20. "You should not remove *jizihuang*; it cannot be replaced by soft-boiled chicken eggs otherwise the efficacy will decrease".

#### 2.2. Liver-Spleen Disharmony

#### 2.2.1. L-S Dis population characteristics and signs/symptoms

The populations associated with this pattern are women (2), young people (2). L-S Dis is also associated with psychological (3) and physical (2) comorbidities, and acute-onset insomnia (2).

The SSs indicating L-S Dis are presented in Figure 2-6.



Figure 2-6. Signs and symptoms associated with the L-S Dis pattern. The font is darker for SSs with a high specificity level and bigger for SSs with a high sensitivity level.

#### The twelve core SSs of L-S Dis are:

- 1. Agitation (40% sen, 8% spe)
- 2. Fine pulse (37% sen, 10% spe)
- 3. Pale tongue (33% sen, 11% spe)
- 4. Wiry pulse (33% sen, 9% spe)
- 5. Lack of appetite (33% sen, 11% spe)
- 6. Yellow fur (30% sen, 11% spe)
- 7. Fatigue (30% sen, 11% spe)
- 8. Red tongue (27% sen, 8% spe)
- 9. Rapid pulse (27% sen, 8% spe)
- 10. Frequent dreams (27% sen, 7% spe)
- 11. Constipation (23% sen, 19% spe) and
- 12. Depression (23% sen, 18% spe)

Five high-specificity SSs were identified:

- 1. Preference for hot drinks (13% sen, 100% spe)
- 2. Delirious speech (13% sen, 100% spe)
- 3. Deficient pulse (10% sen, 100% spe)
- 4. Mania (10% sen, 100% spe) and
- 5. Throat pain (7% sen, 100% spe)

#### 2.2.2. Prescription for L-S Dis

The herbs used by the clinician for L-S Dis are shown in Figure 2-7.



Figure 2-7. Herbs used for the L-S Dis pattern. The font is darker for herbs with a high specificity level and bigger for herbs with a high sensitivity level.

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## 3. Interpretation and discussion

#### 3.1. Pathological systems

Three pathological systems composed of causes and mechanisms that are closely associated one another have been identified. These systems, which are relatively independent from one another,

are the liver stagnation system, the *yin* deficiency and fire system and the heart and spleen deficiency system.

#### 3.1.1. Liver stagnation system

The liver stagnation system has a core composed of the Liver Stagnation, Liver Fire and Liver-Spleen Disharmony patterns and two branches, i.e. Phlegm-Heat and Blood Stasis. The three core patterns share common ingredients (e.g., *chaihu*, *huangqin*, *baishao*) and also common SSs (e.g., wiry pulse, stress and irritability, frequent dreams). Excessive emotions, which can provoke stagnation and fire, are the main pathological cause of this system.

Stagnating fire is a common feature of these three patterns, and it is understood by clinicians across patterns that stagnating fire has to be treated with both clearing and dispersing herbs. Nevertheless, this feature is particularly significant in the Liver Fire pattern, for which bitter taste in mouth, dark and scanty urine, rapid pulse and yellow coating are major SSs. The core herbs of Liver Fire are mainly cold herbs such as *huangqin*, *shengdi* and *zhizi*.

Liver Stag and L-S Dis are literally twin patterns. Liver stagnation and spleen deficiency are the main features of both patterns. The reasons for the two being separated during the cluster analysis is that they differ in terms of herbs used. L-S Dis is almost exclusively composed of classical formulas, in which dazao, shengjiang and gancao are widely used. Some may argue that these herbs have a limited role in the formula and do not represent its direction. However, dazao, shengjiang and gancao may represent a basic feature of the treatment of diseases by Zhang Zhongjing, i.e. the regulation of the spleen-stomach with sweet and neutral or warm herbs. Therefore, there is some logic in clustering chaihu-type formulas, guizhi-type formulas and Ban Xia Xie Xin Tang.

Beside the use of *dazao*, *shenjiang* and *gancao*, the main difference of Liver Stag and L-S Dis is the tendency toward blood deficiency of Liver Stag and the tendency toward *yang* deficiency of L-S Dis. For example, *danggui* and *baishao* are core herbs of Liver Stag, and it is associated with middle-aged

females, while *guizhi* is a core herb of L-S Dis, for which *yang* deficiency is a main modification situation. Although both are associated with mood disorders, there is a tendency toward psychosomatic symptoms such as running pain and electric sensations in the body for Liver Stag and a tendency toward physical conditions and symptoms such as fatigue and throat pain, as well as psychosis (which is a major indication of Chai Hu Jia Long Gu Mu Li Tang in the *Shanghan Lun*), for L-S Dis.

Emotion-induced liver stagnation is the first step of the liver stagnation system, which evolves gradually toward phlegm and blood stasis. Unsurprisingly, Liver Stag is associated with acute insomnia while Phlegm-Heat and Blood Stasis are associated with persistent insomnia.

Phlegm-Heat differs from the rest of the system because of its association with spleen-stomach. Indeed, the main cause of Phlegm-Heat is excessive diet with sweet and greasy food, which can cause phlegm-heat through food stagnation and/or spleen deficiency. Nausea/vomiting and belching are common SSs of Phlegm Heat. Phlegm-Heat is also associated with metabolic disorders such as obesity and hyperlipidemia. Unblocking the intestinal tract is crucial for this pattern, as we can see by the importance of *dahuang* in the modification methods and as stated by one clinician. A slimy fur (and the related sticky sensation in mouth) is a strong indicator of Phlegm-Heat, as shown in the high specificity of this sign and as stated by three clinicians.

Compared to Liver Stag, Yin-Def-Fire and Phlegm Heat, Blood Stasis is relatively uncommon. Blood Stasis is strongly associated with persistent and treatment-resistant insomnia. This pattern is almost exclusively associated with Xue Fu Zhu Yu Tang. Rough pulse and purple tongue are common and highly specific signs of this pattern.

#### 3.1.2. Yin deficiency and fire system

The Yin-Def-Fire pattern is by far the most common pattern of insomnia, yet also one of the most heterogeneous. This pattern is composed of two main mechanisms, i.e. kidney yin deficiency and

heart fire, and can be divided in sub-patterns according to the ratio of yin deficiency and fire, with formulas such as Zhi Zi Chi Tang on the fire end, formulas such as Liu Wei Di Huang Wan on the *yin* deficiency end, and formulas such as Huang Lian E Jiao Tang, Suan Zao Ren Tang and Zhu Sha An Shen Wan in the middle.

The presence of kidney-yang-tonic formulas such as Shen Qi Wan and Er Xian Tang and the common combination of Jiao Tai Wan and Huang Lian E Jiao Tang show that there is no strict delimitation between kidney yin and kidney yang deficiency. Kidney yin deficiency and kidney yang deficiency can aggravate each other and both of them can provoke the surge of deficient fire.

The *yin* deficiency and fire system differs from the liver stagnation system in terms of pathological mechanism and population. The liver stagnation system is mainly caused by excessive emotions touching a relatively young and healthy population, whereas the yin deficiency and fire system is mainly based on constitutional causes such as weak constitution, chronic diseases and aging touching a relatively old and unhealthy population. However, some connections exist between the two systems through liver blood deficiency and heart-liver fire.

#### 3.1.3. Heart and spleen deficiency system

H-S Def pattern is relatively isolated from the other pathological systems of insomnia. H-S Def has unique features, i.e. it is the only pure deficient pattern; it is caused by overstrain (including working and thinking too much); the insomnia is aggravated by activity (in the other patterns the sleep gets better with activity); it is the only pattern for which agitation is NOT one of the main SSs.

H-S Def has a relatively strong connection with spleen deficiency, which is one of the main causes of the pattern. Some of the core herbs of this pattern are spleen-regulating herbs such as *baizhu*, *muxiang* and *fushen*. Regulating the spleen is the most common modification methods. The use of heavy sedative herbs should be limited as these herbs can harm the spleen-stomach. Spleen

deficiency is also the (thin) point of connection of this pattern with other patterns such as L-S Dis, Liver Stag and Phlegm-Heat.

#### 3.2. Comparison with current pattern classifications

The present classification system presents many similarities with current pattern classifications from textbooks and clinical guidelines. Yin Deficiency and Fire, Phlegm-Heat and Heart and Spleen Deficiency are widely recognised as main patterns of insomnia. Wen Dan Tang, Gui Pi Tang and Long Dan Xie Gan Tang are also widely recognised as main formulas for insomnia. However, some discrepancies exist between our classification and the current official position.

First, various patterns such as Kidney Yin Deficiency, Heart Yin Deficiency, Heart Fire, Yin Deficiency with Fire, and Non-Communication between Heart and Kidney are grouped under one single category in our classification.

Secondly, in our classification Liver Stagnation is considered as a major and also a key pattern in the pathological model of insomnia, whereas it is rarely put forward in current classification without "Transforming into Fire". The reason might be that Liver Stagnation does not explain directly how insomnia is generated in a conventional way (i.e. the hear-spirit is neither disturbed nor lack of nutrition). This could be a difference between a conceptual approach and a clinical approach of the classification of insomnia patterns.

Thirdly, the Heart and Gallbladder Qi Deficiency pattern is absent from our classification. Although An Shen Ding Zhi Wan is one of the most common formulas for insomnia in our classification, it was classified into different categories depending on the variables of the cluster analysis. In no case it was able to create a cluster by itself or lead other formulas to create a cluster. It means that An Shen Ding Zhi Wan lacks a clear direction in terms of composition compared to other formulas such as Wen Dan Tang, Gui Pi Tang or Xue Fu Zhu Yu Tang which can be identified by specific phlegm-transforming, tonifying and blood-moving herbs, respectively.

Fourthly, Food Stagnation is absent from our classification. Bao He Wan is proposed by many clinicians for the treatment of insomnia, however this formula does not create or lead a cluster no matter how the cluster analysis is adjusted. This is mainly due to its proximity with Wen Dan Tang, the leading formula of Phlegm-Heat pattern. These two formulas do not only share ingredients such as *chenpi*, *banxia* and *fuling*, they have also many SSs in common and share pathological pathways (excessive diet and spleen deficiency). According to our study, Phlegm-Heat can actually be considered as a consequence of Food Stagnation.

# Chapter 3 Atypical Patterns of Insomnia

Besides the seven patterns described in the Chapter 2, we identified four "atypical" patterns through thematic analysis (analysis of words instead of formula composition). These atypical patterns cannot be identified with the ingredients of the formula as they do not represent one single direction but rather a higher conceptual level. Therefore, the formulas of one atypical pattern can cover the range of several "typical" patterns (see Table 3-1).

The five atypical patterns are "Non-Interaction between Heart and Kidney (Non-Int H-K)", "Qi and Yang Deficiency (Qi/Yang Def)", "Stomach Disharmony (Sto Dis)", "Disharmony between Nutritive and Protective (N-P Dis)", and "Heart and Gallbladder Deficiency (H-G Def)" (Table 3-1).

Atypical pattern	Main formulas	Typical pattern classification	Formulas number
Non-Int H-K	Huang Lian E Jiao Tang, Jiao Tai Wan, modifications of Liu Wei Di Huang Wan	Yin Deficiency and Fire, Phlegm-Heat	75
Qi/Yang Def	Shen Qi Wan, Gui Zhi Gan Cao Long Gu Mu Li Tang, Bu Zhong Yi Qi Tang and Qian Yang Dan	Yin Deficiency and Fire, Liver-Spleen Disharmony	67
Sto Dis	Bao He Wan, Wen Dan Tang, Ban Xia Shu Mi Tang	Phlegm-Heat, Liver-Spleen Disharmony, Liver Stagnation	47
N-P Dis	Gui Zhi Tang, Gui Zhi Jia Long Gu Mu Li Tang	Liver-Spleen Disharmony	18
H-G Def	An Shen Ding Zhi Wan, combination of Suan Zao Ren Tang and An Shen Ding Zhi Wan	No equivalence	39

Table 3-1. Main characteristics of atypical patterns

## 1. Non-Interaction between Heart and Kidney

Chinese medicine focuses on the balance of different energies in the body. The heart is located in the upper burner, at the top of the body, and is associated with the element (or movement) fire. The

kidney is located in the lower burner, at the bottom of the body, and is associated with the element (or movement) water. In order to keep a balance within the body, the water of the kidney has to go up and connect with the heart, keeping its fire controlled; the fire of the heart has to go down and connect with the kidney, keeping it warm. The absence of interaction between heart and kidney causes an imbalance in the body and can provoke medical conditions such as insomnia.

Four different types of situations (or patterns) of Non-Interaction between Heart and Kidney have been found (Table 3-2). The Kidney Yin Deficiency and Heart Fire Excess are relative to each other and appear most of the time simultaneously, therefore treatment should combine both aspects by using a combination of Huang Lian E Jiao Tang and Jiao Tai Wan for example.

Pattern	Mechanism	Formulas
Kidney Yin Deficiency	The <i>yin</i> -essence of the kidney is exhausted because of aging, chronic illnesses, etc., and cannot interact with the heart	Huang Lian E Jiao Tang, Tian Wang Bu Xin Dan, Liu Wei Di Huang Wan, Zuo Gui Wan
Heart Fire Excess	Excessive emotions create fire in the heart, preventing its <i>yang</i> to connect with the kidney	Jiao Tai Wan
Kidney Yang Deficiency	Kidney Yang is too weak to steam the kidney yin upward to the heart	Qian Yang Dan, Er Xian Tang, Shen Qi Wan
Pathogen in the Middle Burner	The interaction between heart and kidney is blocked by an excess pathogen in the middle burner such as dampness, phlegm and food, in relation with spleen deficiency	Ban Xia Xie Xin Tang, Er Chen Tang, Wen Dan Tang

Table 3-2. Non-Interaction between Heart and Kidney patterns, pathological mechanism and related formulas.

#### [The text was cut here]

# 4. Disharmony between Nutritive and Protective

#### 4.1. Definition of N-P Dis

The theoretical background behind Disharmony between Nutritive and Protective as a pattern of insomnia is the idea that the sleep-wake cycle is related to the movements of the protective *qi*,

which circulates in the *yang* when we are awake and in the *yin* when we are asleep. Another theory is that according to the classic Huangdi Neijing "the nutritive and protective have to be regulated when the heart is damaged".

According to the clinicians, there are three different aspects of Disharmony between Nutritive and Protective, i.e. nutritive and protective qi deficiency, a stagnation of the nutritive and protective qi, and an imbalance between nutritive qi and protective qi. The first and second aspects are linked as the nutritive and protective have to be both sufficient and moving to be effective. In the third aspect, the protective is excessively strong and cannot penetrate the nutritive-yin.

#### 4.2. Prescription for N-P Dis

However, this separation does not matter in terms of treatment as Gui Zhi Tang and its modified forms can be used to address these three aspects, i.e. it can tonify and move the nutritive and protective, and also bring the protective back to the nutritive-yin. However, the primary cause of the disharmony has to be addressed. For example, if the deficiency of the nutritive and protective is due to spleen deficiency, it has to be treated with Si Jun Zi Tang. If the lack of movement of the nutritive and the protective is due to a global stagnation in the three burners, it has to be treated with Xiao Chai Hu Tang. The formulas used for this pattern are shown in Figure 3-3.

Er Chen Tang

Si Jun Zi Tang

# Gui Zhi Tang

Ban Xia Xie Xin Tang

# Gui Zhi Jia Long Gu Mu Li Tang Xiao Chai Hu Tang

Sheng Yang Yi Wei Tang

Dang Gui Bu Xue Tang

Figure 3-3. Formulas used for Disharmony between Nutritive and Protective

#### 4.3. Diagnostic features of N-P Dis

The indications for Disharmony between Nutritive and Protective can be different depending on the definition of this pattern. For example, the indication for Ban Xia Xie Xin Tang is "low mood, sadness, difficulty falling asleep, frequent sigh, fatigue, lack of appetite, deep and wiry pulse"; the indication for Gui Zhi Jia Long Gu Mu Li tang is "vertigo, hair fall, abdominal pain, sperm emission, light tongue, thin white coating, deficient or slow pulse"; and the indication for Gui Zhi Tang is "difficulty falling asleep, bad sleep quality, frequent dreams, frequent awakenings, vulnerability to catch cold, palpitations, breathlessness and sweating after effort, vertigo".

According to the clinicians, Disharmony between Nutritive and Protective can be diagnosed when there is no significant imbalance between *yin* and *yang* (1) or no significant deficiency (1), and especially in case of external affection (1).

# 5. Heart and Gallbladder Deficiency

#### 5.1. Definition of H-G Def

The Heart and Gallbladder Deficiency pattern is also called Heart Deficiency and Timidity pattern.

This pattern is not typical as it represents a psychological characteristic, literally a small-gallbladder (danxiao 胆小), which can be translated as timidity, cowardice or lack of courage. It is also associated with an inability to make decisions (jueduan 决断), which is the function of the gallbladder. This pattern is associated with psychological disorders such as depression or neuroticism (1).

#### 5.2. The pathological mechanism of H-G Def

Heart and Gallbladder Deficiency is mainly caused by

- Constitutional weakness (15) manifested by a tendency to be easily frightened (6), introversion (1) and a sensitive personality (1)
- 2. Sudden panic (14) related to a trauma
- 3. Excessive emotions (1) and
- 4. Severe or long-term diseases (1)

The mechanism of this pattern is vaguer, as the direction of the pattern in terms of deficiency/excess and heat/cold is not as clear as in other patterns. The "deficiency" in the name of the pattern shows a tendency toward deficiency pattern, however both tonifying herbs and eliminating herbs are used for this pattern. Heart and Gallbladder Deficiency is associated with

- 1. Qi and blood deficiency (2)
- 2. Liver stagnation (2)
- 3. Phlegm (2)
- 4. Liver blood deficiency (1)
- 5. Yang deficiency (1) and
- 6. Spleen deficiency (1)

#### 5.3. Diagnostic features of H-G Def

The SSs associated with Heart and Gallbladder Deficiency are shown in Figure 4. These are mainly psychological symptoms and physical symptoms related to anxiety such as breathlessness, palpitations, sweating and fatigue.

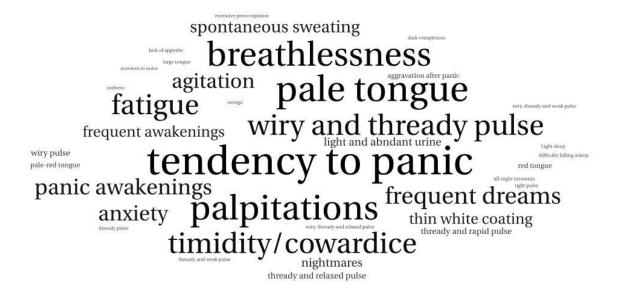


Figure 4. Signs and symptoms associated with Heart and Gallbladder Deficiency

#### 5.4. Prescriptions for H-G Def

The formulas used to treat Heart and Gallbladder Deficiency are

- 1. An Shen Ding Zhi Wan (20)
- 2. The combination of An Shen Ding Zhi Wan with Suan Zao Ren Tang (9)
- 3. Chai Gui Wen Dan Ding Zhi Tang (1)
- 4. The combination of Sheng Mai San and Suan Zao Ren (1)
- 5. Xiao Chai Hu Tang (1)
- 6. Bu Xin Zhuang Dan An Shen Tang (1)
- 7. Gan Dan Liang Yi Tang (1)
- 8. Wu You Tang (1)
- 9. Hu Zhu San (1)
- 10. Wen Dan Tang (1) and
- 11. Several self-designed formulas

The composition of the formulas of this pattern is mainly a mix of spirit-calming herbs (including both heart-nurturing and heavy-sedative herbs) and *qi*-tonifying such as *renshen*, *dangshen* and *gancao*. Sometimes, phlegm-transforming, blood-nurturing, heat-clearing and liver-draining herbs are added to the formula.

