

# 針灸與中藥預防及治療失眠

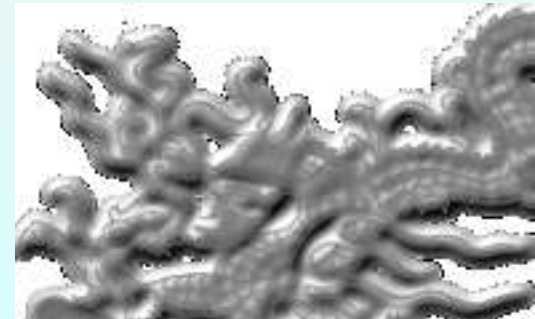
## Prevention and treatment for insomnia using acupuncture and/or Chinese herbal medicine

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# Epidemiology

- ◆ Around 9-15% in the general population suffer from insomnia symptoms, including difficulty initiating sleep (難入睡), maintaining sleep (難維持睡眠) and non-restorative sleep (睡醒後不能得到休息) that are associated with daytime consequences.



# Consequences of Insomnia 失眠導致的問題

- Depression/ anxiety/ suicide
- Alcohol and drug abuse or dependence

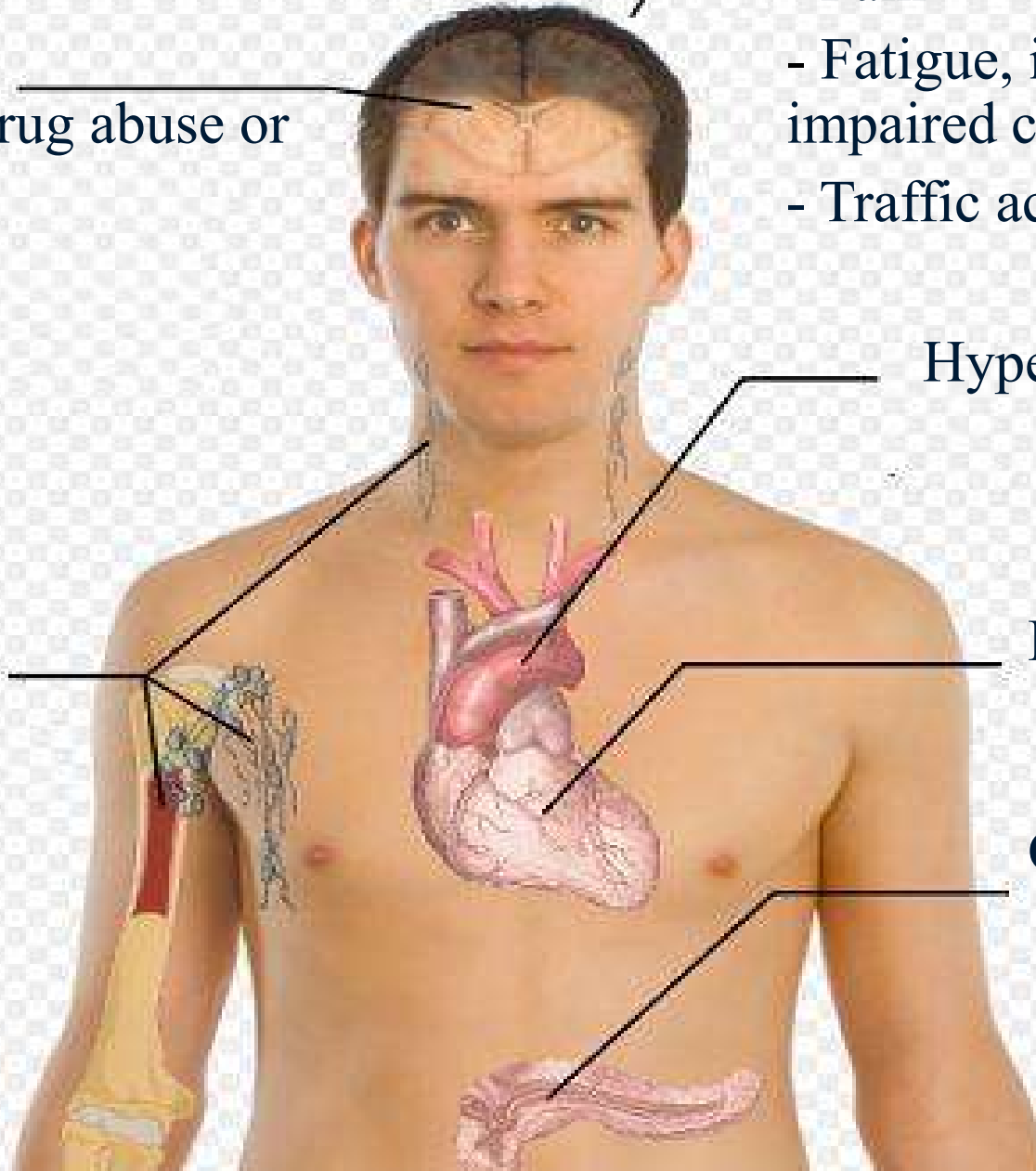
- Pain
- Fatigue, irritability, impaired concentration,
- Traffic accidents

Reduced quality of life and immune functions

Hypertension

Heart disease

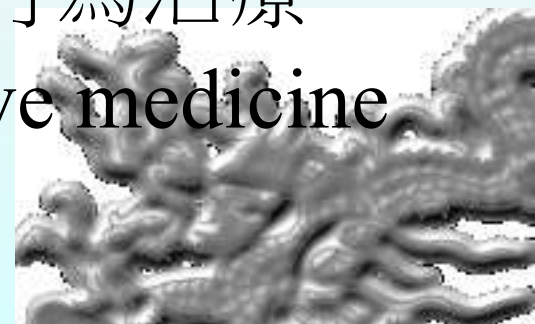
Obesity



# Treatment for insomnia

## 失眠的治療

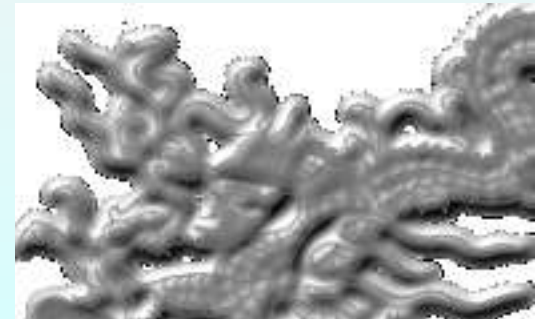
- ◆ Prescribed drugs 處方藥物 (Benzodiazepine, Zopiclone, Zolpidem, Trazodone)
- ◆ Over-the-counter drugs 非處方藥物 (Promethazine, Melatonin, Western herbs)
- ◆ TCM 中醫 (Chinese herbal formula, acupuncture, others)
- ◆ Cognitive behavioral therapy 認知行為治療
- ◆ Other complementary and alternative medicine therapies 另類療法



# How we have studied the TCM treatments for insomnia

## 我們過往有關中醫治療失眠的研究

- ◆ Systematic reviews (系統性文獻回顧)
- ◆ Randomized placebo-controlled trials (隨機安慰對照研究)
- ◆ Pragmatic randomized clinical trials in TCM settings (實用性中醫臨床試驗)



# Traditional needle acupuncture treatment for insomnia: A systematic review of randomized controlled trials

Wing-Fai Yeung<sup>a</sup>, Ka-Fai Chung<sup>a,\*</sup>, Yau-Kwong Leung<sup>a</sup>, Shi-Ping Zhang<sup>b</sup>, Andrew C.K. Law<sup>a</sup>

## A B S T R A C T

**Objectives:** Previous reviews regarding traditional needle acupuncture (TNA) treatment for insomnia were limited to English scientific literature. A comprehensive review including Chinese and English literature has therefore been conducted to examine the efficacy of TNA for insomnia.

**Methods:** We performed systematic review of randomized controlled trials (RCTs) of TNA as intervention for insomnia against placebo, Western medication, and non-treated controls. The methodological quality of the studies was assessed by the modified Jadad score and the acupuncture procedure was appraised by the STRICTA criteria.

**Results:** Twenty RCTs were identified for detailed analysis. Majority of the RCTs concluded that TNA was significantly more effective than benzodiazepines for treating insomnia, with mean effective rates for acupuncture and benzodiazepines being 91% and 75%, respectively. In two more appropriately conducted trials, TNA appeared to be more efficacious in improving sleep than sleep hygiene counseling and sham acupuncture. Standardized and individualized acupuncture had similar effective rates. Despite these positive outcomes, there were methodological shortcomings in the studies reviewed, including imprecise diagnostic procedure, problems with randomization, blinding issues, and insufficient safety data. Hence, the superior efficacy of TNA over other treatments could not be ascertained.

**Conclusion:** Since the majority of evidence regarding TNA for insomnia is based on studies with poor-quality research designs, the data, while somewhat promising, do not allow a clear conclusion on the benefits of TNA for insomnia. Moreover, the results support the need for large scale placebo-controlled double-blinded trials.





# Acupressure, reflexology, and auricular acupressure for insomnia: A systematic review of randomized controlled trials

Wing-Fai Yeung<sup>a</sup>, Ka-Fai Chung<sup>a,\*</sup>, Maggie Man-Ki Poon<sup>a</sup>, Fiona Yan-Yee Ho<sup>a</sup>, Shi-Ping Zhang<sup>b</sup>, Zhang-Jin Zhang<sup>c</sup>, Eric Tat-Chi Ziea<sup>d</sup>, Vivian Taam Wong<sup>d</sup>

## A B S T R A C T

Previous randomized controlled trials (RCTs) have shown that acupuncture may be efficacious for insomnia. Instead of needling, acupressure, reflexology, and auricular acupressure are procedures involving physical pressure on acupoints or reflex areas. These variants of acupuncture are gaining popularity, perhaps due to their non-invasive nature. A systematic review has therefore been conducted to examine their efficacy and safety for insomnia. Two independent researchers searched five English and 10 Chinese databases from inception to May 2010. Forty RCTs were identified for analysis. Only 10 studies used sham controls, four used double-blind design, nine studies scored three or more by the Jadad scale, and all had at least one domain with high risk of bias. Meta-analyses of the moderate-quality RCTs found that acupressure as monotherapy fared marginally better than sham control. Studies that compared auricular acupressure and sham control showed equivocal results. It was also found that acupressure, reflexology, or auricular acupressure as monotherapy or combined with routine care was significantly more efficacious than routine care or no treatment. Owing to the methodological limitations of the studies and equivocal results, the current evidence does not allow a clear conclusion on the benefits of acupressure, reflexology, and auricular acupressure for insomnia.

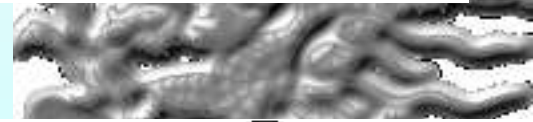


# Chinese herbal medicine for insomnia: A systematic review of randomized controlled trials

Wing-Fai Yeung<sup>a</sup>, Ka-Fai Chung<sup>a,\*</sup>, Maggie Man-Ki Poon<sup>a</sup>, Fiona Yan-Yee Ho<sup>a</sup>, Shi-Ping Zhang<sup>b</sup>, Zhang-Jin Zhang<sup>c</sup>, Eric Tat-Chi Ziea<sup>d</sup>, Vivian Taam Wong<sup>d</sup>

## S U M M A R Y

Chinese herbal medicine (CHM), either in single herb or in herbal formula, has been used to treat insomnia for more than 2000 years. A systematic review including Chinese and English literature of randomized controlled trials was conducted to examine the efficacy, safety, and composition of CHM for insomnia. Among the 217 studies we have reviewed, only eight had a Jadad score  $\geq 3$ , and seven out of these eight studies had at least one domain with high risks of bias. Meta-analyses of the studies with Jadad score  $\geq 3$  found that CHM was similar to Western medication (three studies) and placebo (three studies) in treating insomnia. Due to the poor methodological quality of the studies and the small number of trials included in meta-analyses, the current evidence is insufficient to support the efficacy of CHM for insomnia. The frequency of adverse events associated with CHM was similar to that of placebo, but lower than with Western medication. Gui Pi Tang was the most commonly used standardized formula, while Suan Zao Ren (*Ziziphus jujuba*) was the most frequently used single herb. Further studies with a double-blind placebo-controlled design are needed to accurately determine the benefits and risks of CHM for insomnia.