#### 6. Interpretation and discussion

The five atypical patterns identified in this study represent five important concepts in the pathology of insomnia. As the conceptual architecture of these concepts is different from the mainstream organ diagnosis system (e.g., liver fire, kidney deficiency), they are not represented by a core group of herbs and therefore not detected by the cluster analysis.

Being said, their relationships with the typical pattern system vary widely. Non-Int H-K is very similar to the typical pattern Yin-Def-Fire as it is built on the same main pathological mechanisms, i.e. kidney deficiency and heart fire. The only difference is that Non-Int H-K integrates middle *jiao* issues, which block the communication between heart and kidney. H-G Def has no direct relationship with any typical pattern as its main formulas An Shen Ding Zhi Wan and Suan Zao Ren Tang tend to jump from one typical pattern to another depending on the parameters of the cluster analysis.

The clarity of the definition of these atypical varies greatly. Qi/Yang Def has very strict categories with clear explanations regarding the pathological mechanism. This is not the case for N-P Dis, for which there is no clear consensus on what it is, why it causes insomnia and how to manage this pattern. The term "stomach" disharmony can refer to various situations (indigestion or chronic digestive condition) and different conceptual levels (symptom or mechanism).

Despite being composed of 67 formulas, which makes it larger than most typical patterns, Qi/Yang Def is completely absent from current textbooks and guidelines. This may be because it challenges the idea that insomnia is a condition in which "the [excessive] *yang* cannot penetrate the [deficient] *yin*". According to mainstream views, using tonic herbs for insomnia is somehow taboo. This study shows that this is not completely true, tonic and warm herbs should be used when appropriate.

These herbs have yet to be used carefully and to be combined with heavy sedative herbs or richtonifying herbs.

The Sto Dis pattern spreads across various typical patterns such as Liver Stag, L-S Def, Phlegm-Heat and H-S Def. This shows that although there is no typical pattern of insomnia focused on the spleen-stomach, regulating the spleen and stomach is a background strategy that has to be considered for various patterns (see also chapter 11 Clinical Note on the Use of Herbs).

# Chapter 4 Disease-Based Treatment with Herbal Medicine

In CHM, clinical diagnosis can use a pattern differentiation or a disease differentiation approach. In the pattern differentiation approach, a global clinical phenotype is determined through the analysis of signs and symptoms (SSs). Multiple individualized treatments can be proposed for the same disease (e.g., insomnia), according to the clinical phenotype.

Pattern differentiation is considered the more effective approach but is difficult to implement due to the variations of pattern definitions and classifications. The pattern differentiation is also more easily subject to misdiagnosis due to the similarity of different patterns. In contrast, the disease differentiation approach proposes one standardized formula for a particular disease (e.g., insomnia) regardless of the SSs of the patient. This approach, which has been recorded by the *Prescriptions for Fifty-Two Diseases* from the Han dynasty, may be the oldest diagnostic approach in Chinese medicine and has been consistently used until nowadays.

The guidelines for the treatment of insomnia do not however, propose treatment protocols based on disease differentiation, possibly because standardized treatments are considered to reflect poor clinical reasoning. As such there is a lack of documented protocols to guide consistent practice despite the widespread use of the disease differentiation in the clinic. This section categorizes the protocols based on disease-differentiation (not on clusters of signs and symptoms) as reported in clinical experience reports. We investigated the reason why clinician found appropriate to use a single formula to treat insomnia.

#### 1. Overview

Sixty-one clinical experience reports provided a single-formula protocol for the treatment of insomnia with Chinese herbal medicine. These 61 main formulas were composed of 705 herbs in total (Figure 4-1). The most commonly recommended herbs (with number of formulas in brackets) are gancao (43), suanzaoren (43), fuling (30), chaihu (26), chuanxiong (25), shouwuteng (21), longgu (20), yuanzhi (20), baishao (19) and banxia (19). Except the ingredients of Suan Zao Ren Tang, we can observe spirit-calming herbs (shouwuteng, longgu, yuanzhi), liver-draining herbs (chaihu, shaoyao) and banxia. We can point out that some clinicians consider chaihu, baishao and banxia to be spirit-calming herbs (see the article on "Spirit-Calming Herbs").



Figure 4-1. Herbs of the main formulas. The size of the word is proportional to the number of formulas in which the herb is present.

#### 2. Main formula

In the disease approach, a main formula is used regardless of the SSs of the patient and can be modified according to the pattern. The 61 main formulas we identified were categorised into four categories, i.e. "Shen-Calming", "Big and Diverse", "Liver-Draining", and "Suan Zao Ren Tang". These four categories included 51 formulas (84% of the total), among which four formulas were part of both the "Liver Draining" and "Big and Diverse" categories.

#### 2.1. Shen-Calming formulas

Some clinicians gather different kinds of herbs that have *shen*-calming effect into the same formula as a treatment of insomnia. This category is the largest of the disease-based approach, including 23 formulas. It was defined as formulas having at least 50% of herbs with *shen*-calming effects in the composition. The 9 core herbs of these formulas are

- 1. Suanzaoren (83%)
- 2. Gancao (48%)
- 3. Yejiaoteng (44%)
- 4. Longgu (44%)
- 5. Muli (44%)
- 6. Fushen (39%)
- 7. Baiziren (39%)
- 8. Fuling (35%) and
- 9. Yuanzhi (35%)

#### 2.2. Big and Diverse formulas

Some clinicians combined herbs with different effects such as *yin*-nurturing, liver-draining, phlegm-transforming and of course spirit-calming into the same formula. These formulas have usually a large number of ingredients compared to the other categories and we called them "Big and Diverse" formulas. We included in this category 15 formulas which have at least 13 ingredients and have ingredients from at least 8 herb categories. The 17 core herbs of this category are

- 1. Suanzaoren (80%)
- 2. Gancao (67%)
- 3. Yuanzhi (67%)
- 4. Chaihu (60%)

- 5. Fuling (60%)
- 6. *Chuanxiong* (53%)
- 7. *Yejiaoteng* (53%)
- 8. Baishao (53%)
- 9. Longgu (47%)
- 10. Zhizi (40%)
- 11. Dangshen (40%)
- 12. Banxia (40%)
- 13. Muli (40%)
- 14. Hehuanpi (40%)
- 15. Fushen (33%)
- 16. Changpu (33%) and
- 17. Baiziren (33%)

#### [The text was cut here]

# 4. Interpretation and discussion

Pattern-differentiation is usually praised as the unique or best diagnostic and therapeutic approach. In this context, it can be surprising that so many clinicians propose a disease-based approach. What is then the rationale behind this use? We can obviously only speculate on the rationale behind the disease approach, which may include the following

#### 4.1. Calming the shen

Shen-calming herbs, which by definition help people sleeping better, are used consistently by all clinicians for insomnia regardless of the pattern. However, the mainstream position is that shen-calming herbs should not be overused when treating insomnia (see chapter 9 Shen-Claming Herbs). Nevertheless, using shen-calming formulas as the main formula in the disease approach is not surprising and shows that a symptomatic approach to the treatment of insomnia can be a

therapeutic option. Indeed, 70% of the most common herbs in the disease approach are *shen*-calming herbs and 100% of them have *shen*-calming effects.

This rationale does not only explain the Shen-Calming Formulas category, it is also visible in other categories of disease-based treatment. Suan Zao Ren Tang has two herbs with *shen*-calming effects, i.e. *suanzaoren* and *fuling*. The majority of the core herbs of the Big and Diverse formulas are *shen*-calming herbs. *Shen*-calming herbs were also used consistently in every pattern of the pattern-based treatment. All the question is really about what ratio of *shen*-calming herbs do we want to use. Most clinicians use around 15% of *shen*-calming herbs in the pattern-based approach, but this ratio can exceed 50% in the *Shen*-Calming Formulas category.

#### 4.2. Targeting the core mechanism

In the chapter 2 Pattern-Based Treatment of Insomnia with Chinese Herbal Medicine we already discussed about the three pathological systems of insomnia. The core mechanism of the largest system is liver *qi* stagnation, which is associated with liver fire and blood deficiency and can lead to phlegm-heat and blood stasis (see chapter 2).

Formulas such as Xiao Chai Hu Tang and Xiao Yao San target this core mechanism and can be adapted if the patient presents other patterns such as phlegm-heat, liver fire or spleen deficiency. Interestingly, liver *qi* stagnation is a minor pattern in the pattern-based approach yet is a major aspect in the disease approach, not only for Liver-Draining formulas but also in the Big and Diverse formulas, and to a certain extent in Suan Zao Ren Tang formulas. This shows that although insomnia patient rarely present with a typical pattern of Liver Qi Stagnation, liver *qi* stagnation is omnipresent in the pathological mechanism of insomnia and needs to be addressed.

Interestingly, *yin*-nurturing, heat-clearing herbs and *qi*/blood tonics are relatively absent from the disease-based formulas. This may further indicate the prevalent position of the liver stagnation system over the *yin*-deficiency with fire system and the heart and spleen deficiency system. In this

regard, yin-nurturing and heat-clearing formulas and *qi*/blood tonifying formulas may not be appropriate to use regardless of the pattern and should be used only on the basis of the pattern.

#### 4.3. Using a flexible formula

In the cluster analysis of the pattern-based formulas (see article "Pattern-Based Treatment with Herbal Medicine"), we found that some formulas generate consistently a pattern regardless of the parameters of the analysis and some other fomulas jump from one pattern to another depending on the parameters of the analysis. For example, Gui Pi Tang quite consistently leads the "Heart and Spleen Deficiency" pattern and "Xue Fu Zhu Yu Tang" can almost always form a cluster of its own. On the other hand, Suan Zao Ren Tang would jump from the "Yin Deficiency with Fire" pattern to the "Liver-Spleen Disharmony" pattern or the "Liver Stagnation" pattern.

The reason is that, in terms of composition, Suan Zao Ren Tang does not have a clear direction. It is composed of one *shen*-calming herb, one blood-moving herb, one diuretic herb, one heat-clearing herb and one tonifying herb. Although Suan Zao Ren Tang is sometimes considered to be indicated for "Liver Blood Deficiency", it is not clearly oriented toward this pattern. This makes Suan Zao Ren Tang an ideal formula in the disease-based approach as it can be easily adapted to the situation of the patient. It can link the "liver stagnation system" with the "*yin*-deficiency with fire" system, and even, arguably, the "heart and spleen deficiency" system.

This flexibility is not only observed in Suan Zao Ren Tang but also to some extent in Xiao Chai Hu Tang and Xiao Yao San, which have many famous modifications such as Chai Hu Gui Zhi Tang, Chai Qin Wen Dan Tang, Dan Zhi Xiao Yan San, Hei Xiao Yao San, etc. It shows that these formulas are appropriate in the disease-based approach as they can be relatively easily adapted to the specific condition of the patient.

#### 4.4. Covering all pathological aspects

The main formula of the Big and Diverse group has on average 17 herbs, which is two times bigger than the average number of herbs in the main formula of the pattern-based approach. They include diverse types of herbs such as *yin*-nurturing, blood-nurturing, liver-draining, fire-draining, *shen*-calming, phlegm transforming, etc. The reason for mixing such different herbs in the formula is unclear. It may be that clinicians are trying to catch all the possible mechanisms of insomnia at the same time and ensure that they cover every single aspect of the condition.

It is not uncommon to have patient manifesting multiple patterns at the same time. Moreover, as clinical diagnostic methods are always limited, not being able to identify a certain pattern does not mean that the patient does not have this certain pattern. In this context, being conservative and trying to cover a pathological area as large as possible somewhat makes sense.

#### 4.5. Personal understanding of the core mechanism of insomnia

Clinicians understand clinical phenomenon through their own experience and beliefs. Because of these biases, they may think that the core mechanism of insomnia is either phlegm-heat, blood stasis or *yin* deficiency with fire. As this is not a widespread position, only one or two formulas can be grouped under the same mechanism or pattern, which is not enough to create an identifiable group of formulas. This is a why these formulas remained unclassified.

The only mechanism that could reflect a shared understanding of the core mechanism of insomnia is liver stagnation, as 10 liver-draining formulas were identified in the disease-based approach.

#### 4.6. Conclusion

According to this study, "disease-differentiation" is not merely a symptomatic approach based on Western medicine pathology and pharmacology. It may reflect the attempt of the clinician to grasp the core mechanism of insomnia, using a flexible formula that can be easily modified according to the patient or trying to cover as many aspects of the pathological mechanism as possible. Even though it may not be the most effective approach, it may be the best choice when pattern diagnosis is not clear or not available. Anyway, investigating the rationale behind the use of disease-based

treatment can deepen our understanding of the condition and provide additional tools to the therapeutic palette.

# Chapter 5 Treatment Adaptation According to the Person, the Season and the Location

In Chinese medicine, treatments can be adapted according to the features of the person, according to the season and according to the location. This is called the "triple adaptation (*sanyin zhiyi*)" principle. In this chapter, we present the specific methods for the triple adaptation relevant to the treatment of insomnia.

# 1. Treatment adaptation according to the person

The treatment can be adapted according to the age, the sex, the constitution, the personality and the comorbidities of the patient.

#### [The text was cut here]

#### 1.4. Personality of the person

Some personality traits such as sensitivity, introversion, emotional instability, and being conservative or stubborn traits all increase the vulnerability to insomnia (1). One of the reason is that being sensitive and not adaptive enough increases the probability of external stimuli to provoke emotions (1). More generally, different personality traits act as a "ground" for certain types of insomnia. For example, timid and coward people are subject to panic, which can lead to panic-type insomnia (1). This type of insomnia has to be treated with heavy-sedative spirit-calming herbs (1). More common patterns and their "ground" personality traits are summarized in Table 5-2.

Pattern	Personality trait	
Heart and Spleen Deficiency	Introverted and prone to thorough consideration (1)	
Heart and Gallbladder Deficiency	Introverted, easily frightened and timid (1)	

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Liver Qi Stagnation

Introverted (3), irritable (2), depressed (2) and sentimental

(1)

Heart and Liver Fire

Irritable (1)

Congestion of Phlegm and Qi

Suspicious (1) and worried (1)

Table 5-2. Common patterns of insomnia and their "ground" personality traits.

#### 1.5. Comorbidities of the person

The complex question of comorbidities is covered in another article, i.e. "Managing Comorbidities".

# 3. According to the location

According to the clinicians, the location can influence people's constitution in three ways, i.e. the climate, local food and local culture. For example, a humid climate tends to create dampness, high-fat and sweet local food creates dampness, and a high-paced culture tends to create liver congestion. Sometimes the combination of climatic and cultural factors creates the pathological mechanism, e.g. humid climate with spicy food and hot climate with high-fat food can both create dampness-heat. The location can be considered in three ways:

- 1. Direct cause of a pathological mechanism (i.e., a pattern)
- 2. Increases the vulnerability of the person to a certain pattern
- 3. Background factor that has to be taken into consideration (e.g., adding *qi*-moving herbs such as *muxiang* and *zisugeng* when treating *qi* and blood deficiency in a patient from the humid South-of-Mountains region)

The influence of the location on the pathological mechanism of insomnia is shown in Table 5-.

Region	Local factor	Pattern
South-of-Mountains ( <i>Lingnan</i> ), roughly Guangdong and Guangxi provinces	Humid and hot climate (4), eating sweet food (1) and cold tea (1), high-paced and stressful lifestyle (1).	Phlegm-heat (4), dampness (2), spleen deficiency (1), liver congested fire (1) and yin deficiency (1)
Sichuan	Humid climate (1), high-fat and spicy food (1)	Phlegm-dampness (1)

	Chinese Medicine for Insomnia Clinical Experience Synthesis	
Hunan	Humid climate (1) and spicy food (1)	Phlegm-heat (1)
Xinjiang	Hot and dry climate (1) and high-fat, sweet, meat-rich and roasted food (1)	Dampness-heat (1)
Yunnan	Cold and humid climate (1)	Cold-dampness (1)

Table 5-3. Local factors and pattern caused in different regions.

### 4. Interpretation and discussion

We can see from the above that the characteristics of the patient, the season and the location have an influence on the clinical reasoning of the clinicians yet do not determine the main diagnosis and the main treatment for insomnia. The main treatment is usually pattern-based (on the basis of groups of signs and symptoms) or disease-based (on the basis of the pathological characteristics of insomnia).

The patient's characteristics, the season and the location can help the clinician to understand the pathological mechanism of insomnia, which can influence pattern diagnosis and the subsequent treatment. For example, if the patient is a menopausal woman, the gradual consumption of essence and blood leading to effulgent fire can be considered as a potential mechanism. If the patient is introverted, the possibility of liver *qi* stagnation should be considered. If the patient comes from a region where people eat high-fat, sweet and spicy food, phlegm-heat should be considered.

The patient's characteristics, the season and the location can be the direct cause of insomnia, can have an influence on the vulnerability to have insomnia and can influence the type of pattern of the patient. It can also be a background information to keep in mind when treating patients. For example, not using excessively dry herbs to treat menopausal women, who have a tendency toward essence and blood deficiency, or adding *qi*-moving herbs when treating a patient who lives in a humid region.

In addition to the above considerations, the identification of the constitution of the patient can lead to a treatment extending beyond the limits of the disease. After remission of the symptoms, the

patient can continue to take a constitution-based treatment that will allow him to have a better health globally and prevent relapse.

# Chapter 6 Treatment According to Insomnia Subtype

There is a variation to the disease-based treatment. The treatment is based or oriented according to the specificities of the disease. In the case of insomnia, it is the main complaint or symptom, the time of the episode of insomnia, and the stage or type of insomnia. This approach is still different from the pattern-based approach, in which a pattern is identified according to signs and symptoms that may or may not be directly related to insomnia such as tongue and pulse features.

### 1. Treatment according to the complaint

There are four main complaints of insomnia: difficulty falling asleep (DFA), frequent awakenings (FA), frequent dreams (FD) and early morning awakenings (EMA). In most cases, insomnia patients present multiple symptoms at the same time and their symptoms may evolve through time.

Nevertheless, some subsets of patients present one single and persistent symptom. In this case, the type of complaint may guide the reasoning of the clinician.

#### 1.1. Difficulty falling asleep as the main complaint

Insomnia with a complaint of DFA is associated with excess pattern (2). More specifically it is associated with

- Liver or heart fire/heat (5)
- Liver or shaoyang stagnation (4)
- Phlegm (2)
- Blood stasis (2)
- Blood deficiency (2)
- Yin deficiency (2) with hyperactive yang (1)

- Non-interaction between heart and kidney (1)
- Nutritive-protective disharmony (1)

A main complaint of DFA is also associated with anxiety (2) and obsession (1).

#### 1.2. Frequent awakening as the main complaint

Insomnia with a complaint of FA is associated with deficiency pattern (1), more specifically

- *Yin*-blood deficiency (3) with liver stagnation (1)
- Heart-gallbladder qi deficiency (1)
- Qi and blood deficiency (1)
- Lung yin deficiency (1)
- Lung qi deficiency (1)
- Lung phlegm (1)

It is also associated with depression (1).

#### 1.3. Frequent dreams as the main complaint

Insomnia with a complaint of FD is associated with the liver (2) as the spirit *hun*, which is associated with dreams, corresponds to the liver. More specifically, it is associated with

- Blood deficiency (5)
- Blood stasis (3)
- Liver stagnation (3)
- Liver heat (2)
- Phlegm-heat (1)
- Yin deficiency (1).

#### 1.4. Early-morning awakenings as the main complaint

Insomnia with a complaint of EMA is associated with mostly deficiency patterns and the kidney.

More specifically it is associated with

- Yin deficiency and hyperactive yang (2)
- Kidney *yang* deficiency (2)
- Kidney *yin* deficiency (1)
- Heart blood deficiency (1)
- Heart-gallbladder disharmony (1)
- Nutritive-blood heat and liver stagnation (1)

This type of insomnia is also associated with depression (3) and cerebral vascular insufficiency (1).

#### 1.5. Quantitative analysis

In order to test the association between complaints and pattern diagnosis, we conducted quantitative analyses with the dataset of herbal formulas used on a pattern basis. We first selected the formulas in which only one of the three main complaints (DFA, FA and EMA) was expressed in the description of SSs. We then calculated for each pattern the percentage of formulas for which the specific complaint was an indication to use the formula.

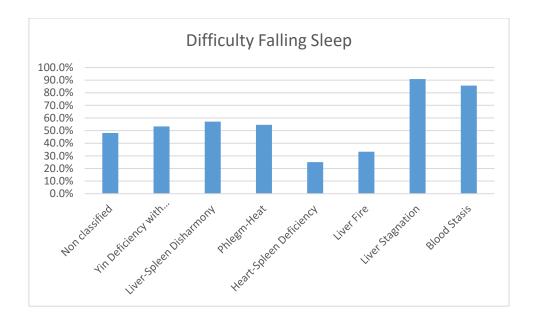


Figure 1. Percentage of formulas in which DFA was the main complaint

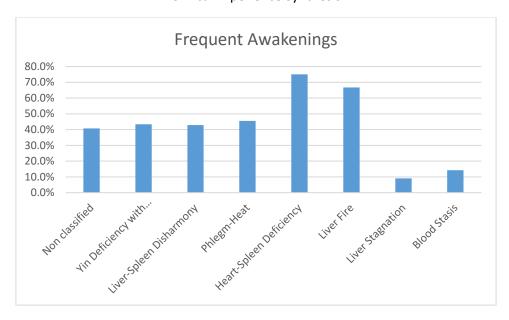


Figure 2. Percentage of formulas in which FA was the main complaint

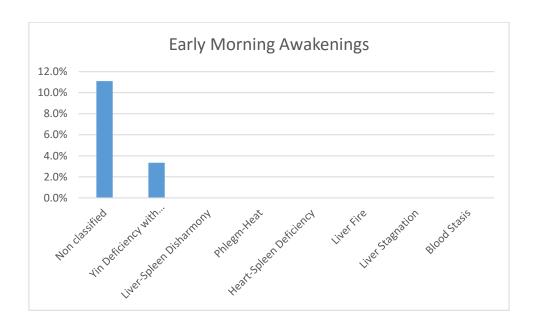


Figure 3. Percentage of formulas in which EMA was the main complaint

We can see from the results of the quantitative analysis that clinicians tended to associate Heart-Spleen Deficiency and Liver Fire with a unique complaint of DFA instead of FA. They also tended to associate Liver Stagnation and Blood Stasis with a unique complaint of FA instead of DFA. EMA was associated only with Yin Deficiency with Fire.

#### 1.6. Summary

We can see from the above that there is no strict consensus on the meaning of the complaint.

Generally speaking, DFA is associated with excess pattern and especially fire, FA is associated with deficiency pattern and especially blood deficiency, FD is associated with liver conditions and especially blood deficiency, EMA is associated with deficiency and especially kidney deficiency. DFA is also associated with anxiety while EMA is associated with depression.

## 2. Treatment according to the time of the symptoms

Insomnia can also be diagnosed and treated according to the time of the symptoms. In Chinese culture, *shichen* (i.e., couple of hours) are associated with organs. The *shichen* related to insomnia symptoms are *zi* (from 11 pm to 1 am) which is associated with the gallbladder, *chou* (1 am to 3 am) which is associated with the liver and *yin* (3 am to 5 am) which is associated with the lung.

Except the *shichen* system, the movement of the *yang* are also related to time, with the *yang* going inward in the evening, the *yin* being extreme at midnight and the *yang* going outward in the morning.

#### 2.1. Insomnia during *zi* hours

According to the clinicians, DFA occurring during the *zi* hours (11 pm to 1 am) is caused by the gallbladder-pivot being blocked (1) and has to be treated with *chaihu*-type formula (1) or Chai Hu Jia Long Gu Mu Li Tang (1).

#### 2.2. Insomnia during chou hours

If clinicians agree that awakenings during the *chou* hours (1 am to 3 am) are related to the liver (3), there is no consensus on the mechanism, which can be either an impossibility for the liver-wood to move upward and outward (1), a deregulation of liver function caused by emotions (1) or an imbalance with both heat and cold in the *jueyin* treated with Wu Mei Wan (1).

#### 2.3. Insomnia during *yin* hours

EMA during the *yin* hours (3 am to 5 am) is linked with kidney-water cold (2), the kidney *yang* floating prematurely as it is pushed by the coldness. Also, the lung-metal cannot descend as it is

blocked by the coldness (1). This condition has to be treated with warm-tonifying herbs and immersing-oppressing herbs (1).

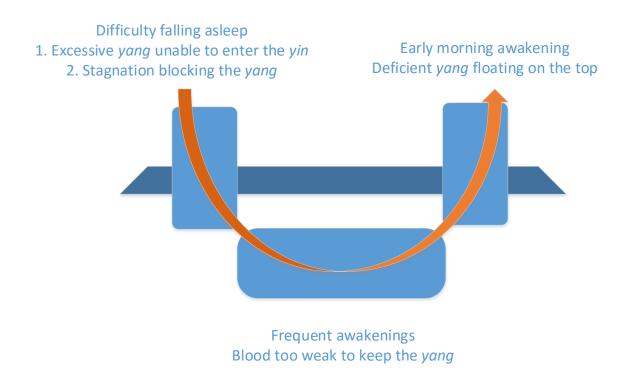


Figure 6-1. Visualisation of the mechanism of insomnia according to the main complaint

#### 2.4. Summary

We can see from the above that the association between time of insomnia episodes and mechanism are mainly driven by the *shichen* theory. However, these associations are not followed blindly as *yin*-hours insomnia is mainly associated with the kidney, not the lung which is the *yin* organ.

# 3. Treatment according to the stage

#### 3.1. Early-stage and late-stage insomnia

The treatment of early-stage or acute insomnia was reported far less than the treatment of late-stage or chronic insomnia. Unsurprisingly, early-stage insomnia is associated with excess (2) while late-stage insomnia is associated with deficiency (2). In the first case, *zhenzhumu*, *hupo* and *duan* 

*longgu* are added to a perverse-removing formula and in the second case *xiyangshen*, *ejiao* and *quiban* are added to a regular-tonifying formula (1).

The association between early-stage insomnia and excess pattern is supported by the fact that clinicians associated acute insomnia with liver stagnation (5), liver and heart fire (4), phlegm-heat (2), disturbed *shen* (2) and non-interaction between heart and kidney (1).

The association between late-stage insomnia and deficiency pattern is far less consensual. One clinician believes that the mechanism of late-stage anxiety-type insomnia is either liver stagnation with spleen deficiency or phlegm and blood stasis creating fire (1). Another clinician considers that long-term insomnia has a complex pathological mechanism (1) and has to be treated with a combination of Chinese herbal medicine combined and either Western medicine or psychotherapy (1).

#### 3.2. Persistent insomnia

#### 3.2.1. Definition of persistent insomnia

As many as 77 articles focused on persistent insomnia. The definition of "persistent insomnia" varied greatly from one article to another. Persistent insomnia is defined by

- Long duration (14)
- Resistance to treatment (7)
- Frequent relapse (3)
- Short total sleep time (3) and
- Serious social impairment (3)

The criterion for duration can be

- Undefined (9)
- More than 1 month (1)
- More than 3 months (2)

More than 1 year (1)

The criterion for short total sleep time can be less than 2 hours (2) or less than 3 hours (1).

From the above criteria, we can see that the definition of persistent insomnia is not much different from the definition of insomnia, which refer to 3-month long insomnia. In some articles, "persistent insomnia" is even used interchangeably with "insomnia" or directly defined as "insomnia". It seems that "persistent insomnia" is mostly similar to the concept of chronic insomnia, which generally last for years, rather than a particular subtype of chronic insomnia.

#### 3.2.2. Pathology of persistent insomnia

Persistent insomnia has a complex aetiology (2), including constitutional factors, the influence of the disease and its treatment (1). Mixed patterns of deficiency/excess and cold/heat can happen when for example a person with a *yang*-deficiency constitution gets congested fire because of emotions (1).

As depression (4) and anxiety (4) are intertwined with persistent insomnia, a common pathway is insomnia-induced emotions (3) provoking liver stagnation (4) which in turn can provoke other mechanisms such as phlegm, blood stasis or fire.

The patterns of persistent insomnia are

- Blood stasis (12)
- Phlegm (6)
- Yang deficiency (3)
- Yin deficiency with excessive fire (2)
- Kidney deficiency (2)
- Qi deficiency (1).

#### 3.2.3. Prescriptions for persistent insomnia

The formulae of the 77 CERs in which the treatment of persistent insomnia was reported were compared to the treatment of the general insomnia population.

In terms of herbs categories formulas for persistent insomnia included more

- Blood-activating herbs (+72%)
- Phlegm-transforming and anti-coughing herbs (+32%)

#### They included less

- Water-draining herbs (-29%)
- Blood-tonifying herbs (-12%)
- Spirit-calming herbs (-8%)

In terms of individual herbs, formulas for persistent insomnia included more

- Yinyanghuo (+554)
- Honghua (+227%)
- Jiegeng (+200%)
- Niuxi (+170%)
- Taoren (+170%)
- Cishi (+145%)
- Chishao (+121%)
- Zhiqiao (+89%)
- Shengdi (+28%)

#### They included less

- Shudihuang (-72%)
- Danpi (-58%)
- Hehuanpi (-53%)

- Wuweizi (-44%)
- Fuling (-37%)
- Zhimu (-35%)
- Baizhu (-32%)
- Suanzaoren (-28%)
- Baishao (-24%)

From the quantitative analysis, we can see that the main difference between the treatment of insomnia in general and the treatment of persistent insomnia is a tendency to use blood-moving and phlegm-transforming herbs for persistent insomnia. Interestingly, with the exception of *yinyanghuo*, tonic herbs are not more commonly used for persistent insomnia but actually less commonly used. This contradicts the idea that long-term condition present deficiency patterns.

## 4. Interpretation and discussion

The analysis of the mechanism of insomnia according to the insomnia symptoms shows there is no strict consensus about the meaning of the main complaint of insomnia or of the timing of symptoms. The quantitative and qualitative analyses of the association between main complaint and pattern are not completely consistent either. This shows that clinician should not understand the main complaint as a strict indicator of one specific mechanism or pattern but rather guide the clinical thinking toward a certain direction.

Difficulty falling asleep is generally speaking associated with heat and fire as the excessive yang is unable to penetrate the *yin*. It is also associated with liver stagnation and blood stasis as they block the penetration of the *yang* at dawn. Frequent awakenings are associated with blood deficiency as a weak blood is unable to keep the *yang* (or spirit) within itself. Frequent dreams are associated with liver pathology in general, including stagnation, blood stasis, fire and blood deficiency. Early morning awakening is associated with kidney deficiency, either *yin* or *yang* deficiency. Either the *yin* is too weak to contain the *yang* that is rising or the *yang* is pushed by the coldness of the kidney.

As the theory states that acute conditions are associated with excess and chronic conditions with deficiency, we might expect acute insomnia to be associated with fire, phlegm, and blood stasis and chronic insomnia to be associated with *yin* deficiency or *qi* and blood deficiency. This is not the case. The course of insomnia can be seen as a tree, in which the trunk is composed of liver *qi* stagnation and fire, and the branches consisting in phlegm, blood stasis and kidney deficiency. The association between persistent insomnia and kidney deficiency was even not obvious in the quantitative analysis of the characteristics of persistent insomnia. This evolution is consistent with the "liver *qi* stagnation" system (see chapter 2 Pattern-Based Treatment of Insomnia with Chinese Herbal Medicine) in which emotion-induced liver *qi* stagnation progresses to liver fire, phlegm-heat and blood stasis.

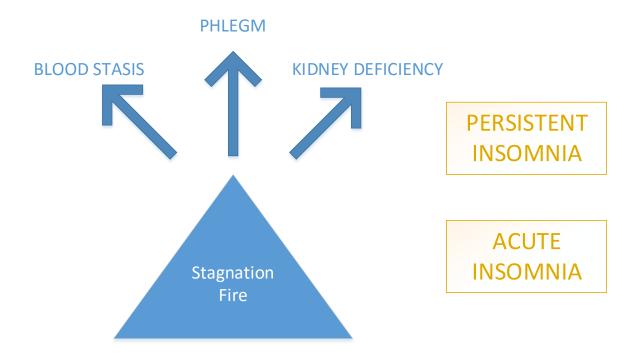


Figure 6-2. Visualisation of the mechanisms of acute and persistent insomnia

This shows that clinicians do not blindly apply the theory but take into consideration clinical observation.

# Chapter 7 Managing Comorbidities

Insomnia is strongly associated with physical conditions such as chronic pain and psychological conditions such as depression and anxiety. We call these conditions "comorbidities". As many clinicians have presented the treatment of insomnia in populations with a certain comorbidity, we were able to synthesise their perspective on the methods to manage insomnia present with comorbidities.

#### 1. Common comorbidities of insomnia

Insomnia is often present along other medical conditions, i.e. comorbidities. These comorbidities are

- Diabetes (12)
- Depression (9)
- Hepatic conditions (7)
- Anxiety disorder (5)
- Coronary heart disease (4)
- Stroke sequels (4)
- Gastric conditions (4)
- Respiratory conditions (3)
- Hypertension (3)
- Cardiac arrhythmias (3)
- Cervical spondylosis (2)
- Chronic kidney failure (1)
- Female urethral syndrome (1)
- Parkinson's disease (1)
- Prostatic hypertrophy (1)

- Cerebral arteriosclerosis (1)
- Brain trauma (1)
- Autism (1)
- Obsessive-compulsive disorder (1)
- AIDS (1)
- Cancer (1)
- Heart failure (1)
- Myocarditis (1)
- Chronic diarrhoea (1)

# 2. Relationship between insomnia and the comorbidity

According to the clinicians, these comorbidities are either present before the start of the insomnia or at the same time, but never developed on the basis of insomnia. The causality between insomnia and the comorbidity is more complex. Insomnia and the comorbidity can be either not related or have the same aetiological and pathological pathway (Table 7-1). In both case there is no cause or consequence. The most common relationship is the comorbidity (or primary disease) being the cause of insomnia. According to clinicians, insomnia does not cause the comorbidity but can sometimes aggravate it.

Comorbidity	Common aetiological and pathological pathway	
Diabetes	Phlegm-dampness and inner heat	
Diabetes	Excessive diet, emotions, work-life imbalance	
Diabetes	Yang deficiency	
Anxiety	First liver stagnation producing fire, then phlegm, blood stasis, spleen deficiency and blood deficiency	
Anxiety	Lack of yin and blood with deficient fire rising	
Anxiety	Non-interaction between heart and kidney	
Depression	Disharmony of heart and gallbladder	

Obsessive-compulsive disorder Stagnating fire of shaoyang

Coronary heart disease Liver stagnation, spleen deficiency and blood stasis

Coronary heart disease Phlegm and blood stasis

Cardiac condition (coronary heart disease, myocarditis, arrhythmia)

dition (coronary heart Emotions, mental strain or catching cold

Palpitation Gallbladder or stomach impairment

Hypertension Liver-kidney deficiency, hyperactive liver yang, phlegm-heat

Respiratory condition Lack of rest and inappropriate treatment of cold, emotions

and mental strain

Table 7-1. Common aetiological and pathological pathways of insomnia and the comorbidity.

We have identified five ways in which the comorbidity (or primary disease) is a basis for the development of insomnia.

- The first possibility is insomnia being a symptom of the primary disease,
   e.g. depression (2) or chronic hepatitis B (1).
- 2. The second possibility is that the insomnia is caused by a symptom of the primary disease.

  e.g. stomach discomfort (4), frequent urination (4), bodily pain (3), cough or dyspnoea (2), itching (2), thoracic pain (1), diarrhoea (1), abdominal bloating (1), pain in the liver area (1), palpitations (1), sleep apnoea (1), and teeth pain (1).
- 3. The third possibility is that the primary disease leads to emotional distress (i.e., excessive despair, anxiety and rumination), which then causes insomnia. This emotional distress is due to an incorrect view of the disease, worry about relapse or aggravation, financial burden, social despise and pressure, adverse reactions from treatment, the stress of constantly monitoring the disease (e.g., glycaemia for diabetics).
- 4. The fourth possibility is that the treatment of the primary disease causes insomnia. For example, in the case of cancer, chemotherapy can harm the *qi* and blood, which leads to insomnia (1).
- 5. The fifth possibility is the evolution of the pathology of the primary disease (Table 4). Both the original mechanism and the evolution of the disease are extremely varied. For example,

*yin* deficiency can lead to fire; *qi* stagnation and heat can provoke phlegm, fire and blood stasis; fire can consume *yin* and blood; the source of *qi* and blood can be impaired.

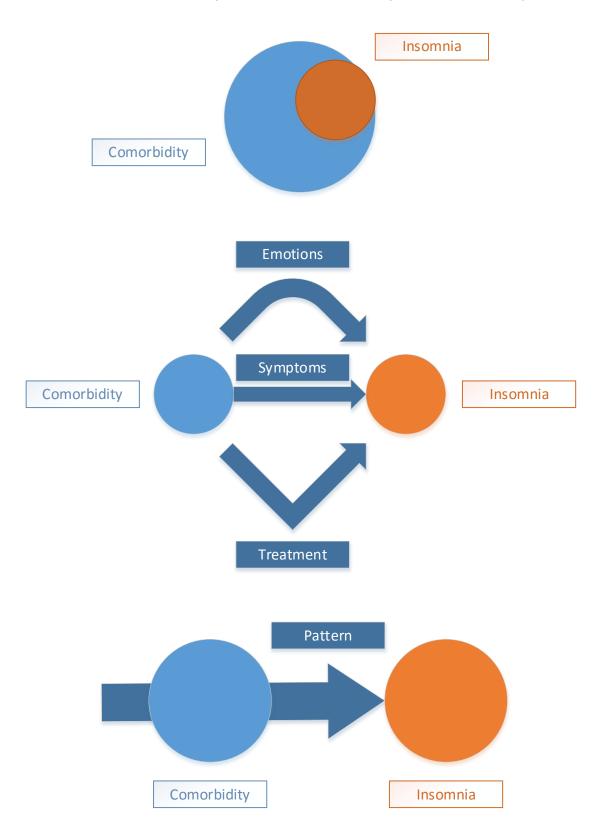


Figure 7-1. Visualisation of the causality relation between insomnia and comorbidities

Primary disease	Aetiology and mechanism	Evolution
Diabetes (9)	Yin deficiency with dryness-heat (4); excessive diet creating phlegm-dampness overwhelming spleen and excessive emotions impairing the liver (1); qi and yin deficiency	Phlegm and phlegm-heat (6); blood stasis (4); liver stagnation producing fire (3); fire disturbing the heart (2); liver blood deficiency (1); <i>qi</i> and blood deficiency (1)
Stroke (3)	Heat, phlegm, blood stasis, deficiency and inner wind (1); phlegm-heat (1)	Blood stasis (1); phlegm-heat (1); yin-yang deregulation (1)
Hepatic condition (3)	Dampness-heat and liver stagnation (1)	Liver <i>qi</i> stagnation (2); dampnessheat in the liver meridian (2); liver blood deficiency (2); spleen unable to produce blood (1); <i>yin</i> deficiency with effulgent fire (1); liver stagnation producing fire (1) and phlegm-fire (1)
Digestive disorder (2)	Excessive emotions impairing the liver, which harms the spleen (1)	Stomach disharmony (1); <i>qi</i> and blood deficiency (1); phlegmdampness (1)
Respiratory conditions (2)	Stagnation, heat, phlegm, dryness or coldness in the lung (1)	The lung <i>qi</i> cannot produce the blood (2)
Chronic renal failure	The kidney is not able to transform the turbid, which blocks the three burners	The <i>qi</i> and blood are deficient or do not circulate well
Parkinson's disease	Liver-kidney <i>yin</i> deficiency	Excessive heart fire
Cervical spondylosis	External affection of wind, cold and dampness, trauma or chronic damage leads to contraction of tendons and joint displacement	The <i>qi</i> and blood cannot irrigate the brain
Cerebral arteriosclerosis, cervical spondylosis, brain trauma, hypertension		Blood stasis
Depression	Liver stagnation due to irregular emotions	Stagnating fire harming the yin
Autism	Heart, liver, spleen and kidney functions impairment, phlegm and blood stasis	Yin-yang imbalance and abnormal circulation of nutritive and protective

Table 7-1. Aetiology and mechanism of the primary disease and evolution leading to insomnia.