# Conclusion

## 結論

- ◆ The majority of the previous studies were of low methodological quality.
- ◆ In general, the TCM treatments were shown to produce better sleep than placebo, Western medication, psychotherapy, and non-treated controls.
- ◆ There was insufficient high-quality evidence and therefore better designed studies were needed.



# Electroacupuncture for Primary Insomnia: A Randomized Controlled Trial

Wing-Fai Yeung, BCM, BSc<sup>1</sup>; Ka-Fai Chung, MBBS; MRCPsych<sup>1</sup>; Shi-Ping Zhang, MB, PhD<sup>2</sup>; Tuan-Gee Yap, MBBS, PhD<sup>3</sup>; Andrew C.K. Law, MD, PhD, FRCPC<sup>1</sup>

**Study Objectives:** To evaluate the short-term efficacy and safety of electroacupuncture for the treatment of primary insomnia.

**Design:** Randomized, single-blind, placebo-controlled, parallel-group.

**Setting:** A university-based sleep clinic.

**Participants:** Community sample of 60 Chinese adult volunteers who report having insomnia 3 or more nights per week, whose symptoms meet the DSM-IV criteria for primary insomnia for at least 3 months, and who have an Insomnia Severity Index total score of at least 15. Participants were screened with polysomnography and the Structured Clinical Interview for the DSM-IV prior to randomization.

**Intervention:** Electroacupuncture at Yintang (EX-HN3), Baihui (GV20), bilateral ear Shenmen, Sishencong (EX-HN1), and Anmian (EX) 3 times per week for 3 weeks or placebo acupuncture using Streitberger needles at the same points.

**Measurements and Results:** Self-reported questionnaires, 1-week sleep diaries, and 3-day actigraphy were collected at baseline and 1 week after treatment. The Insomnia Severity Index was used as the primary outcome measure. Both groups showed significant improvement

compared with the pretreatment baseline. One-way analysis of covariance adjusted for baseline scores showed that there were significantly greater improvements in sleep efficiency by sleep diary and actigraphy in the electroacupuncture group. However, no significant between-group differences were observed in the Insomnia Severity Index and other outcome measures. The proportions of subjects having less than 30 minutes of wake after sleep onset and a sleep efficiency of at least 85% at the posttreatment visit were significantly higher in the electroacupuncture group. All adverse events were mild in severity.

**Conclusion:** We found a slight advantage of electroacupuncture over placebo acupuncture in the short-term treatment of primary insomnia. Because of some limitations of the current study, further studies are necessary to verify the effectiveness of acupuncture for insomnia.

**Keywords:** Acupuncture, electroacupuncture, insomnia, randomized controlled trial, sleep, traditional Chinese medicine.

**Citation:** Yeung WF; Chung KF; Zhang SP; Yap TG; Law ACK. Electroacupuncture for primary insomnia: a randomized controlled trial.

**SLEEP** 2009;32(8):1039-1047.



# Electroacupuncture for Residual Insomnia Associated with Major Depressive Disorder: A Randomized Controlled Trial

Wing-Fai Yeung, BCM, BSc, PhD<sup>1</sup>; Ka-Fai Chung, MBBS, MRCPsych<sup>1</sup>; Kwok-Chu Tso, MBChB, FHKAM<sup>1</sup>; Shi-Ping Zhang, MB, PhD<sup>2</sup>; Zhang-Jin Zhang, BMed, MMed, PhD<sup>3</sup>; Lai-Ming Ho, PhD, CStat<sup>4</sup>

**Study Objectives:** To evaluate the efficacy and safety of electroacupuncture as an additional treatment for residual insomnia associated with major depressive disorder (MDD).

**Design:** Randomized, placebo-controlled.

**Setting:** A psychiatric outpatient clinic.

**Participants:** 78 Chinese patients with *DSM-IV*-diagnosed MDD, insomnia complaint, a Hamilton Rating Scale for Depression (HDRS<sub>17</sub>) score  $\leq 18$ , and fixed antidepressant dosage.

**Intervention:** Electroacupuncture, minimal acupuncture (superficial needling at non-acupuncture points), or noninvasive placebo acupuncture 3 sessions weekly for 3 weeks.

**Measurements and Results:** Insomnia Severity Index (ISI), Pittsburgh Sleep Quality Index (PSQI), HDRS<sub>17</sub>, 1 week sleep diaries, and 3 day actigraphy were administered at baseline, 1 week post-treatment, and 4 week post-treatment. There was significant group by time interaction in ISI, PSQI, and sleep diary-derived sleep efficiency (mixed-effects models,  $P = 0.04$ ,  $P = 0.03$ , and  $P = 0.01$ , respectively). Post hoc pairwise comparisons revealed that electroacupuncture and minimal acupuncture were more efficacious than placebo acupuncture in ISI and PSQI at 1 week and 4 week post-treatment. Minimal acupuncture resulted in greater improvement in sleep diary-derived sleep efficiency than placebo acupuncture at 1 week post-treatment. There was no significant between-group difference in actigraphy measures, depressive symptoms, daily functioning, and hypnotic consumption, and no difference in any measures between electroacupuncture and minimal acupuncture.

**Conclusion:** Compared with placebo acupuncture, electroacupuncture and minimal acupuncture resulted in greater improvement in subjective sleep measures at 1 week and 4 week post-treatment. No significant difference was found between electroacupuncture and minimal acupuncture, suggesting that the observed differences could be due to nonspecific effects of needling, regardless of whether it is done according to traditional Chinese medicine theory.

**Clinical Trial Information:** Acupuncture for Residual Insomnia Associated with Major Depressive Disorder; Registration #NCT00838994; URL - <http://clinicaltrials.gov/ct2/show/NCT00838994?term=NCT00838994&rank=1>

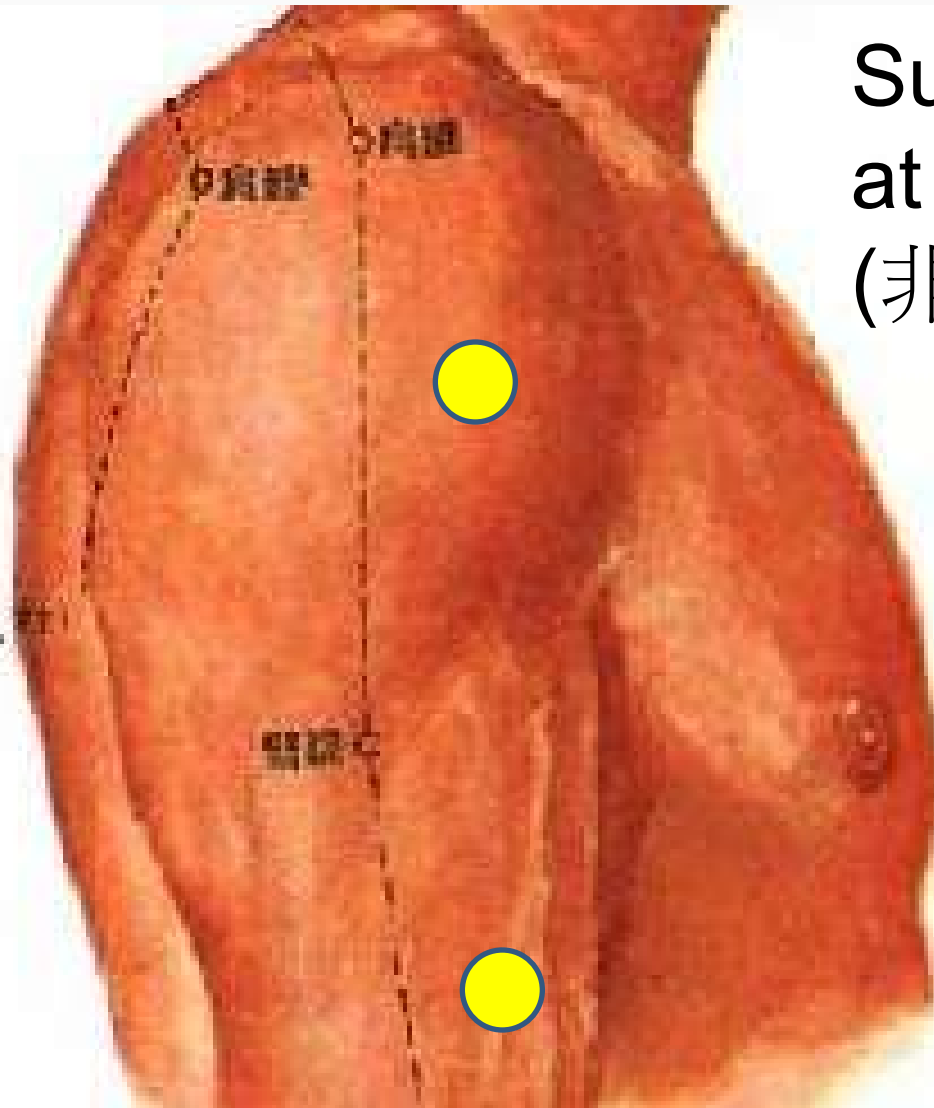






# Minimal Acupuncture Group

## 微針灸組



Superficial needling  
at non-acupoints  
(非穴位位置淺針)

“Deltoides”

“Upper arm”



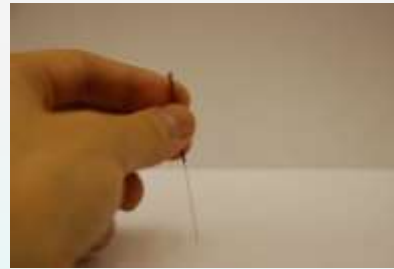




# Placebo Acupuncture Group 安慰針灸組

## *Placebo Acupuncture*

- ◆ Non-invasive telescopic placebo needles (非穿透性伸縮安慰針) designed by Streitberger (1998) were used
- ◆ Blunt tip
- ◆ Handle slides over the needle without penetrating the skin



# Therapeutic components

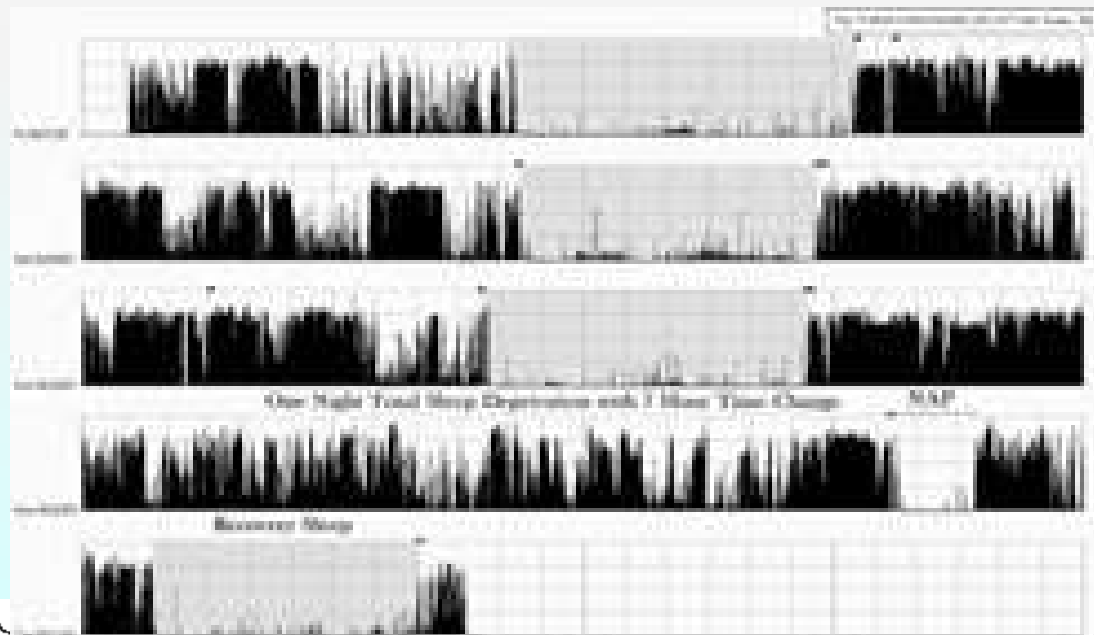
## 構成治療要素

	Traditional Acup 中醫針灸	Minimal Acup 微針灸	Placebo Acup 安慰針
Specific Acupoint 準確穴位位置	●		
“De qi” effect & deep needling 得氣及深刺	●		
Electric stimulation 電刺激	●	●	
Skin penetration 穿透皮膚	●	●	
Placebo effect 安慰作用	●	●	●