Insomnia can also aggravate the comorbidity (i.e., stroke, coronary heart disease) by

- Disrupting the endocrine system (1)
- Creating anxiety (2)
- Exciting the sympathetic system (1)
- Increasing insulin antagonist hormones (1)

As one of the clinicians put it "it is hard to differentiate which one is the cause and which one is the consequence".

#### 3. Treatment of comorbid insomnia

#### [the text was cut here]

# 4. Interpretation and discussion

Among the comorbidities that were described by the clinicians, we can find conditions that are known to be associated with insomnia such as mental disorders and neurological diseases. From a biomedical perspective, there is no direct association between insomnia and cardiovascular diseases, diabetes, liver conditions and digestive conditions. However, in Chinese medicine these conditions can be related. Cardiovascular diseases and insomnia both involved the "heart" and therefore share common pathological pathways. In diabetes and liver conditions, the pattern can evolve and lead to insomnia (this may involve complex endocrine, neurological and immunologic mechanisms). Finally, digestive conditions are associated with insomnia from the Chinese medicine perspective of "when the stomach is not in harmony, the sleep is agitated".

Interactions between insomnia and the comorbidity are complex and involve the two conceptual levels of "pattern" and "disease". Insomnia and the comorbidity can be unrelated. In this case, the clinician has the choice to treat insomnia without targeting the comorbidity, focus on the main condition and add herbs to target the secondary condition, or use a mix of two formulas that target each condition. If the two conditions share a common pattern, the treatment has to focus on the pattern. This is the most common situation. Finally, if insomnia is caused by the comorbidity (or

primary condition) then the treatment should target the comorbidity, with eventually the use of shen-calming herbs as a disease-based treatment.

# Chapter 8 Cooking, intake methods and treatment duration

# 1. Cooking methods for insomnia patients

Only a few recommendations on the cooking of the herbs method. These are cooking spirit-calming herbs for a longer time (1) and asking the family to cook the herbs in order to avoiding exhausting the patient (1).

## 2. Timing of the intake

In terms of time of intake, it is usually recommended to take the herbs once in the afternoon and once in the evening (8) instead of the traditional morning-evening intake. The reason for this are

- To attain an optimum blood concentration (3)
- To adhere to the natural rise of the *yin* during the second half of the day (2)
- To increase the strength of the treatment without having to increase the dose (1)
- To avoid daytime sleepiness (1)

The precise time can be 2 pm (1) or 4 pm (1) for the afternoon intake and 8 pm (1), 9 pm (1), 1 to 1.5 hours before bedtime (1) or 2 hours before bedtime (1) for the evening. It is also possible to take the first cooking (which is more concentrated) 2 hours before bedtime and the second cooking (which is less concentrated) in the morning (3).

Other alternatives include

- Taking the herbs three times a day, either before the meals (1) or twice during daytime and once at night (1)
- Taking all the herbs at once (2), especially in case of severe case (1)

# 3. How to deal with weak patients?

If the patient is weak (1) or if he/she has stomach conditions (1), he/she should take low doses of decoction frequently. If the patient cannot handle decoctions, herbal infusions can be used instead (1).

#### 4. Before or after meals?

It is preferable to take the decoction before the meal in case of

- Deficiency pattern such as Heart-Spleen Deficiency, Liver Blood Deficiency or Liver-Kidney
   Deficiency (1)
- Phlegm-Dampness or Phlegm-Heat as the herbs will help to regulate the stomach during the meal (1)

It is preferable to take the decoction after the meal in case of

- Congested fire in the upper part of the body as it would provoke vomiting if taken before the meal (1)
- Blood stasis as qi-moving herbs and blood-activating herbs can damage the stomach (1)

# 5. Using different formulas in the same day

Taking different formulas during daytime and night-time is another alternative (4). The night-time formula can either be the same formula added with heavy-sedative herbs (1) or a completely different formula (3). In this case, the daytime formula mainly regulates the movements of the qi (1),

regulate the *yinyang* (1) or regulate the liver (1), and the night-time formula appearses the spirit (2) or drains the liver and appearses the spirit (1).

# 6. Duration of the treatment

The duration of the treatment is rarely mentioned by clinicians. According to them, the treatment has to be taken for 1-2 weeks (1), 2 weeks (1) or 2-4 months (1).

# Chapter 9 Shen-Calming Herbs

Shen-calming are herbs which, by definition, have a calming or inhibiting effect on the spirit or shen. Pharmacological studies found that many of these herbs have sedative and hypnotic effects. They are used on a symptomatic basis to treat palpitations and insomnia. There are two categories of shen-calming herbs, the heavy-sedative herbs and the heart-nurturing herbs. Additionally, many herbs which do not belong to the category of shen-calming herbs such as fuling have shen-calming effects.

#### 1. Overview

As the disturbance of the spirit is one of the main features of insomnia, using spirit-calming herbs for the treatment of insomnia is not surprising. In most cases, clinicians recommend to use spirit-calming herbs on the basis of pattern differentiation (25). Many clinicians recommended to avoid treatment with mainly spirit-calming herbs (10) or even to limit their use (3), especially the use of heavy-sedative herbs (3). They explained that the efficacy of this approach is low (2), especially for moderate and severe types of insomnia (1). Only one clinician recommended to use a spirit-calming formula as the main formula (1).

### 2. Categories

Except the two main categories of spirit-calming herbs (heart-nurturing and heavy sedative), two other categories of spirit-calming herbs have been proposed by the clinicians, i.e. stagnation-eliminating and orifice-opening (Table 1). The stagnation-eliminating spirit-calming herbs are indicated when there is both liver *qi* stagnation and a disturbed spirit, while the orifice-opening spirit-calming herbs are indicated when there is loss of memory.

Some other herbs are known for their spirit-calming properties but are not classified in any category, therefore we labelled them "other typical spirit-calming" herbs. Finally, some herbs that are not considered to have spirit-calming properties were identified by the clinicians as spirit-calming. This is the case for *banxia* (5), *huanglian* (3), *chaihu* (1), *kushen* (1), *baishao* (1) and *chantui* (1). These herbs were identified as spirit-calming on the basis of either individual experience or pharmacological studies.

Heart- nurturing	Heavy- sedative	Stagnation- eliminating	Orifice- opening	Other typical	Atypical
suanzaoren baiziren yejiaoteng hehuanpi hehuanha longyanrou lianzirou lingzhi	longgu muli zhenzhumu cishi hupo zhusha longchi zibeichi shengtieluo	huashengye hehanhua hehuanpi gansong suxinhua	changpu yuanzhi	fuling fushen xiecao wuweizi	banxia huanglian chaihu kushen baishao chantui

Table 9-1. Different categories of shen-calming herbs



Figure 9-1. *Shen*-calming herbs used in the pattern-differentiation approach. The size of the word is proportional to the frequency of use. The colour represents the category. Orange = heart-nurturing,

Grey = heavy-sedative, Green = stagnation-eliminating, Red = orifice-opening, Blue = other typical shen-calming.

The type of shen-calming herb used has to be chosen according to

A. The duration and severity of the disease

Heavy-sedative herbs for short-term (2) and severe conditions (1), and heart-nurturing for long-term (2) and mild conditions (1)

B. The pattern of the patient (3)

Use *qi*-moving, blood-moving or phlegm-transforming *shen*-calming herbs if there is *qi* stagnation, blood stasis or phlegm (1); heavy-sedative for "moving" pattern and heart-nurturing for "quiet" pattern (1), or heavy sedative for excess pattern and heart-nurturing for deficiency pattern (1).

There is a debate on this last point as some clinicians recommend to use heavy-sedative herbs (5) or heart-nurturing herbs (5) on a disease differentiation basis regardless of the pattern. A possible explanation is that both types of *shen*-calming herbs can be used for any type of insomnia but are more appropriate for some types of insomnia. Indeed, one clinician mentioned that *suanzaoren* is more appropriate for Yin Deficiency but can be used for other patterns when used in combination with other herbs.

# 3. Use of shen-calming herbs according to the pattern

3.1. Use of shen-calming herbs according to excess or deficiency patterns

In order to test the hypothesis "heavy-sedative herbs are recommended mostly (or only) for excess patterns and heart-nurturing herbs are recommended mostly (or only) for deficiency patterns", we analysed the relationship between the use of this herbs and the degree of deficiency/excess of the

pattern. The degree of deficiency/excess of the pattern was defined as the percentage of tonic herbs (such as *renshen*, *dangqui*, etc.) in the formula.

The percentage of heart-nurturing, heavy-sedative, typical (including heart-nurturing, heavy-sedative, stagnation-eliminating, orifice-opening and other typical *shen*-calming herbs) and all *shen*-calming (including both typical and atypical spirit calming herbs) herbs according to the percentage of tonic herbs (which reflects the excessive of deficient nature of the pattern) is shown on Figure 2.

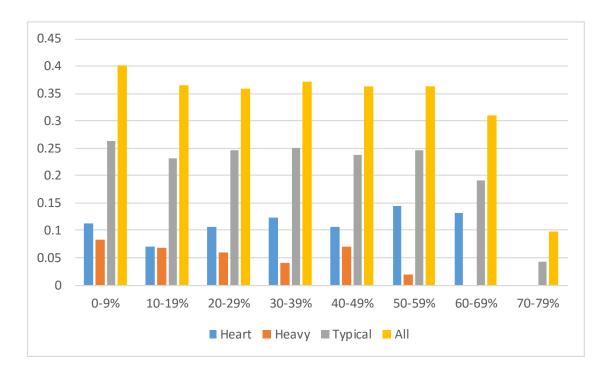


Figure 9-2. Categories of *shen*-calming herbs used according to the percentage of tonic herbs. The Y-axis represents the proportion of *shen*-calming herbs in the formula while the X-axis represents the percentage of tonic herbs in the formula.

The percentage of tonic herbs is positively correlated (r=0.102, P=0.023) with the percentage of heart-nurturing herbs, negatively correlated (r=-0.243, P<0.001) with the percentage of heavy-sedative herbs. This means that heart-nurturing herbs are more commonly used in more deficient patterns and heavy-sedative herbs more commonly used in more excessive patterns. However, the relationship is weak.

Heart-nurturing herbs constitute around 9% of excess-pattern formulas and around 14% of deficiency-pattern formulas. The percentage of heavy-sedative herbs is relatively consistent regardless of the pattern, constituting around 6% of the formula. However, heavy-sedative herbs are rarely used for mostly deficient patterns, constituting less than 2% of the formula.

The overall percentage of typical *shen*-calming herbs and all *shen*-calming herbs is relatively consistent regardless of the pattern, except for formulas with at least 60% of tonic herbs.

### 3.2. Use of *shen*-calming herbs according to the pattern category

The percentage of heart-nurturing, heavy-sedative, typical *shen*-calming and all *shen*-calming herbs according to the pattern is shown on Figure 3.

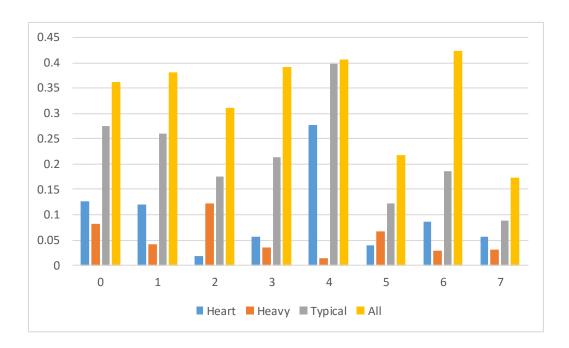


Figure 3. Categories of herbs used according to the pattern. The Y-axis represents the proportion of *shen*-calming herbs in the formula while the X-axis represents the pattern. 0 = not classified, 1 = Yin Deficiency with Effulgent Fire, 2 = Liver-Spleen Disharmony, 3 = Phlegm-Heat, 4 = Heart-Spleen Deficiency, 5 = Liver Fire, 6 = Liver Stagnation, 7 = Blood Stasis.

Heart-nurturing and heavy-sedatives constitute 11% and 5% of the formulas for insomnia on average. Heart-nurturing herbs are used significantly more for Heart-Spleen Deficiency and

significantly less for Liver-Spleen Disharmony, Phlegm-Heat, Liver Fire and Blood Stasis. Heavy-sedatives are used significantly more for Liver-Spleen Disharmony and Liver Fire and significantly less for Heart-Spleen Deficiency, Liver Stagnation and Blood Stasis.

Typical *shen*-calming herbs constitute 24% of the formulas for insomnia on average. They are used significantly more in the Heart-Spleen Deficiency pattern and significantly less in the Liver-Spleen Disharmony, Phlegm-Heat, Liver Fire, Liver Stagnation and Blood Stasis patterns.

## 4. Adverse reactions of *shen*-calming herbs

Shen-calming herbs are considered to have adverse reactions. More specifically

- 1. Cold-type shen-calming herbs can damage the stomach (1)
- 2. As heavy-sedative herbs can damage the stomach (3), they have to be used in low quantity (below 30g for *longgu* and *muli*) (1), they have to be used in combination with spleen-strengthening (1) or food-eliminating herbs (1), and they cannot be used for a long time (1)
- 3. Mineral *shen*-calming herbs can lead to dementia (1)
- 4. Sour-collecting herbs like *wuweizi* and *suanzaoren* can aggravate the phlegm-heat (1) or food, dampness and phlegm stagnation (1); they cannot be used in case of slimy fur (1)
- 5. Yuanzhi is slightly toxic and cannot be used on a long-term period (1).

## 5. Clinical notes on the use of *shen*-calming herbs

#### [The text was cut here]

## 6. Interpretation and discussion

The mainstream position about the use of *shen*-calming herbs is that they should be used regardless of the pattern but not constitute the majority of the formula. Only a minority of clinicians think they should be the core of the treatment of insomnia (see chapter 4 Disease-Based Treatment with

Herbal Medicine). Most clinicians believe that *shen*-calming herbs and herbs with *shen*-calming effect should constitute approximately 16% and 24% of the formula, respectively.

In textbooks there are two categories of *shen*-calming herbs, i.e. the heart-nurturing herbs and the heavy-sedative herbs. These most commonly used of these herbs for insomnia are *suanzaoren*, *yejiaoteng*, *yuanzhi*, *longgu* and *muli*. We identified two additional categories, i.e., the stagnation-eliminating and the orifice-opening *shen*-calming herbs. Some clinicians mentioned that herbs such as *banxia* and *huanglian* have *shen*-calming properties. These herbs are commonly used for insomnia.

Heart-nurturing herbs tend to be used more commonly for deficiency patterns but the association is weak. The ratio of heart-nurturing herbs and heavy-sedative herbs is more related with the category of pattern.

In the liver stagnation system (see chapter 2 Pattern-Based Treatment of Insomnia with Chinese Herbal Medicine), which include Liver Stagnation, Liver Fire, Phlegm-Heat and Blood Stasis, clinicians tend to use less *shen*-calming herbs, especially less heart-nurturing herbs. This may be because the focus has to be on clearing and draining the stagnation of *qi*, phlegm, fire and blood, not on calming the mind. Moreover, *shen*-calming herbs might aggravate the stagnation. There are two exceptions to this rule, Liver Fire and Liver-Spleen Disharmony. In the former, heavy-sedative herbs are commonly used to bring down or inhibit the rising fire. In the latter, *longgu* and *muli* are used not only to calm the *shen* but also to collect the deficient *yang*.

In the *yin* deficiency with fire and the heart-spleen deficiency systems, clinicians tend to use more *shen*-calming herbs, especially heart-nurturing herbs. This may be due to the fact that blood deficiency leading to the heart not being nurtured is a central mechanism of these patterns.

However, heavy-sedative are not used in case of heart-blood deficiency. This may be because heavy-sedative herbs can harm the spleen and stomach, aggravating the deficiency of *qi* and blood.

Clinicians tend to recommend to use high doses of *shen*-calming herbs for insomnia, up to 120g for *suanzaoren*, up to 80g for *yejiaoteng* and up to 30g for *banxia*. This does not apply to heavy sedatives though as they can harm the spleen-stomach and lead to dementia. Clinicians also recommend to use *shen*-calming herbs in the evening before bedtime.

## Chapter 10 Clinical Notes on the Use of Herbs

According to the clinicians, attention should be payed to these following points when using Chinese medicine herbs for insomnia.

## 1. Protect the spleen and stomach

Several clinicians recommended to protect the spleen and stomach (10) as insomnia is a chronic condition which can impair the spleen and stomach (1). The use of certain herbs can also affect the spleen and stomach and should be used carefully.

- Rich-tonifying (zibu 滋补) herbs such as shengdi and shudihuang can block the stomach and qi-regulating herbs such as chenpi, zhiqiao, muxiang, dampness-removing herbs such as fuling and sharen, and food-transforming herbs such as shanzha, jineijin and guya can be added to the formula (1).
- Cold (1) and heavy (1) spirit-calming herbs can affect the spleen and stomach (2). In case of acid reflux and heartburn one can use *huanglian*, *wuzhuyu*, *haipiaoxiao* and *zhebeimu* (1), or *ganjiang* and *rougui* to warm the stomach (1), or use *baizhu*, *jineijin* and *sharen* to strengthen the spleen (1).
- Bitter-cold heat-clearing herbs damage the spleen and stomach (3) and should not be used for long-term (1) or in case of spleen-stomach *yang* deficiency (1). Low-doses of *ganjiang* (1) and spleen-protecting herbs such as *baizhu*, *jineijin* and *sharen* (1) can be used.

When protecting the spleen and stomach, liver-draining and stomach-harmonising herbs such as *foshou*, *lvmeihua*, *meiguihua* and *bayuzha* should be used instead of warm-dry-dispersing herbs such as *chenpi*, *muxiang*, *houpo* and *banxia* (1) and neutral herbs such as *taizishen*, *zhi gancao*,

shanyao, dazao and longyanrou should be used instead of sweet-warm herbs such as huangqi and dangshen (1).

#### [The text was cut here]

## 5. Keep balance

More generally, there should be a balance in the formula, for example cold formulae must be supplemented with low-doses of *rougui*, *guizhi* or *wuzhuyu* and tonifying formulae must be supplemented with *qi*-moving herbs (1).

## Chapter 11 Other Herbal Treatment

Herbal decoctions taken orally are the main way to use Chinese herbal medicine to treat insomnia. Six other types of herbal treatments have been identified in the clinical experience reports. They include

- Herbal foot bath (9)
- Herbal manufactured products (6)
- Herbal pillow (3)
- Herbal infusion (3)
- Herbal paste (2)
- Injections (2)

### 1. Herbal foot bath

Herbal foor bath are commonly used as a health preservation (yangsheng) method and as an adjunctive method.

#### 1.1. Formula

The herbs used for herbal foot bath to treat insomnia are the herbs that have been cooked for pattern-based herbal decoctions (1) or standardised formulas prescribed specifically for the foot bath (4). The standardised formula is composed of

- Spirit-calming herbs such as yejiaoteng (3), cishi (2) and hehuanhua (1)
- Heat-clearing herbs such as juhua (2), huangqin (1) and zhizi (1)
- Vessel-unblocking herbs such as honghua (2), tougucao (1), sumu (1) and jixueteng (1)

Warming herbs such as fuzi (1), aiye (1) and shengjiang (1)

The first two categories are commonly used for oral decoctions for insomnia and the two last categories are commonly used for foot baths.