# Outcome assessment

## 結果評估

- ◆ Sleep diary (睡眠日記)
- ◆ Subjective insomnia scales (主觀睡眠測量)
- ◆ Actigraph (腕動計)
  - Estimate sleep pattern by recording patient's wrist movement for 3 consecutive nights



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**Conclusion:** We found a slight advantage of electroacupuncture over placebo acupuncture in the short-term treatment of primary insomnia. Because of some limitations of the current study, further studies are necessary to verify the effectiveness of acupuncture for insomnia.

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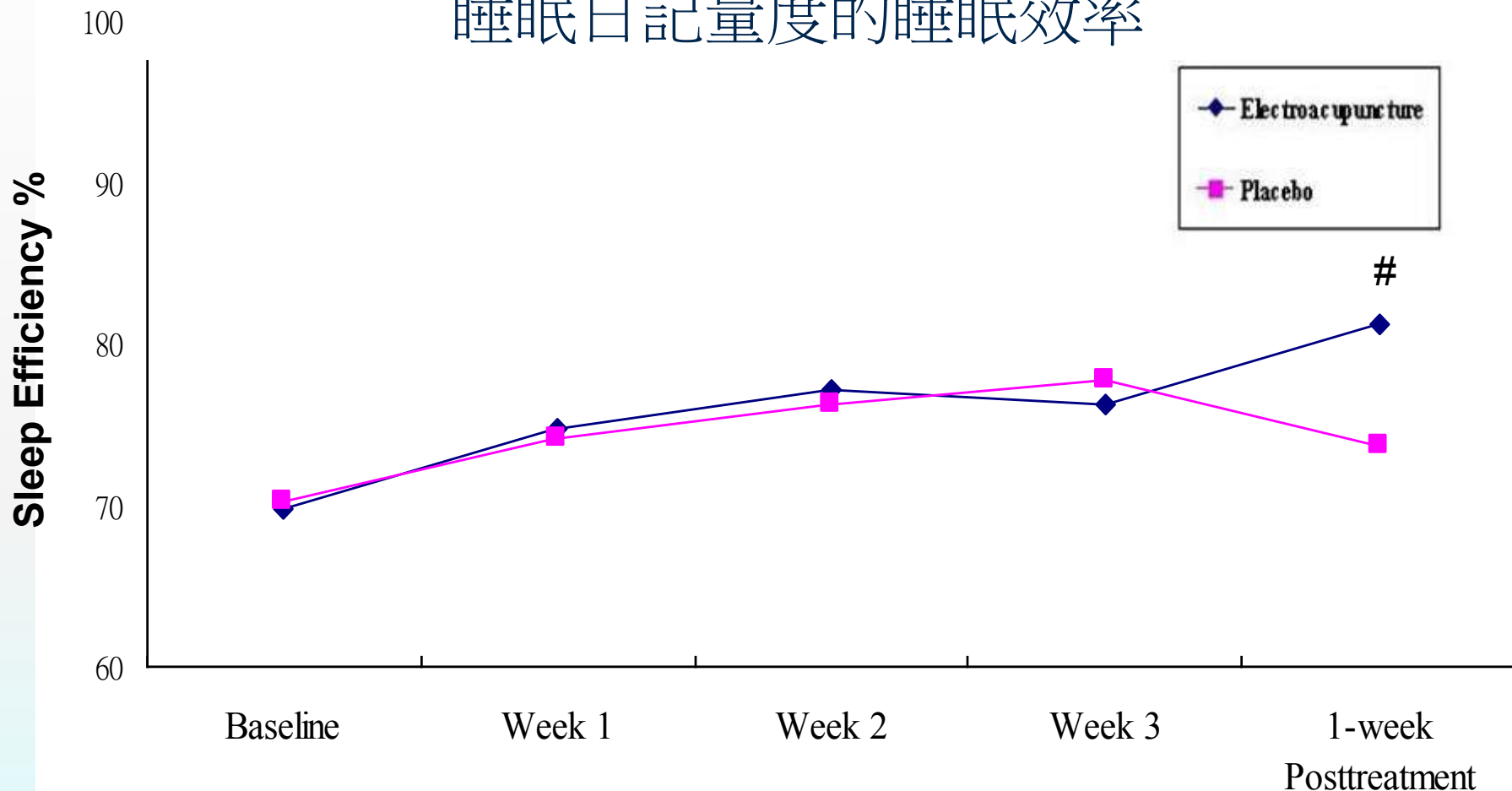
**SLEEP** 2009;32(8):1039-1047.





# Sleep Efficiency Measured by Sleep Diary

## 睡眠日記量度的睡眠效率

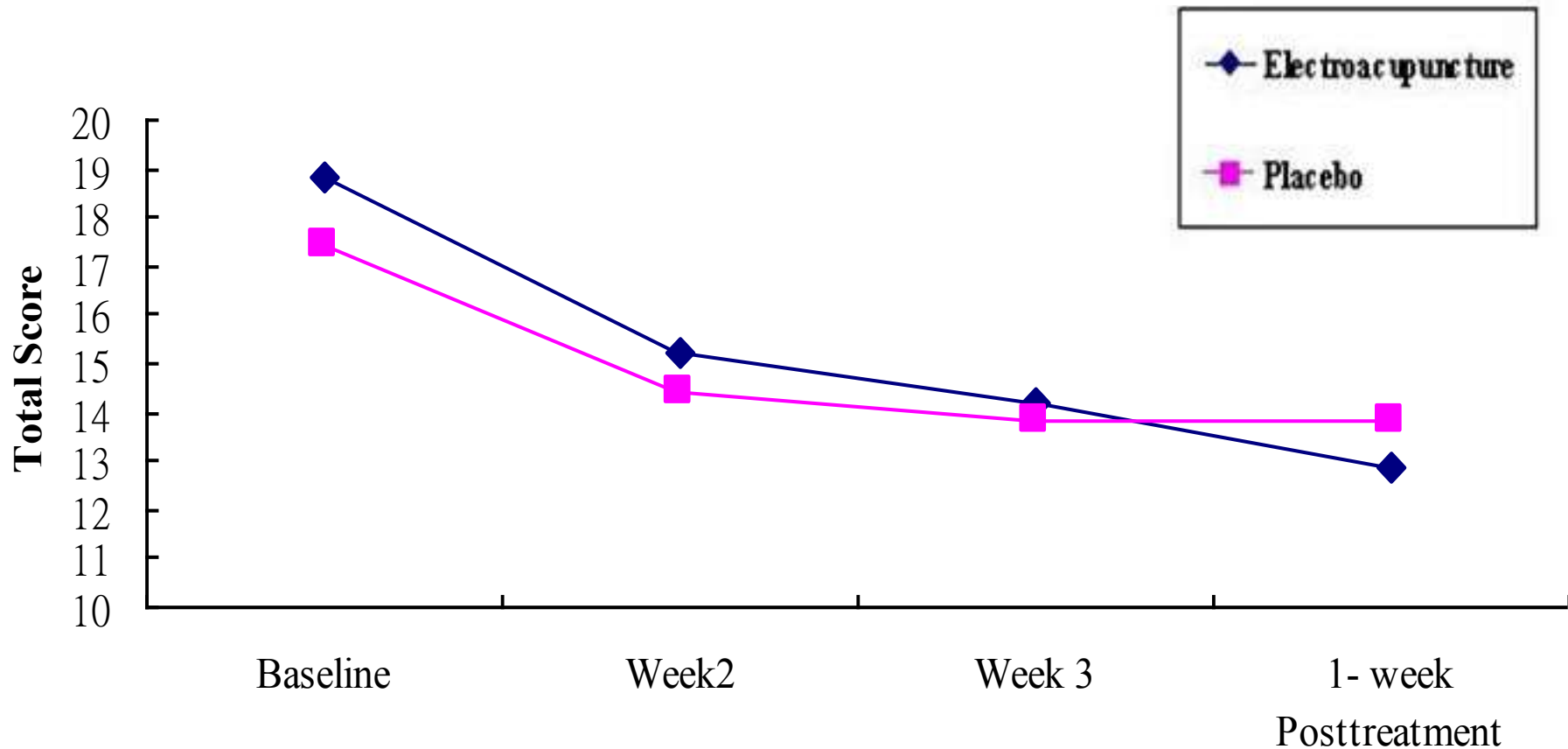


# Electroacupuncture group showed a significantly greater SE at 1-week posttreatment when compared with the Placebo Acupuncture group ( $P = 0.002$ , ANCOVA using baseline measure as a covariate)

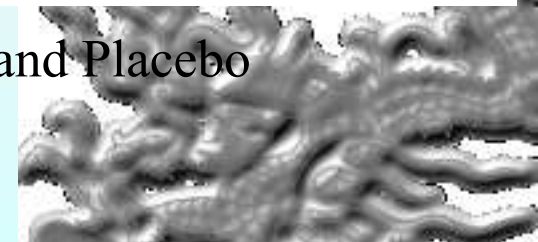
$$\text{Sleep Efficiency} = \text{Total Sleep Time} / \text{Total Bed Time} \times 100\%$$