#### 1.2. Method of preparation

The average (range) dose is 76g (min 60g, max 90g) of herbs (5). The herbs have to be cooked, then removed and 5000ml of warm water added (2). The temperature of the water should be 30-40 °C (1) or 40-45 °C (2). The water level should be above the ankles (1). The average (range) duration of the footbath should be 18 minutes (min 10 minutes, max 30 minutes) (8). The herbal footbath has to be conducted 1 hour (1) or just before bedtime (2) every evening (1) during 3 to 6 months (1). It is particularly adapted for patients with difficulty falling asleep (1).

## 2. Herbal manufactured products

Herbal manufactured products are standardised pharmaceutical products manufactured in factories with extracts of herbs. They are usually sold over-the-counter in pharmacies (in Asian countries) and in Asian stores (in Western countries).

Compared to herbal decoctions, herbal manufactured products are more convenient to use (1). They are used either on a pattern-differentiation basis (3) or on a disease-differentiation basis (3). Herbal manufactured products used on a disease-differentiation basis are shown in Table 11-1. *Luo Hua An Shen* mixture (1) and *Tian Wang Bu Xin Dan* (1) are used for all types of insomnia, and *An Shen Bu Nao Ye* is used for insomnia in older adults (1).

Pattern	Product name (CN)	
Blood Deficiency and Liver Excess	Yang Xue Qing Nao granules (2)	
Non-Interaction between Heart and Kidney	Wu Ling capsule (2)	

Heart-Spleen Deficiency Gui Pi pills (1)

Liver Stagnation and Blood Deficiency Xiao Yao pills (1)

Heart Qi Deficiency Qi Ye Shen An tablet (1)

Yin Deficiency with Heat Bai Le Mian capsule (1)

Blood Deficiency Zao Ren An Shen capsule (1)

Heart Shen Disturbance Xin Shen Ning tablet (1)

Kidney Deficiency Tian Meng oral solution (1)

Hyperactive Liver Yang Song Ling Xue Mai Kang (1)

Table 11-1. Herbal products used on a pattern-differentiation basis. CN = citation number

## 3. Herbal pillows

Herbal pillows are pillows that are stuffed with herbs and used to support the head at night. We have identified three formulas of herbal pillows.

- Juhua and juemingzi (1)
- 100g of juhua, 100g of cishi, 100g of yejiaoteng, 30g of zhu dengxincao, 30g of dingxiang, 60g of changpu, 60g of yuanzhi, 60g of fushen, 20g of tanxiang and 10g of bingpian (1). In case of frequent dreams, 100g of longgu and 60g of muli are added to the formula (1)
- Baiziren, yejiaoteng and cansha (1). In case of Non-Interaction between Heart and Kidney tusizi and yuanzhi are added; in case of Blood Deficiency with Liver Excess suanzaoren, juemingzi, juhua and hehuanhua are added; in case of gallbladder deficiency and phlegm hupo, yujin and changpu are added; in case of kidney deficiency with blood stasis shudi, danggui and hanliancao are added (1)

The herbs have to be grinded into gross powder and inserted into a fabric bag, and used as a pillow (2).

### 4. Herbal infusions

Herbal teas can be used according to the pattern such as *meiguihua* for Liver Stagnation and *maidong* for Yin Deficiency (1). Peanut stem extremities are used for postpartum insomnia (1) and a combination of *gouqizi* and *meiguihua* for perimenopausal insomnia (1). The herbs have to be placed in 150 ml of boiling water and taken as a tea (1).

## 5. Herbal paste

Paste are herbal decoction that are cooked for a long time until forming a paste. Usually, paste-like ingredients such as *ejiao* and *guijia* are added inside (1). The formula *Zi Shen Yang Xue* paste, composed of *nvzhenzi*, *hanliancao*, *gancao*, *xiaomai*, *dazao*, *baihe*, *shengdihuang*, *ejiao*, *guijia*, *taoren* and *heizhima* is used for perimenopausal insomnia in order to nurture the essence and the blood (1). Paste is also used for the more general insomnia population in case of deficiency in order to tonify qi and blood, or after the treatment in case of excess in order to help the patient recover (1). When preparing paste, attention should be paid to the taste, colour and smell of the paste (1). It can be also useful to regulate the spleen and stomach for one week before starting the treatment (1).

## 6. Injection

One clinician recommends to use *ciwujia* injection with intravenous drip for 7 to 10 days on the basis of other treatments for insomnia (1). Another clinician recommends to use vitamin B12 injections on GB20 *fengchi* in order to stimulate the point for treating perimenopausal insomnia (1). For the latter, 1 ml of vitamin B12 injection is injected in each points at 4:30 pm every day (1).

## 7. Interpretation and discussion

The alternative of oral herbal decoction are usually convenient treatment methods that can be easily conducted at home such as herbal foot bath and herbal pillow. They do not require proper diagnosis from a doctor and are available over-the-counter. Treatments like infusions and manufactured products are milder than herbal decoctions, which make them less dangerous but also less appropriate for complicated or severe conditions. As there is no preparation needed for treatments such as manufactured products and paste, they are more convenient for long-term use.

These alternative to herbal decoction are usually disease-based instead of pattern-based (at the exception of manufactured products which can be used under the two principles). However, the choice of herbs does not entirely rely on the diagnosis of insomnia. It also depends on the characteristics of the treatment itself. For example, warm and moving herbs are used for foot bath as one of the objectives is to bring the fire down. Rich *qi*, blood and essence tonics are used for paste, as they can tonify people on a long-term basis. Fragrant-dispersing herbs are used for herbal pillows as they allow to relax the mind. Herbs used in infusions are usually fruits and flowers.

## Chapter 12 Body Acupuncture Treatment

In this chapter we present the treatment of insomnia with body acupuncture, including the disease-based formulas, the pattern-based formulas and the rationale behind the treatment protocols.

Micro-systems of acupuncture such as scalp and ear acupuncture and additional techniques such as moxibustion, bleeding, etc. are covered in other chapters.

## 1. Acupuncture points and meridians

The 42 disease-based formulas proposed by the clinicians include in total 275 points (Figure 12-1). The clinicians proposed 70 different points for the treatment of insomnia. The meridians that are the most commonly used are the *dumai* (20% of total of points), the bladder meridian (16%), the *renmai* (14%), the liver meridian (8%) and the gallbladder meridian (8%). The pericardium and the heart meridians are at the 6<sup>th</sup> and 7<sup>th</sup> position with 8% and 7% of the total of points, respectively.



Figure 12-1. Acupuncture points recommended for the treatment of insomnia

## 2. Point selection rationale

#### [The text was cut here]

## 3. Core points

The 42 main formulas used for insomnia had on average seven points. The core points of the main formula are GV 20 *baihui*, EM 1 *sishencong*, HT 7 *shenmen*, PC 6 *neiguan*, LR 3 *taichong*, GV 24 *shenting* and EM 3 *yintang*. These seven points account for 39% of the total number of points for the disease-based treatment of insomnia. The techniques used on the core acupuncture points are indicated in the Table 12-2.

Point	Sen	Insertion	Manipulation	Notes
GV 20 baihui	57%	Flat insertion (3) or oblique insertion (4).	Twirling (6) reinforcement (2) or neutral (5). Use 5 Hz continuous wave electro acupuncture (2).	The needle can be kept for 6-24 h. (1); important point for insomnia (3).
EM 1 sishencong	36%	Flat insertion (3) toward GV20 baihui (2) or oblique insertion (2).	Twirling (2) neutral (3) method.	Experience point for insomnia (1); important head point to regulate the spirit (1).
HT 7 shenmen	36%	Perpendicular insertion (2) on 0.5 cun (2).	Reinforcement (2) method.	Important point to regulate the spirit (2) and to treat mental illnesses (1).
PC 6 neiguan	33%	Insert 0.8 cun (2).	Twirling (3) method.	Important point to treat insomnia (1).
LR 3 taichong	33%			Important point for mental disorders (1)
GV 24 shenting	31%	Insertion toward GV20 <i>baihui</i> (3).	Twirling (2) method. Use continuous wave electro acupuncture (3).	Point specialised for mental diseases (2)
EM 3 yintang	29%	Insertion toward the nose (2) on 0.5 cun (3).		Important point to regulate the spirit and awaken the brain (1)

Table 12-2. Core points of the main formula for the treatment of insomnia with acupuncture.

The reasons behind the use of these points for the treatment of insomnia are shown in Table 3. This table shows the specificities of the points, which are mainly the location of the points and their role (such as *luo* point or original point). The functions of the points can be related to their specificities, for example LR 3 *taichong* can drain liver *qi*, nurture liver blood, clear liver heat and calm the liver as it is the original point of the liver meridian.

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(2)
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1
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GV 24 shenting	Located on the <i>dumai</i> (4), which penetrates the brain (2);	<ol> <li>Appeases the heart-spirit (6)</li> <li>Sedates (3)</li> <li>Regulates the spirit (2)</li> </ol>
E <b>M</b> 3 yintang	Located on the <i>dumai</i> (5), which penetrates the brain (3);	<ol> <li>Appeases the heart-spirit (4)</li> <li>Increases qi and blood circulation in the head (2).</li> </ol>

Table 12-3. Specificities and functions of the acupuncture points

## 4. Modification according to the pattern

The causes and mechanism of insomnia reported by the clinicians were synthesised. The causes and mechanisms that were reported by at least two clinicians are shown in Figure 12-2. A total of 9 different mechanisms was finally synthesised, among which spleen deficiency and liver *qi* stagnation were the most commonly cited.

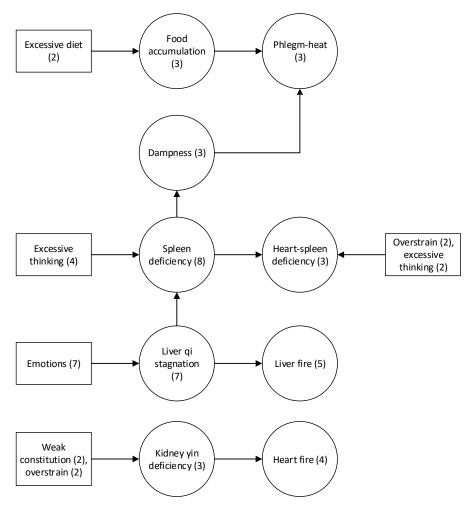


Figure 12-2. Flowchart of the causes and mechanisms leading to insomnia described by the authors in the context of the pattern-based modification of acupuncture formulas for insomnia. Causes are

presented in rectangles and mechanisms are presented in squares. Arrows show a causality relationship. Causes have been placed on both side of the flowchart to allow a better readability of the chart.

We identified 8 categories of pattern among the 143 pattern-based modification formulas. These categories are:

- Non-Interaction Between Heart and Kidney, 14 formulas
- Heart-Gallbladder Qi Deficiency, 15 formulas
- Heart-Spleen Deficiency, 26 formulas
- Phlegm-Heat (including Stomach Disharmony), 24 formulas
- Liver Fire (including Hyperactive Liver Yang), 8 formulas
- Liver Qi stagnation (including Liver Stagnation with Spleen Deficiency), 8 formulas
- Kidney Deficiency, 7 formulas
- Yin Deficiency with Effulgent Fire, 14 formulas

The core SSs and the core points of the pattern-based modification formulas are reported in Table 12-4.

Category	Core SSs	Core points (sensitivity, specificity), manipulation
Non- Interaction Between Heart and Kidney	Sore and weak lower back and knees (36, 50), tinnitus (36, 29), dizziness (36, 25), agitation (36, 19), night sweating (29, 57) and lack of fur (29, 50)	KI 3 taixi (57, 38), BL15 xinshu (50, 21) BL23 shenshu (43, 50)
Heart- Gallbladder Qi Deficiency	Frequent panic (33, 83), light tongue (33, 31), wiry pulse (33, 29) and thin pulse (33, 20)	BL15 <i>xinshu</i> (53, 24) with reinforcement method (2), BL19 <i>danshu</i> (47, 78), GB 40 <i>qiuxu</i> (33, 100), PC6 <i>neiguan</i> (33, 24), HT7 <i>shenmen</i> (33, 17)
Heart-Spleen Deficiency	Light tongue (39, 63), thin pulse (39, 40), loss of memory (35, 64), fatigue (35, 60) and palpitations (35, 50)	BL20 <i>pishu</i> (58, 83) with reinforcement method (3), BL15 <i>xinshu</i> (58, 44) with reinforcement method (3), ST36 <i>zusanli</i> (42, 39) with reinforcement (2) or neutral (2) method, SP6 <i>sanyinjiao</i> (39,

		42) with reinforcement (2) or neutral (2) method
Phlegm-Heat	Slimy fur (42, 100), slippery pulse (38, 100), oppression in the chest (38, 82) and agitation (33, 31)	ST40 fenglong (67, 94) with reduction method (4), ST44 neiting (42, 84), ST36 zusanli (37.5, 32.1) with reduction method (2), CV12 zhongwan (25, 75) with neutral method (2)
Liver Fire	Stress and irritability (46, 79), dizziness (38, 45), eye redness (33, 100), bitter taste in mouth (33, 57) and yellow fur (33, 53)	LR3 taichong (54, 48) with reduction method (4), LR2 xingjian (38, 90) with reduction method (3), BL18 ganshu (29, 78), LI4 hegu (17, 44)
Liver Qi Stagnation	Hypochondriac distension (25, 67), frequent sighs (25, 67) and white fur (25, 25)	LR3 taichong (75, 22), ST36 zusanli (38, 11), CV12 zhongwan (25, 25), LI4 hegu (25, 22), GV20 baihui (25, 18)
Kidney Deficiency	Sore and weak lower back and knees (29, 20) and nocturnal urination (14, 100)	CV4 guanyuan (43, 75), KI3 taixi (43, 14), SP6 sanyinjiao (43, 13)
Yin Deficiency with Effulgent Fire	Red tongue (75, 29), rapid pulse (75, 24), thin pulse (75, 24), agitation (63, 19), heat sensation in the palms and soles of feet (50, 57), lack of fur (50, 50), tinnitus (50, 24) and sore and weak lower back and knees (38, 30)	KI 3 <i>taixi</i> (64, 43) with reinforcement method (3), SP6 <i>sanyinjiao</i> (36, 21), LR3 <i>taichong</i> (36, 19), KI7 <i>fuliu</i> (21, 100)

Table 12-4. Modification of the acupuncture treatment according to the pattern

## 5. Equipment, procedures and treatment regimen

#### [The text was cut here]

## 6. Interpretation and discussion

The synthesis of clinical experience about the treatment of insomnia with body acupuncture showed similarities and discrepancies with current guidelines. The "disease-based basic formula modified according to the pattern" model, which is used in current guidelines, is also the one preferred by most clinicians. However, the basic formula was found to have on average seven acupuncture points, which is significantly larger than the ones in current guidelines. According to clinician's experience, GV 20 *baihui* is clearly a leading point, yet this point is often absent from guidelines. On the other hand, SP 6 *sanyinjiao* is not a major point according to the clinicians, which is different

from current guidelines as well. The order of importance of the meridians is also different. In current guidelines, the treatments are mainly focused on the heart and pericardium meridians, yet we found that the ones used most frequently by clinicians are the *dumai*, the bladder meridian, the *renmai*. The reason for these discrepancies is not clear, but may be related to an emphasis on "the heart controls the mind" in the guidelines opposed to "the brain controls the mind" in clinical experience reports, and an emphasis on the regular meridians as opposed to the extraordinary vessels in guidelines.

The synthesis of clinical experience also shows significant differences between the treatment of insomnia with herbal medicine and with acupuncture. The main approach for herbal medicine is the pattern-based approach, where a formula specific to a certain pattern of signs and symptoms is provided to the patient, whereas the main approach for acupuncture is the disease-based approach, where a standardised formula is given to every insomnia patient regardless of the signs and symptoms, but is often modified according to the pattern. This shows an important difference in the medical reasoning between herbalists and acupuncturists. Herbs have different natures and functions, they can be hot or cold, tonifying or draining, while acupuncture points are mainly used according to their location. Therefore, it is important to treat according to the physiopathology (hot or cold, deficient or replete) of the patient when using herbs but not so much when using acupuncture.

In terms of patterns themselves, herbalists tend to have a flexible way of using pattern-related concepts such as phlegm, heat, *yin* deficiency, spleen deficiency, etc. The meaning of these concept can be very different from one herbalist to another (see chapter 2 Pattern-Based Treatment of Insomnia with Chinese Herbal Medicine). For this reason, it is difficult to combine pattern-based herbal formulas using the name of the pattern given by the clinician. However, acupuncturist use relatively standardised pattern names, which makes the combination of formulas according to the name of the pattern easier. This may be due to the relatively low importance of pattern

differentiation in acupuncture. Acupuncturist also tend to use more frequently organ-based pattern diagnosis such as heart-gallbladder *qi* deficiency and kidney deficiency and less frequently substance-based pattern diagnosis such as blood stasis. This can be explained by the relative importance of organs in the therapeutic system of acupuncture, in which organs can be treated via their related meridians, *mu* points and *shu* points. The treatment of substance-based patterns in acupuncture is much less straightforward.

The importance of liver pathology and more specifically liver stagnation in the pathological mechanism of insomnia is highlighted by the prevalent use of the liver and gallbladder meridians (which are the most commonly used regular meridians after the bladder meridian) and the prevalent use of points such as LR3 taichong. Five of the 18 rationales behind point use are related with liver and qi regulation. The emphasis on the importance of liver stagnation made by acupuncturists is in line with the use of liver-draining formulas such as Xiao Chai Hu Tang and Xiao Yao San in the disease-based treatment of insomnia with herbal medicine (see chaper 4 Disease-Based Treatment with Herbal Medicine) and the importance of the liver stagnation system in the pathological mechanism of insomnia described by herbalists (see chapter 2 Pattern-Based Treatment of Insomnia with Chinese Herbal Medicine). After shen disturbance (which is treated with shen-calming method), liver stagnation seems to be the most central feature of the pathology of insomnia.

# Chapter 13 Scalp Acupuncture and Ear Acupuncture

In body acupuncture, which is also called macro-acupuncture, the whole body can be needled according to the condition. In micro-acupuncture systems such as scalp acupuncture and ear acupuncture, one specific area of the body is used to treat conditions from any part of the body. The rationale is based on the bio-holographic principle, which stands that every parts of the body represents the body as a whole. Even though many systems of micro-acupuncture exist, only scalp acupuncture and ear acupuncture were identified in the clinical experience reports.

## 1. Scalp acupuncture

Two protocols of scalp acupuncture were proposed. In the first one, the middle line of forehead and the lateral line 1 of forehead are used, both needled with horizontal needling backward. In the second protocol, the frontal-parietal line and the extension of the lateral line 1 of the forehead.

Another protocol combines body acupuncture points located on the scalp and scalp acupuncture points, i.e., GV 20 baihui, EM 1 sishencong, the lateral line 1 of forehead and the lateral line 2 of forehead. The rationale for using these points is that they allow to regulate the cortex of the frontal lobe, which is situated below the needling area.

## 2. Ear acupuncture

Auricular acupuncture protocols were proposed in ten different reports. The points used in the formula are shown in Figure 1. All these protocols were disease-based.



Figure 13-1. Auricular acupuncture points used for insomnia. The size of the word is proportional to the number of citations.

A sead of vacaria (which is the Chinese medicine herb *wangbuliuxing*) (3), a magnetic bead (2), a sticker (1) or a pushing needle (1) can be used to stimulate the points. The patient is asked to stimulate the point on average 3.3 (min 2, max 5) times a day (4) and before bedtime (2). The sticker can be remained on the ear for on average 3.2 (min 2, max 5) days (5). The two ears are treated alternatively (2).

## 3. Interpretation and discussion

Both scalp acupuncture and ear acupuncture use a disease-based approach that aims at regulation the spirit and the heart, the organ controlling the spirit. In both scalp and acupuncture the influence of biomedicine is important. In scalp acupuncture, points on the forehead are used as they regulate the underneath frontal lobe, which has an important role in the cognitive and emotion-regulating process. In ear acupuncture, points related to stress reaction such as the subcortical point, the autonomic point and the hypothalamo-hypophyseal axis point are commonly used. Indeed, emotional regulation and the related Chinese medicine concept of liver *qi* movement are central in

the treatment of insomnia (see chapters on Disease-Based Treatment, Body Acupuncture, and Psychotherapy).

# Chapter 14 Other Acupuncture-Related Therapies

Acupuncture includes techniques that involve acupuncture points and meridians but are not performed with needles. These techniques are moxibustion (5), herbal patches (5), bloodletting (4), cupping (3), plum-blossom needling (3), *guasha* (1), and embedding (1).

[The text was cut here]

## Chapter 15 Tuina massage

Only ten clinicians proposed protocols for the treatment of insomnia with Chinese medicine massage (also called *tuina*). Eight of these protocols used a disease approach and two used a pattern approach. In this chapter, we present the disease-based and the pattern-based Chinese medicine massage treatments for insomnia as well as relevant clinical notes. As the rationale for points/area selection was rarely presented in the CERs, we did note report it here.

## 1. Disease-based treatment

The eight disease-based treatments include four whole-body massage protocols and four protocols of massage on specific areas only. The massage is generally focused on the back (6), the facial area (5), especially the forehead and around the eyes, the scalp (4), the neck (4), and the abdomen (4). If the protocol included the whole body, the body is either massaged in a bottom-up manner (2) or a top-down manner (2).

In terms of techniques, for the head, finger pushing (tui) methods are used on the forehead vertically ("open tianmen") and horizontally ("pushing kangong"); finger pressing-rotary kneading (anrou) techniques are used on acupuncture points, especially points on the forehead, around the eyes and on the temples; the sweeping (saosan) techniques is used on the scalp. On the neck, finger rotary kneading (rou) technique is used on GB20 fengchi. On the back, pinching-pulling (niena) techniques are used on GB21 jianjing; palm pushing (tui) and rubbing (ca) techniques are used on the governor vessel and the bladder meridian; palm rotary kneading (rou) and rolling (gun) techniques are used on the bladder meridian; finger rotary kneading (rou) techniques are used on back shu points. On the abdomen, pressing (an) and rotary kneading (rou) techniques are used with

the palm in the abdomen area, often on a circular manner, and with the fingers on acupuncture

points; palm vibrating (zhen) technique can also be used on the abdomen.

Protocol 1: head, back, and abdomen

[The text was cut here]

2. Pattern-based treatment

The pattern-based protocols and the modification of disease-based treatments were combined. The

points and areas are selected on the basis of the organ related to the pattern, i.e. heart and spleen

for Heart-Spleen Deficiency, heart and kidney for Yin Deficiency with Effulgent Fire, Spleen and

Stomach for Phlegm-Heat, and liver and gallbladder for Liver Stagnation creating Fire. These points

and areas are

Back-shu points

Mu points

Original points

The meridian of the affected organ

Specific area related to the organs (e.g., the lumbar area to tonify the kidney, the side of the

body for the liver).

The pattern-based massage treatments for insomnia are as follow.

2.1. Heart-Spleen Deficiency (5)

Pressing-rotary kneading (anrou) BL15 xinshu (3), BL17 geshu (1), BL18 ganshu (1), BL23

shenshu (1), HT7 shenmen (1), ST25 tianshu (1), ST36 zusanli (4), PC6 neiguan (1), BL20 pishu

(3), BL21 weishu (3), SP6 sanyinjiao (2).

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- Rubbing straight (zhica) on the governor vessel and the bladder meridian on the back until hot (2).
- Thumb rotary kneading (rou) and pressing (an), and palm pushing (tui) on the heart and spleen meridians with a light technique and emphasis on acupuncture points and trigger points (1).
- Rubbing horizontally the left spleen-stomach area of the back (T7 to T12) and the governor vessel until hot (1).

## 2.2. Yin Deficiency with Effulgent Fire (3) or Non-Interaction between Heart and Kidney (2)

- Pressing-rotary kneading BL15 xinshu (1), BL44 shentang (1), CV17 danzhong (1), PC6
   neiguan (2), HT7 shenmen (1), LR3 taichong (1) and BL23 shenshu (1).
- Pushing (tui) qiaogong point 20 times on one side then 20 times on the other side (2).
- Rubbing (ca) KI1 yongquan until hot (3); thumb rotary kneading (rou) and pressing (an), and palm pushing (tui) on the heart and kidney meridians with a strong technique on the heart meridian and a light technique on the kidney meridian, and emphasis on acupuncture points and trigger points (1).
- Horizontal rubbing (hengca) on the lumbar area (4).

### 2.3. Phlegm-Heat (3) or Phlegm-Dampness (1)

- Finger pressing-rotary kneading (anrou) on HT7 shenmen (2), PC6 neiguan (3), ST40 fenglong
   (4), BL15 xinshu (1), BL44 shentang (1), CV17 danzhong (1), BL20 pishu (2), BL21 weishu (2),
   BL22 sanjiaoshu (1), BL23 shenshu (1), ST36 zusanli (4), CV12 zhongwan (1), ST44 neiting (1),
   SP6 sanyinjiao (1), SP4 gongsun (1) and LI10 shousanli (1).
- Rubbing horizontally (hengca) BL20 pishu and BL21 weishu until hot (1).

- Thumb rotary kneading (rou) and pressing (an), and palm pushing (tui) on the stomach and spleen meridians, with a relatively light technique on the spleen meridian and a relatively strong technique on the stomach meridian, and emphasis on acupuncture points and trigger points (1).
- Rubbing vertically (zhica) the governor vessel and rubbing horizontally (hengca) the lumbar area (1).
- Rubbing horizontally the left spleen-stomach area of the back (T7 to T12) and baliao until
  hot (1).

#### 2.4. Liver Stagnation creating Fire (3)

- Finger pressing-rotary kneading (anrou) on GB20 fengchi (1), BL18 ganshu (3), BL19 danshu
   (3), CV17 danzhong (1), HT7 shenmen (1), PC6 neiguan (1), LR14 qimen (2), LR13 zhangmen
   (2), LR2 xingjian (1) and LR3 taichong (2).
- Rubbing (cuo) the sides of the body (2).
- Thumb rotary kneading (rou) and pressing (an), and palm pushing (tui) on the liver and gallbladder meridians, with a strong technique and emphasis on acupuncture points and trigger points (1).
- Pushing (tui) downward between the first two metatarsals and pressing-rotary kneading (anrou) on LR3 taichong, trigger-points and nodes (1).

## 3. Clinical notes

- The technique has to be soft and gentle; avoid using too much strength; apply the techniques for relatively long periods (1).
- In terms of tonification and dispersion methods, soft techniques tonify and strong techniques disperse; slow movements tonify and fast movements disperse; clockwise

movements tonify and anti-clockwise movements disperse; movements along the direction of the meridian tonify and movements against the direction of the meridian disperse (1).

In terms of treatment regimen, the patient has to be treated every day for a course of 15 days (1).

## 4. Interpretation and discussion

The treatment of insomnia with Chinese medicine massage is relatively similar to the treatment of insomnia with acupuncture (see chapter 12 Body Acupuncture Treatment). There is less emphasis on the nature of the disease (cold-hot, deficiency-excess) than with Chinese herbal medicine. The main areas selected for disease-based treatment are the head, the governor vessel and the bladder meridian on the back, and, to a lesser extent, the abdomen. This choice is also consistent with cupping, *guasha* and plum-blossom needling treatments (see chapter 14 Other Acupuncture-Related Therapies). Compared to the acupuncture treatments, there is less emphasis on the liver *qi* movement and heart function in the disease-based massage treatments.

Pattern-based treatments are mainly applied on points and meridians related to certain organs (e.g., liver for liver stagnation) for both acupuncture and massage treatments. The choice of patterns is also consistent, with four block, i.e. Yin Deficiency with Effulgent Fire, Heart-Spleen Deficiency, Phlegm-Heat and Liver Stagnation/Fire, with the exception of Heart and Gallbladder Qi Deficiency in the acupuncture treatment. This may be due to the absence of specific massage treatment for this pattern.

The use of warming methods such as vibrating (zhen) and rubbing (ca) techniques on the lower part of the body such as the abdomen, the lower back and KI1 yongquan is consistent with the use of moxibustion and herbal patches in these areas and points (see chapter on other acupuncture-related therapies). The use of the side of the body for liver stagnation pattern is a specificity of massage treatment. This may be due to the danger of using this area with acupuncture needles.

## Chapter 16 Psychology and Music Therapy

This chapter presents the content of the clinical experience reports relevant to psychology and music therapy. This covers generalities about the place of psychology in the treatment of insomnia, the psychological aspects of the consultation, psychological interventions used to treat insomnia and music therapy as a treatment of insomnia.

## 1. Insomnia and psychology

Psychological interventions were considered part of the treatment by 82 clinicians, however one clinician mentioned that insomnia "could not be treated only with a simple psychological induction". In all the 82 reports that mention psychological interventions, there were used as a complementary treatment, not the main treatment. Unlike Chinese herbal medicine and acupuncture, the definition of psychological interventions in Chinese medicine is broad and vague. The terms to define psychological interventions are varied, including psychotherapy (*xinli zhiliao*), psychological dredging (*xinli shudao*), psychological tutoring (*xinli fudao*), psychological education (*xinli jiaoyu*), psychological care (*xinli huli*), emotional care (*qingzhi huli*) and mental regulation (*jingshen tiaoshe*). The distinction between these terms by the clinicians is not clear. These term can either refer to non-specific aspects of the consultation (such as the attitude, voice, etc.) or to specific therapies or techniques used to treat the patient. In most of the reports, the description of the psychological intervention is limited to a conceptual level (the name of the therapy and the goal of the treatment). The main goal of psychological interventions is to regulate emotions, which are closely associated with insomnia.

## 2. Psychological aspects of the consultation

The non-specific aspects of the consultation include the voice and attitude of the clinician, a patient-centred approach, an active involvement in the emotional factors of the disease and a convincing communication (Table 16-1). The objectives of these non-specific aspects are to create confidence between the clinician and the patient, to control negative emotions, to improve adherence to treatment and make the patient more optimistic about the treatment outcome.

Non-specific aspect	Description
Voice, tone and attitude	The clinician should have a respectful, noble and humble attitude, be careful of his/her wording, be warm, gentle, caring, friendly and compassionate, and be optimistic.
A patient-centred approach	The clinician should put his attention on the patient, listen carefully and sincerely what the patient is saying, answering when appropriate, supporting, comforting, encouraging and praising the patient. The clinician should put himself at the place of the patient. The clinician should not explain excessively, make promises, neglect or despise the patient.
Active involvement	The clinician should look for and try to understand the psychological reasons and emotional factors underlying the symptoms. The clinician should have "heart-to-heart talk" (tanxin), which means discussing about what one's have in his heart, induce catharsis (xuanxie), "open and direct" (kaidao) the patient, which means guiding the patient to see things differently, for example "treating annoying events with a usual mind", and "open the nodes of the mind" (jiekai xinjie), which means letting go of the congestion of emotions and thoughts. The clinician should use reason to control the patient's emotions and use explanations to remove confusion (e.g. about the causes of insomnia or the harm of drugs).
Convincing communication	The clinician should use convincing knowledge, knowledge about physiology and pathology and suggestions of good prognosis in order to convince the patient.

Table 16-1. Description of the non-specific aspects of psychological interventions.

## 3. Psychological interventions

The psychological therapies proposed by the clinicians are reported in Table 16-2. Many of these therapies are similar to Western psychotherapy, such as psycho-education, cognitive therapy and sleep hygiene. However, the way of conducting these therapies is influenced by cultural specificities. For example, seeing the relativity of things is influenced by Daoist philosophy and the *yin-yang* theory; *taiji* and *qigong* are culturally-adapted relaxation methods; creating a positive conditioning

through habits is different from the Western view of avoiding sleep rituals; Morita therapy is also influenced by East-Asian culture.

Therapy (CN)	Protocol
Cognitive therapy (8)	Cognitive therapy targets the false beliefs about sleep, including the consequences of insomnia on health, dreams, worry about insomnia, excessive expectations about sleep, excessive attention on sleep, exaggeration of symptoms, the attribution of daytime symptoms (e.g. psychological factors) and the reasons of the failure of previous treatments. The patient must also understand the relativity of everything, including the relation between oneself and society, between public and private, between obtaining and loosing. In terms of technique, the preparation for the worst (i.e., not sleeping at all) and role play (i.e., explaining sleep knowledge to a friend who has insomnia).
Sleep hygiene (5)	Sleep hygiene include having a regular schedule, improving the sleep environment (comfortable bed, no light), relaxing before bedtime, avoiding strong tea, coffee, tobacco and alcohol, having a frugal dinner, and not using sleep time for entertainment activities such as playing video games.
Relaxation (4)	Relaxation training include muscular relaxation, deep-breathing relaxation, mental imagery, biofeedback, taiji and qigong.
Behavioural therapy (4)	Behavioural therapy includes (1) stimulus-control therapy recommendations such as avoiding to use the bed during the day and staying out of bed when awake; (2) sleep-restriction therapy recommendations such as controlling time in bed and avoiding sleeping during the day; (3) writing up a daily schedule; (4) creating sleep conditioning with habits such as foot bath, wearing pyjamas, low lights, listening to soothing music.
Education (3)	The clinician provides information about the cause, mechanism and characteristics of insomnia, the treatment of insomnia (including hypnotic drugs), and the relations between emotions and insomnia.
Hypnosis (1)	After inducing the patient into hypnosis state, negative ideas are changed into positive ideas, or the patient is asked to imagine a sleep-promoting situation such as travelling in a train, hearing the repetitive sounds of the train and the wind. Self-hypnosis can also be used. In this case, the patients repeat to himself sleep-promoting suggestions such as "sleep, I'm very sleepy, I will fall asleep, etc.", but the patient should not use excessive suggestions such as "I need to sleep, just sleep now!". Also, the patient should not fuss about the results.
Morita therapy (1)	Morita therapy is about going along with nature. The patient is recommended to think "If I stay in bed, I can rest even if I'm not sleeping", and obey to his natural sleepiness instead of trying to control sleep.
Moving- attention-to- change-direction therapy (1)	The patient is recommended to conduct outdoor activities (travelling, hiking, sport, etc.) and hobbies to distract his attention. Other individualised approaches to disperse the attention can be used.

Table 16-2. Psychological therapies proposed by the clinicians. CN = citation number. Only the citations in which the protocol was described were counted.

## 4. Music therapy

The use of music therapy is individualised according to the patient (2). Cheerful music is provided to patients who have *qi* stagnation to excite them and soothing music is provided to anxious patients to relieve their restlessness (1). Listening to soothing music is also recommended for patients with excessive liver fire (1). The music can be also chosen in function of the preference of the patient, his personality, his profession and mood (1).

## 5. Interpretation and discussion

Many clinicians emphasize the importance of psychology in treating insomnia, which is after all a mental disorder. However, there is no consensus on the way to use psychology to help insomnia patients. Most of the recommendations of the clinicians are non-specific, such as using a warm and caring attitude. The psychological interventions recommended by the clinicians are culturally-adapted, yet not fundamentally different from a Western approach such as the ones used in cognitive-behavioural therapy for insomnia (i.e., cognitive therapy, behavioural therapy, sleep hygiene, relaxation).

Interestingly, Chinese medicine psychotherapy such as emotions mutual control therapy (*qingzhi xiangsheng*) and *zhuyou* were not proposed as treatments for insomnia. It may be because these treatments are mainly theoretical and not widely used in the clinic.

# Chapter 17 Integrative Chinese Medicine

Integrative Chinese medicine refers to the integration of Chinese medicine with non-Chinese medicine therapies. In the context of insomnia treatment, these therapies are Western medicine (i.e., pharmacotherapy) and psychotherapy.

## 1. Integration of Chinese medicine and Western medicine

Chinese medicine and Western medicine are integrated in a stepped-care manner. Hypnotics such as Estazolam are used first (6), especially if the insomnia is severe (3), in order to control the symptoms of insomnia quickly and efficiently, and also to relieve the anxiety of the patient. Chinese herbal medicine is then used in second place (6) in order to treat the root of the condition, reduce the dose of Western medicine drugs (which can bring side effects and dependency) and control the secondary symptoms (which can impair sleep) such as hot flushes, frequent urination, and agitation.

If the patient is already dependent on hypnotics, CHM can be used to discontinue the use of hypnotics (3). In this case, it is important to not discontinue the use of hypnotics abruptly but progressively (3). The dose of hypnotics can be reduced at a pace of ¼ or 1/8 of a tablet each week (1). Spirit-calming herbs such as *zhenzhumu*, *yejiaoteng*, *longgu*, *muli*, and *suanzaoren* can be used before bedtime in order to replace hypnotic drugs.

Additionally, anti-depressant and anxiolytics (4) such as Deanxit (1) can be used, especially in case of moderate-to-severe anxiety and depression (2).

Finally, using Western medicine diagnostic methods to understand comorbidities allows the clinician to treat the patient more efficiently (2). For example, in addition to the treatment for insomnia, *qi*-tonifying herbs and blood-nurturing herbs can be used if there is anaemia (2).

## 2. Integration of Chinese medicine and psychotherapy

Chinese medicine can also be combined with CBT-I (4) and hypnosis (1) for the treatment of insomnia. The clinicians have not provided details regarding how these therapies should be integrated with Chinese medicine.

## 3. Interpretation and discussion

From the point of view of the clinicians, hypnotic drugs represent a symptomatic approach to the treatment of insomnia that is similar to the use of *shen*-calming herbs (see chapter 9 *Shen*-Calming Herbs) and the *shen*-calming approach of disease-based Chinese herbal medicine (see chapter 4 Disease-Based Treatment with Chinese Herbal Medicine). Both can be used in a similar manner, i.e. single dose once a day before bedtime (see chapter 8 Cooking, Intake Methods and Treatment duration). Individualised Chinese herbal medicine treatment are used to treat the "root", i.e. the underlying mechanism of the condition.

An integrative approach can be useful when there are comorbidities. Physical and mental comorbidities are fairly common in insomnia patients. We have seen previously (see chapter 7 Managing Comorbidities) that comorbidities can be treated separately with Chinese herbal medicine, e.g., combining two formulas, one targeting insomnia and the other targeting the comorbidity. Using an integrative approach, Chinese medicine and Western medicine can be used to treat insomnia and the comorbidity separately. The typical example is using Western drugs to manage depression and anxiety and Chinese medicine to target insomnia.

As emotions are at the core of insomnia's aetiology and pathology, especially in the liver stagnation system (see chapter 4 Disease-Based Treatment with Chinese Herbal Medicine), psychotherapy is commonly proposed by clinicians as a treatment for insomnia (see chapter 16 on Psychology and Music Therapy). Cognitive-behavioural therapy, which is proposed as the first-line treatment of

insomnia in international guidelines, is particularly recommended (see chapter 16 on Psychology and Music Therapy). However, the clinicians did not explain how Chinese medicine and psychotherapy should be integrated, i.e. stepped-care or simultaneous use? Both targeting insomnia or one targeting comorbidities? Future clinical experience reports should try to answer these questions.

# Chapter 18 *Yangsheng* and Self-Treatment

Yangsheng or "life cultivation" is the art of maintaining and improving health through diet, health-promoting activities and life-work balance. Clinicians often make yangsheng recommendations at the end of the session. In the context of insomnia treatment, these lifestyle changes can be categorised in four categories, i.e. activities, life attitude, sleep behaviours and environment, and diet. Self-treatment methods such as food therapy and acupressure are also recommended for insomnia patients. These self-treatment methods allow the treatment to be continued outside the hospital.