# Insomnia Severity Index (ISI) Score

## 失眠嚴重指數

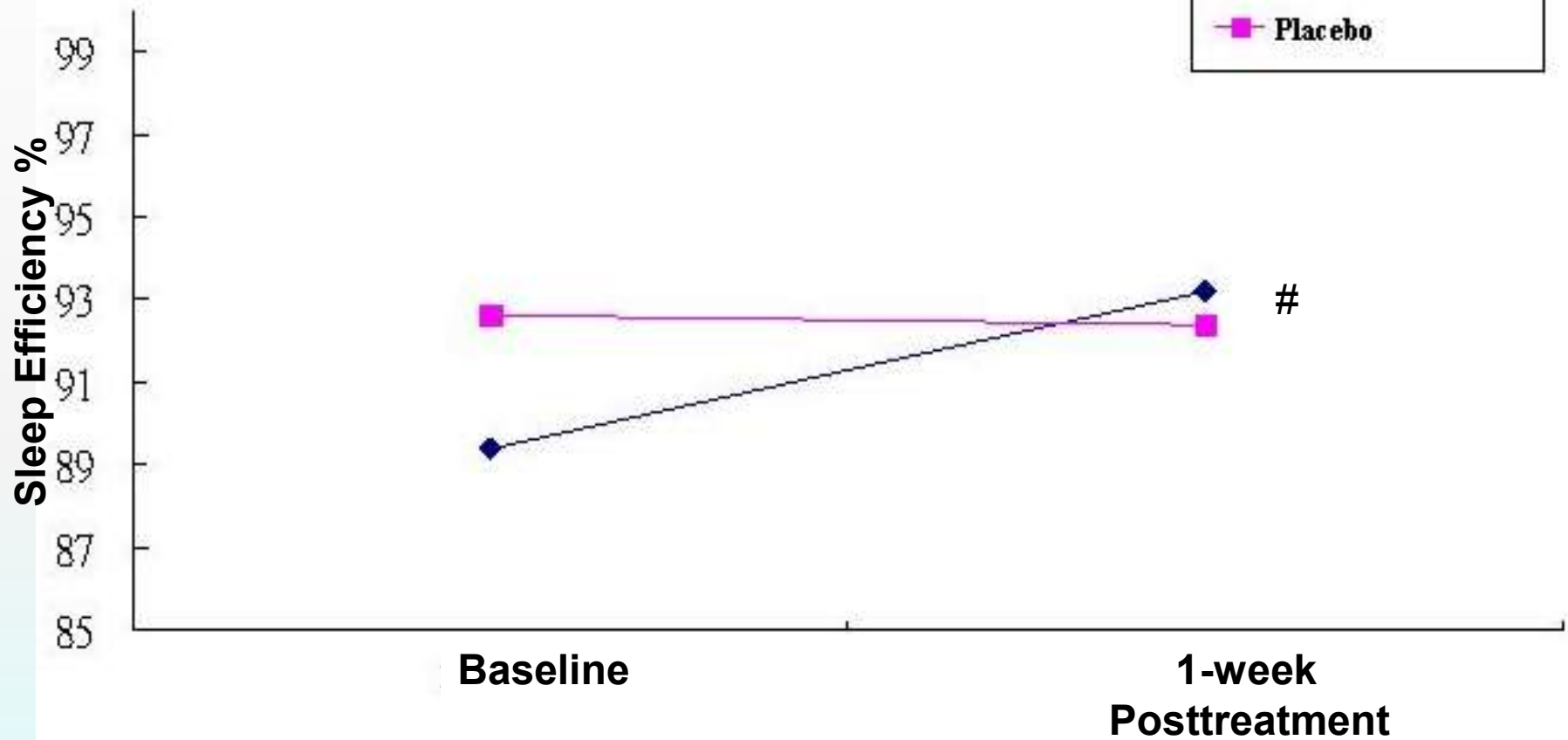


No significant difference between Electroacupuncture and Placebo Acupuncture groups



# Sleep Efficiency Measured by Actigraphy

## 腕動計量度的睡眠效率



# Electroacupuncture group showed a significantly greater SE at 1-week posttreatment when compared with the Placebo Acupuncture group ( $P = 0.04$ , ANCOVA using baseline measure as a covariate)

# Electroacupuncture for Residual Insomnia Associated with Major Depressive Disorder: A Randomized Controlled Trial

Wing-Fai Yeung, BCM, BSc, PhD<sup>1</sup>; Ka-Fai Chung, MBBS, MRCPsych<sup>1</sup>; Kwok-Chu Tso, MBChB, FHKAM<sup>1</sup>; Shi-Ping Zhang, MB, PhD<sup>2</sup>; Zhang-Jin Zhang, BMed, MMed, PhD<sup>3</sup>; Lai-Ming Ho, PhD, CStat<sup>4</sup>

**Study Objectives:** To evaluate the efficacy and safety of electroacupuncture as an additional treatment for residual insomnia associated with major depressive disorder (MDD).

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**Intervention:** Electroacupuncture, minimal acupuncture (superficial needling at non-acupuncture points), or noninvasive placebo acupuncture 3 sessions weekly for 3 weeks.

**Measurements and Results:** Insomnia Severity Index (ISI), Pittsburgh Sleep Quality Index (PSQI), HDRS<sub>17</sub>, 1 week sleep diaries, and 3 day actigraphy were administered at baseline, 1 week post-treatment, and 4 week post-treatment. There was significant group by time interaction in ISI, PSQI, and sleep diary-derived sleep efficiency (mixed-effects models,  $P = 0.04$ ,  $P = 0.03$ , and  $P = 0.01$ , respectively). Post hoc pairwise comparisons revealed that electroacupuncture and minimal acupuncture were more efficacious than placebo acupuncture in ISI and PSQI at 1 week and 4 week post-treatment. Minimal acupuncture resulted in greater improvement in sleep diary-derived sleep efficiency than placebo acupuncture at 1 week post-treatment. There was no significant between-group difference in actigraphy measures, depressive symptoms, daily functioning, and hypnotic consumption, and no difference in any measures between electroacupuncture and minimal acupuncture.

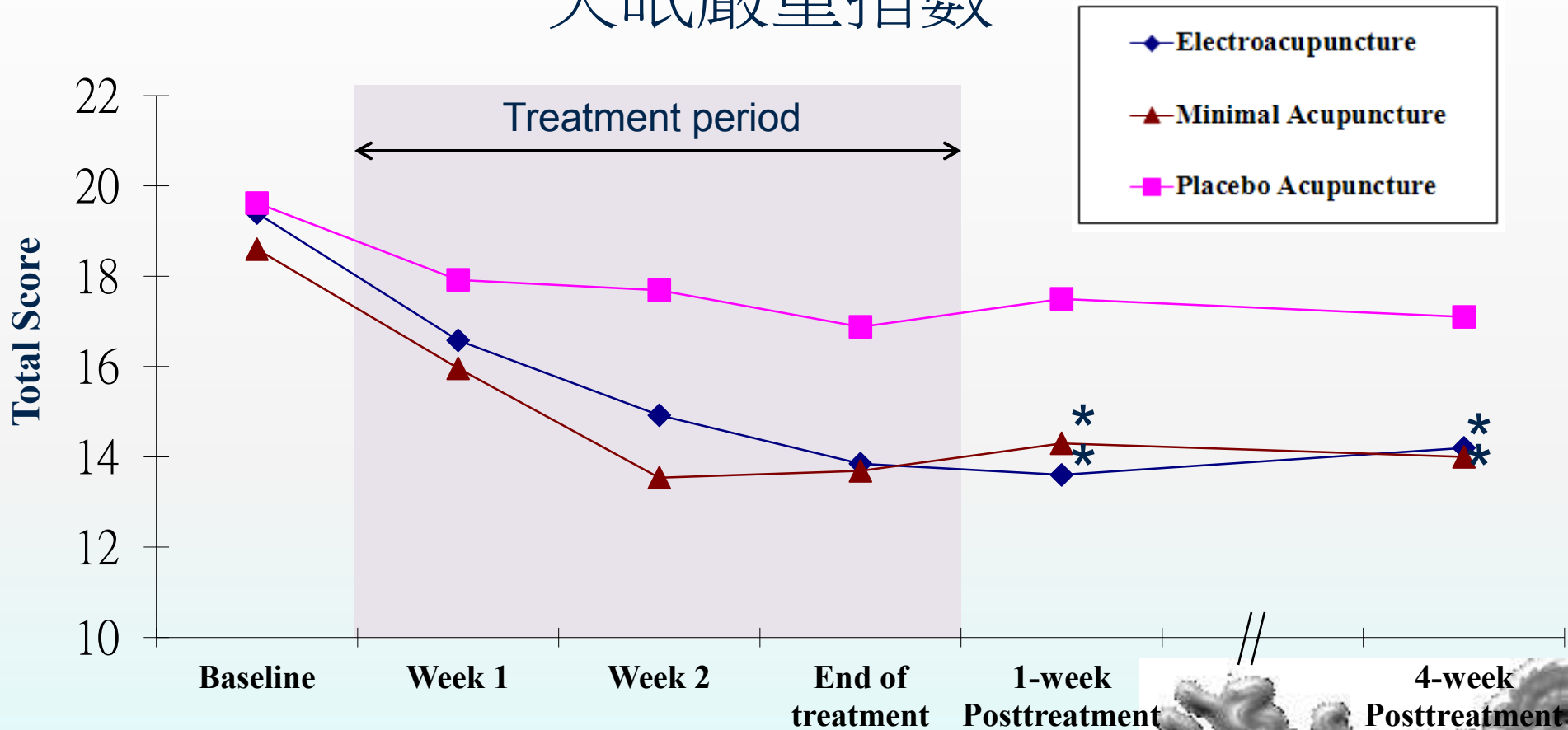
**Conclusion:** Compared with placebo acupuncture, electroacupuncture and minimal acupuncture resulted in greater improvement in subjective sleep measures at 1 week and 4 week post-treatment. No significant difference was found between electroacupuncture and minimal acupuncture, suggesting that the observed differences could be due to nonspecific effects of needling, regardless of whether it is done according to traditional Chinese medicine theory.