# 1. Yangsheng recommendations

The most common recommendations from the clinicians was to conduct more physical exercise (29), including sport, taiji, qigong, etc. Only one clinician mentioned the duration and frequency of the exercise, 30-60 minutes every day. It can be conducted either in the morning (1) or in the late afternoon or evening (1). Physical work is also recommended as a type of physical exercise (3). Physical exercise was recommended for insomnia as it can help to regulate emotions, including by distracting the patient from his/her symptoms, and also to improve the activity/rest balance, as more activity during the day are considered to improve the sleep at night. The second most common recommendation about activities is to have a regular schedule (19). Patients are also recommended to conduct more cultural and entertainment activities (9) such as painting, reading, making calligraphy, etc., having more social interactions (5) including group activities, staying in contact with nature (2), having hobbies (1), conducting cheerful activities and work (1), and staying in contact with happy events (1). A good work/life balance (4) was also recommended, which can be more work or less work depending on the condition on the patient, but always more physical exercise (1).

Life attitude recommendations were also common. The clinicians recommend to the patient to control their emotions (17), especially anger (1), to stay optimistic and happy (10), to keep a "smooth" or "flowing" (shuchang) mood (8), to control and reduce their thoughts and worries (6), to keep a peaceful and plain mind (5), to reduce their psychological pressure (4), to keep an open and not-competing attitude (3), to reduce external psychological stimuli (2), and to not look for fame and money (1) or for perfection (1).

More specifically about sleep, the patients are asked to stay away from exciting substances (i.e., strong tea, coffee, alcohol and tobacco) before bedtime (21), to improve their sleep environment (11), including having a calm and dark sleep environment with fresh air and adapted temperature, a comfortable bed and appropriate pillow, to avoid eating too much (8) and having a light meal (4) for dinner, and avoiding eating 3 hours before bedtime (1). According to the clinicians, the patients should go to bed early (3), preferably before 11 pm (1), and get up early as well (1). The patient should avoid excitement before bedtime (10), including intense exercise or emotional movies, thinking less before bedtime (4), limit daytime sleep (2), and avoid watching TV at night (1), as these activities are harmful to sleep. Sleep-promoting activities that can be used before bedtime are having a hot foot bath (5) followed by the massage of KI1 *yongquan* point (3), drinking hot milk (3), sugar water (1) or hot water with a spoon of vinegar (1), counting (2), using relaxation techniques (2), and having a hot shower (1).

These recommendations are adapted to all insomnia patients, yet some can be individualised according to the pattern. For example, meditation before bedtime is recommended for patients with non-interaction of heart and kidney (1) and the recitation of the Heart Sutra is recommended for patients with liver fire (1).

In terms of diet, a healthy (5), light (4), easily digested (2) and regular (1) diet is recommended for every patient. The patient should avoid spicy and irritating (6), cold (including cold nature) (4), high-fat (4), hard (2), sticky (1), hot-dry (1), raw (1), sweet (1) and gas-producing (1) food. Some

recommendations are adapted to the pattern of the patient. Patients with Phlegm-Heat should have light (3) and easily digested (2) food, avoid high-fat (2), sweet (2), sticky (1) food and meat (1), as well as irritating food (1) such as onions, garlic and chili. Patients with Gallbladder and Heart Deficiency should avoid stimulants (1) such as alcohol and tobacco, and radish (1). Patients with Liver Fire should avoid spicy food (1). Patients with Yin Deficiency and Effulgent Fire should avoid spicy food (1) and alcohol (1). Patients with Spleen and Stomach Yang Deficiency should avoid cold (1), raw (1), high-fat (1) food and mung beans (1).

# 2. Food therapy

Food therapy can be used either on a disease basis or a pattern basis. Food that are considered beneficial regardless of the pattern are pork brain, pork heart, lotus seed (*lianzi*), celtuce, and jujube (*dazao*). The following recipes are also suggested:

#### Sour jujube porridge

Make porridge with 50g of sour jujube (chao suanzaoren) and rice.

#### Polygalacea and sour jujube porridge

Use 15g of polygalacea (*yuanzhi*), 10g of sour jujube (*chao suanzaoren*) and 75g of rice to make porridge.

#### Vinegar and millet porridge

Cook the millet to create porridge. Take the porridge one hour before bedtime. Take 10ml of vinegar half an hour after taking the porridge. Repeat every evening.

#### Longan, lotus seed and pork heart soup

Boil 30g of lotus seed (*lianzi*), 30g of longan (*longyanrou*) and half a pork heart with a bit of salt until cooked. Take once every evening one hour before bedtime.

However, food therapy is mostly adapted to the situation of the patient. Above are the food and recipes prescribed according to the pattern.

# 2.1. Yin Deficiency with Effulgent Fire

#### [The text was cut here]

# 3. Acupressure

Acupressure protocols follow also either a disease basis or a pattern basis. Disease based protocol include the following points:

- KI 1 yongquan (2)
- HT 7 shenmen (2)
- SP 6 sanyinjiao (2)
- EM2 yintang (1)
- EM5 taiyang (1)
- GV 11 shendao (1)
- PC 6 neiguan (1)
- ST 36 zusanli (1)
- the forehead (1)
- the upper back (1)
- the stomach (1)

The pattern based protocols include are reported in Table 17-1.

Pattern	Points
Liver Stagnation creating Fire (1)	GV 24 <i>shenting</i> , EM2 <i>yintang</i> , and the dorsal groove of the ear
Yin Deficiency with Effulgent Fire (1)	SP 6 sanyinjiao and PC 6 neiguan
Heart and Spleen Deficiency (1)	ST 36 zusanli
Heart and Kidney Deficiency (1)	ST 36 zusanli and SP 6 sanyinjiao

SP 6 sanyinjiao

Table 17-1. Points used for pattern-based acupressure treatments

# 4. Interpretation and discussion

Chinese medicine *yangsheng* recommendations share many similarities with Western sleep hygiene education. Having a regular sleep schedule (in relation with the biological clock), improving the sleep environment, avoiding heavy food before bedtime, avoiding exciting activities and substances before bedtime, and doing more physical exercise during the day (in order to increase the sleep pressure) are key components of both.

In Chinese medicine *yangsheng*, there is a stronger emphasis on general healthy behaviors such as keeping a healthy diet, having a better work-life balance, conducting leisure activities and physical exercise during the day, and regulating emotions. The strong emphasis on increased daytime activities in *yangsheng* shows the importance of balance in Chinese medicine. Making the *yang* rise during the day will facilitate its descent at night, improving sleep quality. In Chinese medicine, hot foot bath with massage of KI1 *yongquan* are recommended before bedtime. This recommendation is based on the relationship between heart and kidney (or between *yin* and *yang*). Hot foot bath with massage of KI1 *yongquan* allows to guide heart fire back to the lower part of the body. Finally, *yangsheng* recommendations are individualised according to the pattern of the patient. Sleep hygiene recommendations should also be individualised in theory, but only *yangshen* proposes specific recommendations.

Some important recommendations of Western sleep hygiene education are absent from *yangsheng* recommendations of the clinicians. Avoiding non-sleep-related activities in the spacio-temporal environment of sleep (bed, bedroom and bedtime) is typical of Western sleep hygiene. This is due to the concept of conditioning in behavioural therapy, which has heavily influenced the treatment of insomnia with cognitive-behavioural therapy. Avoiding nap is also absent from *yangsheng* prescriptions. The rationale behind this recommendation is the impact of napping on the sleep pressure and therefore sleep quality at night. Napping is considered as an important aspect of

yangsheng, within the more general ideal of sleep during 11AM-1PM and 11PM-1AM hours (ziwujiao), which is beneficial for health in general.

Some advices are conflictual with ideas from Western medicine and Western psychology. For example, Chinese medicine clinicians recommend patient to control their thoughts and emotions. Emotion regulation is an important goal in Western psychology, but it is generally achieved through acceptance of emotions than active control of emotions. This discrepancy might be due to conservative beliefs in the field of Chinese medicine. The clinicians believe also that insomnia patients should go to bed early. This is in contradiction with the Western concept of sleep pressure, which increases during the day. In cognitive-behavioural therapy for insomnia, patients are advised to sleep as late as possible in order to increase sleep pressure and ultimately sleep quality. This discrepancy might be due to the non-specific nature of *yangsheng* recommendations or to the conservative idea that early bedtime is a "healthy behaviour".

The principles of food therapy are similar to the use of Chinese herbal medicine for insomnia (see chapters 2 and 4). Disease-based treatments include mainly *shen*-calming ingredients, especially *suanzaoren*. Treatments are individualised according to similar patterns, such as Heart-Spleen Deficiency and Yin Deficiency with Effulgent Fire. In food therapy, neutral nurturing ingredients such as *dazao*, *suanzaoren*, *longyangrou* and *lianzi* are relatively more commonly used. There is also less emphasis on liver-draining and heat-clearing methods and more emphasis on spleen-stomach regulation. This may be due to the nature of food therapy. Many foods can regulate the spleen and stomach and nurture *qi* and blood but only a few can clear heat or drain liver *qi*.

The choice of points used in acupressure is within the range of the points commonly used in acupuncture treatments for insomnia (see chapter 12 on Body Acupuncture Treatment). However, there is clearly an emphasis on points located in the extremities of the limbs such as KI1 *yongquan* or HT7 *shenmen* compared to points located on the head or the back. Indeed, these points are easier to reach by the patient himself, which make them more convenient for self-treatment.

# Chapter 19 Methods

This section describes the methodology used to conduct this clinical experience synthesis.

# 1. Study design

The methodology of this study is inspired from the methodology of systematic reviews and qualitative synthesis. A systematic review is a review that aims at identifying, appraising, and synthesizing all relevant studies on a particular research question, using a comprehensive search strategy, a screening process and an analysis methodology determined a priori 244]. The reason of using a systematic review design is to give an overview as complete and representative as possible of the clinical experience of clinicians and to avoid the influence of the review authors opinion. A qualitative synthesis is a systematic interpretation of study findings through a series of expert judgments to represent the overall meaning of the collected work [245]. The approach of this study is inductive (i.e., theory driven from the data instead of hypothesis-testing) [246], integrative (i.e., summarizes the findings without interpretation) [247] and realist (i.e., represents an external reality and not only subjective knowledge) [248]. The qualitative synthesis, derived from content analysis and thematic analysis methodology [249], was both numerical (e.g., frequency of symptoms for a specific pattern) and non-numerical (e.g., basis for decision-making), which will allow to reduce the biases of the author while allowing in-depth analysis of the therapeutic process.

## 2. Review authors

This review was conducted by a field expert (YB) and a non-field expert (MJ) in order to allow indepth analysis and prevent bias at the same time. Yoann Birling is a Chinese medicine practitioner specialized in the treatment of mental disorder. His clinical focus is primarily on Chinese herbs and secondarily on acupuncture. He views insomnia as a bio-psychological disease with maintaining factors being mainly psychological. As a Chinese medicine clinician, he prefers using liver-draining

and phlegm-transforming methods (such as the formula Wen Dan Tang) and blood-nurturing and fire-clearing methods (such as the formula Huang Lian E Jiao Tang) for the treatment of insomnia. Mingxian Jia is a pharmacologist with experience in the conduction of systematic reviews. She views insomnia as a neurological disorder caused by biological and psychological factors. She has no experience or opinion about the treatment of insomnia with Chinese medicine.

#### 3. Search

Five international databases, i.e. EMBASE, PubMed, the Cochrane library, Allied and Complementary Medicine database and PsycINFO, and four Chinese databases, i.e. Chinese National Knowledge Infrastructure, Wanfang, Chinese Biomedical Literature and Chong Qing VIP (CQVIP) were searched from their inception. The searched terms used were ("Chinese medicine" OR "Chinese herbal medicine" OR "acupuncture" OR "massage" OR "food therapy") AND ("clinical experience" OR "treatment") AND ("sleep disturbance" OR "sleep disorder" OR "insomnia"). The databases were all searched with keywords both in English and Chinese in the full text (when possible) and the searches were adapted to each database. The search was conducted by one author (YB) only. The review did not include a manual search of clinical experience present in books as this type of search could be influenced by the authors knowledge and preferences.

# 4. Screening and categorisation

After combining the results of the searches in Endnote, the duplicates were removed (Figure 1). The reports were then screened by the two review authors (YB and MJ) with a two-step process, first using the title and abstract and then using the full text [130] (Figure 1). Disagreements were resolved by discussion, and by the senior Chinese medicine scholar (XZ) if consensus could not be reached. The articles included in the review were categorised directly after the screening.

#### 4.1. Selection criteria

The articles were selected according to the following criteria, in the order in which they are presented here. The article was included only if it fulfilled all the criteria.

#### A. Full text in Chinese or English available

The full text of the article has to be accessible by the reviewer. If the article is presented in the form of an abstract (e.g., for a conference), it was excluded. If the full text is not in Chinese or English, it was excluded.

#### B. Not a duplicate

If the article has already been published, it will be considered as a duplicate and therefore be excluded. If the content is similar to the content of another article written by the same or a different author, but the presentation is different, it will not be considered as a duplicate. If the content and the presentation of the section on the treatment of insomnia with Chinese medicine are identical or quasi-identical to another article already published, no matter if the author is the same or different, the article will be considered as a duplicate.

#### C. Clinical experience report (CER)

To our knowledge, there is no definition of CERs and their characteristics readily available.

Therefore, a definition of CERs and criteria to distinguish CER from other similar type of documents was developed by the two review authors. Articles selected with the title/abstract screening were analysed by the authors independently, who shared their views about CER characteristics and differences with similar documents until consensus was reached. After clear distinction criteria were designed, these criteria were used to screen again all the articles from the beginning.

CERs were defined as articles describing the experience of a clinician. The article can include theoretical analysis and reviews of the literature if the main point of the article (as described in the title, abstract or introduction) is to describe clinical experience. It can also include clinical trial reports and case reports if used to illustrate a particular point of experience or if the experience was drawn from this clinical trial/case. CERs are different from theoretical discussions, case reports, clinical trials, literature reviews, literature analyses, guidelines, consensus and educational material.

#### D. Include treatment

The article does not focus on the aetiology, pathology, prognostic or comorbidities of the disease but described treatment or prevention methods of the disease. The treatment approach has to be described as part of the overall experience and not only in a specific clinical case. The article will be included even if the specific formula is not described, as long as at least one treatment method is stated (e.g. draining the liver and clearing the heat). If the treatment section does not include specific recommendation but only vague suggestion such as "consider the period of the year" or "take account of the specificity of the individual", the article will not be included. The form of administration such as "paste" or "manufactured product" is considered as a description of the treatment but type of treatment such as "acupuncture", "diet therapy" without any further description is not accepted. A treatment approach such as "treating from the perspective of the liver", "regulating the spleen and the stomach" without further description is not accepted either. A list of formulas without the corresponding syndromes is not accepted.

#### E. Focus on insomnia

The article focuses on insomnia as defined by recognized diagnosis standards [74, 75, 250], i.e. a difficulty to induce or maintain sleep. A loose definition of insomnia will be accepted, as international diagnosis standards with stringent criteria in terms of duration, frequency and impact may not be widely used by clinicians. Articles focusing on nonrestorative sleep or dream disorders alone will not be included. Articles focusing on some categories of insomnia such as psychophysiological, chronic or primary insomnia will be included. A condition called "sleep disorder" but which description corresponds mostly to insomnia will be included even if it includes symptoms such as "turning around in the bed", "crying at night" or "having frequent dreams", as long as it does not include other sleep disorders such as sleep apnoea or circadian rhythm disorders.

#### F. Include Chinese medicine therapies

The article must include at least one Chinese medicine related treatment or prevention methods, including Chinese herbal medicine (regardless of the mode of administration), acupuncture and related techniques (cupping, bleeding, moxibustion, *guasha*), *Tuina* (i.e., Chinese massage), Chinese medicine psychotherapy (any type of psychotherapy used on the basis of Chinese medicine principles), Chinese medicine food therapy, *qigong* and *taichi*. Integrative treatments and nursing methods including at least one of the above treatments will be accepted. Chinese medicine techniques such as acupuncture will not be accepted if applied under the principles of ethnic medicines (e.g., Mongolian medicine) or non-Chinese medicines (e.g., Korean medicine, "dry needling").

#### G. Qualitative approach

The experience must come from the clinician directly or results from the observation of the author.

Conclusions drawn from quantitative analysis (e.g., through the analysis of patient data with a software) will not be accepted.

#### H. Clinician as an author

If the clinician is not an author, there must be evidence that he/she has reviewed the manuscript (and therefore acknowledges the content).

#### 4.2. Categorisation

In order to combine the data from CER of the same categories, the articles were categorised according to the following variables.

#### A. Precision

Two degrees of precision:

1. No precision: only treatment principle or method; the name of the basic formula is given, but there are not enough details to know all the ingredients/acupuncture points (e.g., modified formula); the ingredients/acupuncture points of the formula are stated, but not all of them ("etc.").

2. Enough precision: all the ingredients/acupuncture points are known; the formula is famous enough for its ingredients to be known; the formula is "modified" but the ingredients are described in the following text.

The degree of precision concerns only the basic formula, not the modification. If there is a choice (X or Y) in terms of formula or ingredient, the degree of precision is considered as "no precision". If the treatment recommended is a group of formula (e.g., "Gui-Zhi-Tang-type 桂枝汤类"), the article is labelled as having "no precision". The degree of precision of the article is the highest degree of precision reached by any treatment (e.g., for any pattern) described in the article for a particular treatment (e.g., herbs, acupuncture).

#### B. Population

If there is any specificity that is not related to the pattern (e.g., age, gender, comorbidity, severity, duration, etc.), the population is considered "specific". If the population is described as general, if there is no detail on the population or if the specificity concerns the pattern, the population is considered "general". The general population of insomniac can be described as people suffering from "insomnia" as a symptom, "insomnia disorder", "primary insomnia" or "chronic insomnia", since the terms above are acceptable definition of insomnia. A sub-category such as "sleep initiation insomnia", "long-term insomnia", etc. is considered as "specific". If part of the article concerns a specific population and another part of the article concerns a general population, the population is considered "both". If several specific populations are included (e.g., insomniac with liver diseases and insomnia with cardiovascular diseases), the population will be considered as "specific".

#### C. Diagnostic approach

If the treatment is based on the pattern (e.g., Xiao Yao San for Liver Stagnation pattern), the treatment type is considered as "pattern differentiation". If the treatment is based on the disease (i.e., insomnia), without distinction of pattern, the treatment type is considered as "disease

differentiation". If the two approaches are combined (e.g., single formula for insomnia with modification according to the pattern), the treatment type is considered as "both". The modification of the formula according to symptoms is not taken into account. If the treatment does not fall in any of the above category, it is classified as "other".

#### D. Type of treatment

The articles were categorised according to the type of treatment they proposed, i.e. "herbal medicine", "acupuncture", "massage" and "others". The presence of each modality was assessed independently of the others as one article could include several treatment modalities. The "herbal medicine" category included any modality of oral treatment (e.g., decoction, infusion, capsule, granule), manufactured herbal products, herbal foot bath and herbal pillows. The "acupuncture" category included all approaches of needle acupuncture (e.g., body acupuncture, ear acupuncture, scalp acupuncture, abdominal acupuncture) moxibustion, cupping, guasha, fire needles and bleeding techniques. The "massage" category included all kind of manual techniques within the scope of Chinese medicine.

#### 5. Data collection

The articles in which the treatment had "enough precision" were classified according to the population, diagnostic approach and treatment type. The groups including at least 20 formulae (i.e., herbal formula, set of point or set of techniques) were selected for numerical analysis. If the pattern approach is in minority (i.e., including less than 25% of the articles), the data will be combined with the disease approach and each formula will be considered as a pattern-modification formula.

Data from the articles were collected independently by YB and MJ using an excel spreadsheet. Every row was associated with one formula, either the main formula (in both the disease approach and the pattern approach) or the pattern-based modification (in the disease approach). Only the data associated with formulae with "enough precision" were collected. These data included the article ID (assigned before the full-text screening), the type of treatment, the type of population, the

diagnostic approach of the article, the name of the clinician, the diagnostic approach of the formula, the name of the pattern (for pattern approach or pattern-based modification) or the mechanism (for the main formula of the disease approach), the pathological mechanism (including causes, intermediary patterns and final patterns), the signs and symptoms associated with the pattern, the characteristics of the population of the pattern, the name of the formula (if mentioned by the author), the herbs and acupuncture points constituting the formula (including doses of individual herbs), the preparation methods of herbal treatment (e.g., timing and mode of administration) or the technique used for acupuncture treatment (e.g., insertion and manipulation techniques), the analysis of the formula by the author, the modification (excluding the pattern-based modification of the disease approach, which is considered as its own formula; collected regardless of the degree of precision) and notes from the author (i.e., tips and recommendations).

下or the herbs included in the formula, the herb was collected in the herbs column if "usually added 常加入", collected in the modification column if "added when [the symptoms are] severe 重者加,甚者加", but not collected if "sometimes added 时加", "can be added 可加入" or "added according to the circumstances 酌加". If the ingredients of the formula were not described but the name of the formula is well known, the ingredients were added in the "herbs or acupuncture points" column according to a formula manual, without the dose or the preparation method (e.g., raw or stir-fried).

#### 6. Data processing and reporting

#### 6.1. Preliminary data processing

The names of the herbs were standardised according to the Chinese medicine pharmacopeia [217] (e.g., "shanzhi 山栀" changed to "zhizi 栀子"). Names combining two herbs were separated into the names of the two individual herbs (e.g., "sheng longmu 生龙牡" changed to "sheng longgu, sheng muli 生龙骨,生牡蛎"). To our knowledge, there is no existing standard for the standardisation of the names of signs and symptoms (SSs) in Chinese medicine. Therefore, we designed such a standard for the sake of this this CES. This standard includes methods of separating compound SSs (e.g., pain-

distension in the thorax-abdomen 胸腹胀痛) and standardisation of highly-similar terms. The similarity of the SSs was assessed according to clinical significance rather than semantic meaning. The standard was drafted by YB and then reviewed and corrected by a group of eight Chinese medicine clinicians and scholars, first individually and then collectively. In case of disagreement, XZ made the final decision.

The excel functions ISNUMBER and SEARCH were used to identify the presence of herbs or acupuncture points in the "herbs or acupuncture points" column and the presence of SSs in the "signs and symptoms" column. The FALSE or TRUE code was then converted to a 0 or 1 code. The number of herbs, acupuncture points or SSs of each formula were counted manually and then compared to the total of herbs, acupuncture points and SSs identified with the functions. The system was adjusted until the two numbers were identical for each formula. The herbs, acupuncture points and SSs identified in the two reviewers' datasets were then compared and the datasets adjusted until they were identical.

#### 6.2. Formulae classification

For the herbal treatments according to pattern differentiation in both the pattern approach and the pattern-based modification of the disease approach, formulae were clustered according to their composition with a k-means cluster analysis. The reason for choosing the herbs and not the SSs for the cluster analysis is that a preliminary test showed a better distinction between pattern for the clustering according to herbs. This may be because of the higher variety and/or the more subjective interpretation of the meaning of SSs by the clinicians compared to individual herbs. The formulae were not categorised by pattern names as patterns representing the same pathological entity (i.e., similar SSs and herbs) may be labelled differently. The cluster analysis allows to find groups of similar formulae that are used to treat a specific pattern of insomnia.

In order to obtain clusters representing the patterns that are widely accepted, the outliers were eliminated by two ways, i.e. removing the clusters with an excessively low number of cases and

removing cases with an excessively high distance to the centre of the cluster it belongs to. The number of clusters and the thresholds for eliminating outliers were pre-determined by preliminary analyses testing different possibilities. Different options were retained according to the following principles, i.e., each cluster represents a syndrome that can be identified according to Chinese medicine theory (e.g., liver stagnation), each cluster is different from the others, most of the formulae correspond to the pattern represented by the cluster it belongs to, and as many formulae are kept as possible. For every analysis, the cluster analysis was repeated after removing the outliers (removing firstly the small clusters and secondly the distant cases) until no outlier could be removed anymore.

For the pattern approach of the herbal treatment of insomnia, the pre-determined number of pattern were seven, eight, nine and ten clusters, the pre-determined distance to the cluster at which outliers were removed were 2.8, 2.9, 3.0 and 3.1, the pre-determined threshold to remove small clusters was six or less cases. For the pattern-based modification on the basis of the disease approach, the pre-determined number of pattern were six, seven and eight, the pre-determined distance to the cluster at which outliers were removed were 2.0, 2.2, 2.4 and no limit. In both case, the different classifications with the pre-determined parameters were reviewed by the senior clinician (XZ) and the "best" classification (according to the above principles) was selected.

For the pattern-based modification of the acupuncture treatment, no classification representing clearly different patterns could be created with cluster analysis. This may be due to the intrinsic nature of acupuncture points, which can have different functions (e.g., *xin shu* can be used to clear heart heat, to tonify heart *qi* or to nourish heart blood), or to the small number of acupuncture points in each formula. For this reason, and because the pattern names were more systematically given and clearer than for herbal treatments, the formulae were classified according to the pattern name. Formulae with similar pattern names (i.e., "excessive heart fire", "heart fire burning excessively" and "heart fire alone and excessive") were grouped. Formulae having pattern names

sharing some similarities (e.g., "liver stagnation creating fire", "excessive liver fire", "excessive liver yang rising") were grouped when at least half of the core acupuncture points (i.e., the most frequently cited, according to the average number of points cited in the group) were identical.

Finally, the groups with four cases or less were removed.

The patterns resulting from the cluster analysis were labelled according to the pattern names of the cluster, the decision of the name being reviewed by XZ. For the pattern-based modification of the acupuncture treatment, the most commonly used pattern name was used as the label of the pattern. The number of formulae present in each pattern and the most commonly cited, when applicable, were also reported.

#### 6.3. General reporting rules

When possible, numerical data (e.g., individual herb dose, duration of the treatment) was combined and the mean, maximum and minimum were reported. If the numerical value is a range in the original report, the minimum and maximum of the range were used for the calculation of the pooled minimum and maximum and the middle of the range was used for the calculation of the pooled average. The number of herbs, acupuncture points and SSs reported in the results section was determined according to the rounded average number of the herbs, acupuncture points and SSs in the same group. Two parameters, the sensitivity (i.e., the ratio of the number of formulae including the herb, acupoint or SS on the total number of formulae in the group) and the specificity (i.e., the ratio of the number of formulae including the herb, acupoint or SS in this cluster on the total number of formulae including the herb, acupoint or SS) were reported when possible. For non-numerical data (e.g., herb preparation method, manipulation technique), the number of citation of the data was reported in bracket.

For each pattern, the SSs with the highest sensitivity (i.e., the most frequently cited) were reported. High-specificity SSs, defined as SSs both with a 100% specificity level and cited at least two times, were reported as well. High-sensitivity SSs are more widely acknowledged as indicators of the

pattern and may be more frequently encountered in clinic while high-specificity SSs may have a stronger role in differentiating one pattern from another.

The core herbs (i.e., the ones with the highest sensitivity) of each pattern were reported with their sensitivity and specificity, recommended dose, function in the formulae, recommended preparation and notes from the author. The function was reported only when describing specifically one herb and not a group of herb, and only when this function was cited at least two times. Core herbs are important as they reflect the core identity of the pattern. They can also be used to create a formula that can be used for a protocol.

The number of high-sensitivity SSs and core herbs reported was set as the average number of SSs (for the formulae for which SSs were reported) and herbs for the pattern. The SSs and core herbs were reported in order of main parameter (i.e., sensitivity or specificity) and secondary parameter if the main parameter is identical between two SSs. In case the sensitivity level of the last SS or core herb is identical to other SSs or herbs, these SSs or herbs were reported as well, regardless of the average number of SSs or herbs in the cluster.

#### 6.4. General reporting for the pattern approach of herbal treatment

The pathogenesis of the different patterns used in the treatment of insomnia with herbal medicine and acupuncture was synthesised as a flowchart using the content of the pathological mechanism column. Squares were used to represent the causes of diseases (e.g., emotions, overstrain), rounds were used to represent intermediary and final patterns (e.g., Liver Stagnation) and arrows were used to represent causal relationships. Systems (causes, patterns and their causal relationships) were combined when at both sides of at least one relationship were identical or highly similar. The number of times each cause or pattern was cited was recorded, with a limit of one time per formula. The type of transformation from one pattern to another was recorded when applicable. Two patterns that shared similarities (common characteristics, causes or consequences) but were not similar enough to be combined were linked with dashes. The similarity of the elements (causes and

patterns) was assessed by YB and reviewed by XZ. In order to improve the readability of the flowchart, the elements with a low citation score were removed from the flowchart from 1 upward until the flowchart was considered readable by XZ.

"Pattern signatures" of each pattern were also created. These "pattern signatures" are radar plots of the ratio of each herb category (e.g., heat-clearing) used in the pattern. For a better readability, only categories covering at least 5% of the total herb count for at least one pattern are reported. These "pattern signatures" allow the reader to have a better understanding of the similarity between patterns. A general "pattern signature" combining the herbs from all the patterns was also created as a reference.

For the formula names, the terms "supplemented 加味" and "modified 加减,化裁" were removed from the names as they could reduce the weight of the formula. When the formula was composed of two formulae, the name was changed to "X and Y" (e.g., An Shen Ding Zhi Wan and Suan Zao Ren Tang). Word clouds of the formula names used in the pattern approach were designed using wordart [251]. The size and colour of each word (i.e., formula) was set according to the number of time it was cited and the pattern to which it belongs. The formula names were only reported for herbal treatments as acupuncture formulae usually do not have names. There are two goals for the formulae word cloud, the first is to give an overview of the most commonly used formulae for each pattern; the second to allow the reader to know which formulae have been removed from the report by pattern.

In order to facilitate pattern differentiation, a decision tree was created with the CHAID growing method using "cluster" as the dependent variable and all the SSs as independent variables. The maximum tree depth was set at 20 levels and the minimum number of cases at 20 for parent node and 12 for child node. The most represented pattern for each branch were reported, with the percentage of cases belonging to that pattern. Branches that lead to the same decision (i.e., most

represented pattern) were combined. The role of the decision tree is to provide an easy tool for pattern differentiation. It may not reflect the complexity of the pattern differentiation process.

6.5. Pattern-specific reporting for the pattern approach of herbal treatment
In order to give the reader a better overview of the SSs and herbs, word clouds of these information
for each pattern will be created. In addition to the SSs and herbs associated with a specific pattern,
the populations and characteristics associated with the pattern, modification methods and notes
from the author were also reported for each pattern.

The populations (e.g., older adults, women) and characteristics of the disease (e.g., persistent insomnia, acute-onset) associated with the pattern were reported if cited at least two times.

The modification methods were first classified manually according to the global direction (e.g., spirit-calming, purging, heat-clearing) of the modification. As formulae are usually modified according to secondary SSs and/or pattern, the information regarding the SSs, the pattern and the herbs added or removed were divided into three columns. A component of the modification was defined as a sign or symptom (e.g., headache or red tongue), an aspect of the pattern (e.g., liver or qi deficiency), or an herb that was added or removed. Component of the modification were reported if the component was cited at least two times in the group. The group itself was reported only if at least one of the indication (i.e., SSs or pattern) and one associated modification achieved the two-citation threshold.

Notes from the CER author on the formulae included in the pattern were also reported either directly, with quotation marks, or indirectly. This notes covered areas that are relevant to clinical practice (e.g., specificities of the population, lifestyle recommendations) but not included in the other parts of the report.

6.6. Analysis and reporting for the disease approach of herbal treatment

The basic formulae used in herbal treatment with a disease approach were analysed by YB in order to define categories. These categories were reviewed by XZ in order to conduct analyst triangulation.

Quantitative criteria were developed to classify the formulae. These criteria were adjusted to

optimise the distinction between different categories of formulae. The formulae which did not fit into any criteria were classified in a "other" category. The core herbs of each category were reported with their sensibility level, except for the "other" category, for which only formulae were reported with the number of citation.

For the pattern-based modification, the herbal formulae were clustered according to their ingredients with a k-means cluster analysis. The outliers were eliminated by two ways, i.e. removing the clusters with an excessively low number of cases and removing cases with an excessively high distance to the centre of the cluster it belongs to. The number of clusters and the thresholds for eliminating outliers were pre-determined by preliminary analyses testing different possibilities, then the "best" classification was selected by XZ. The patterns resulting from the cluster analysis were labelled according to the pattern names of the cluster, the decision of the name being reviewed by XZ.

#### 6.7. Analysis for the spirit-calming herbs

The formulae were grouped according to content of tonic herbs (i.e., herbs in the category "qi tonic", "blood tonic", "yang tonic" or "yin tonic". The correlation between the percentage of tonic herbs and different types of spirit-calming herbs (heart-nurturing herbs, heavy-sedative herbs, typical spirit-calming and all spirit-calming) was tested with a Pearson correlation test. The impact of the percentage of tonic herbs or the pattern on the percentage of different types of spirit-calming herbs was tested with One-Way ANOVA tests.

#### 6.8. Reporting for acupuncture treatment

For the acupuncture treatment with a disease approach, the core acupuncture points (i.e., the ones the most frequently cited) of the basic formulae were reported. The number of points reported was equal to the rounded average number of points in the basic formulae. Different types of points (i.e., body acupuncture, ear acupuncture, scalp acupuncture) were synthesised separately, when applicable. The points were reported with their sensitivity, the insertion technique, the manipulation

technique and the type of acupuncture (e.g., needling, moxibustion, electro) used. The overall treatment modalities and regimen were also reported.

#### 6.9. Analysis and reporting for specific populations

For specific populations (e.g., older adults), the difference in terms of frequency of use of herbs and herb categories were calculated as following:

$$n_s/N_s - n_g/N_g$$

with

n<sub>s</sub>=number of citations of the herb or herb category in the specific population

N<sub>s</sub>=total number of herbs used in the specific population

n<sub>g</sub>=number of citations of the herb or herb category in the general population

N<sub>g</sub>=total number of herbs used in the general population

This mode of calculation was used to avoid the representation of rarely used herb (for which a difference due to random factor such as preferences is more likely to be significant). Only differences equal or superior in absolute value to 0.5 for herbs and 1.0 for herbs categories were reported. In order to allow an easier reading, the differences were reported in terms of percent of increase or decrease compared to the general population, as calculated according to the following formula:

$$(n_s/N_s - n_g/N_g) / n_g/N_g \times 100$$

#### 7. Thematic analysis

The original articles were imported to NVivo and analyzed using a thematic analysis process. The first step was data familiarization, then initial codes were generated using open-coding, after which themes were searched, reviewed, defined and named, and finally reported [43]. As the primary question is "how to treat insomnia with Chinese medicine?", sections reviewing the literature and

theoretical discussions about the nature of sleep, insomnia and etiological factors were not coded. Coding guidelines, which were built before the coding and modified during the coding are reported in Table 1. The analysis of the data was primarily descriptive (reporting the data from the CERs) but sometimes interpretative (creating theories from the data). The coding was conducted by YB and reviewed by MJ.

	cificities of age groups (children, older adults) and treatment ocols (except if specific to older adults or perimenopause)	Des
person 1.1.1. Age Spec	ocols (except if specific to older adults or perimenopause)	Des
•	ocols (except if specific to older adults or perimenopause)	Des
	rificities of both sex and treatment protocols	
1.1.2. Sex Spec	and the calment protocols	Des
1.1.3. Constitution Trea	tment according to constitution: principles and protocols	Des
1.1.4. Personality Trea	tment according to personality: principles and protocols	Des
1.1.5. Comorbidities		Int
•	tionship between insomnia, comorbidity and pattern, and tment principles	
1.1.5.2. Treatment Trea	tment protocols of comorbid insomnia	Des
_	onale and protocol for modification according to the season imate	Des
_	onale and protocol for modification according to the graphy, including climatic and cultural characteristics	Des
2. Treatment of insomnia subtypes		
	cificities of acute or persistent insomnia and treatment ocols for acute insomnia	Des
	cificities and treatment protocols for insomnia according to complaint	Des
3. General principles of treatment		
3.1. General General recommendations	eral recommendations regarding diagnosis and treatment	Des
	ommendations and information about a specific pattern (if included in the previous analysis)	Des
	tionship between the treatment according to the pattern and ording to the disease	Des-Int
3.4. Treatment pathway Stag	es of treatment or actions when treatment is not effective	Des
4. Herbal medicine		

4.1. Spirit-calming herbs		
4.1.1. Principles	Principles of use of spirit-calming herbs	Des
4.1.2. Types	Types of spirit-calming herbs and indications	Des
4.1.3. Atypical	Description of herbs that are usually not considered spirit-calming	Des
4.1.4. Pharmacology	Use of pharmacology studies as a reference	Des-Int
4.2. Herbs combinations		
4.2.1. Principles	Principles of combining pairs or trios of herbs	Int
4.2.2. Combinations	Description of pairs and trios of herbs	Des
4.3. Preparation and intake methods	Description of preparation and intake methods	Des
4.4. Treatment regimen	Number of doses and treatment duration	Des
4.5. Special patterns		
4.5.1. Non-interaction between heart and kidney	Principles, aetiological pathways, signs and symptoms and treatment protocols	Des-Int
4.5.2. Stomach disharmony	Principles, aetiological pathways, signs and symptoms and treatment protocols	Des-Int
4.5.3. Deregulation between protective and nutritive	Principles, aetiological pathways, signs and symptoms and treatment protocols	Des-Int
4.5.4. Yang and qi deficiency	Principles, aetiological pathways, signs and symptoms and treatment protocols	Des-Int
4.6. Additional herbal treatments		
4.6.1. Herbal footbath	Protocol for herbal footbath	Des
4.6.2. Infusion	Protocol for infusion	Des
4.6.3. Herbal pillow	Protocol for herbal pillow	Des
4.6.4. Manufactured products	Rationale and protocol for manufactured product	Des
4.6.5. Herbal paste	Rationale for use and treatment protocol	Des
4.6.6. Injections	Rationale for use and treatment protocol	Des
<ol><li>Acupuncture and massage</li></ol>		
5.1. Techniques	Acupuncture techniques	Des
5.2. Special approaches	Non-mainstream treatment approaches	Des
5.3. Treatment regimen	Number of sessions and duration of the therapeutic course	Des
5.4. Point selection rationale	Rationale for point selection and related points	Des
5.5. Massage	Treatment protocols	Des
5.6. Scalp acupuncture	Treatment protocols	Des
5.7. Ear acupuncture	Treatment protocols	Des

5.8. Hand and foot acupuncture	Treatment protocols	Des
5.9. Cupping and guasha	Treatment protocols	Des
5.10. Bloodletting	Treatment protocols	Des
5.11. Moxhibustion	Treatment protocols	Des
5.12. Plaster	Treatment protocols	Des
5.13. Buried wire	Treatment protocols	Des
5.14. Plum flower acupuncture	Treatment protocols	Des
6. Additional treatments		
6.1. Psychotherapy	Categories and treatment protocol	Des
6.2. Qigong	Treatment protocol	Des
6.3. Music therapy	Treatment protocol	Des
7. Self-treatment		
7.2. Lifestyle recommendations	Recommendations	Des
7.3. Sleep hygiene	Recommendations	Des
7.4. Food therapy	General and specific recommendations	Des
7.5. Exercise	Recommendations	Des
7.6. Acupressure	Recommendations	Des
8. Combination with other therapies		
8.1. Principles	Principles of combining Chinese medicine with other treatments	Des
8.2. Application	Treatment protocols	Des

Table 1. Codes description and type of analysis

#### 8. Rigor

The rigor of this systematic review, which is qualitative in nature, was enhanced by disclosing the authors' background and perspective about the topic, describing the analysis process in detail (including the decision-making process), using quotes from the source, using analyst triangulation, and with an audit conducted by the main supervisor (XZ).