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# Insomnia Severity Index (ISI) Score

## 失眠嚴重指數

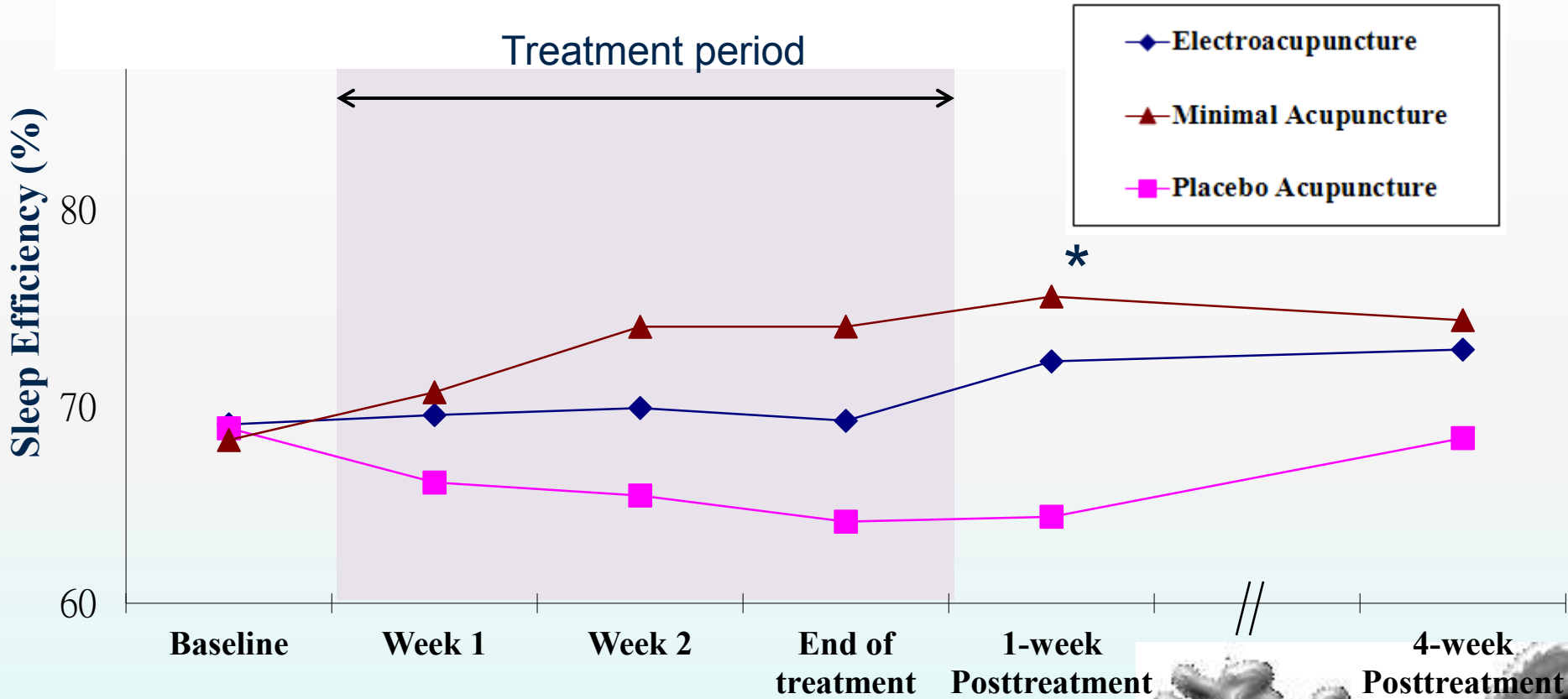


\* Electroacupuncture and Minimal Acupuncture groups showed a significantly greater ISI improvement when compared with the Placebo Acupuncture group (Mixed effects model,  $P = 0.04$ )

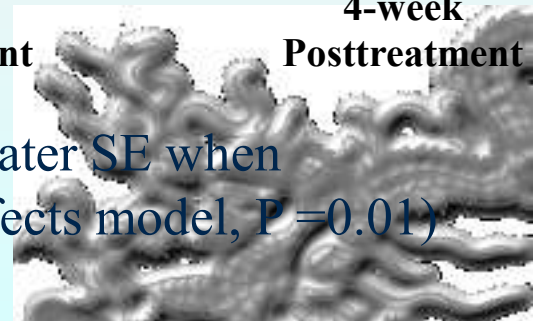


# Sleep Efficiency Measured by Sleep Diary

## 睡眠日記量度的睡眠效率

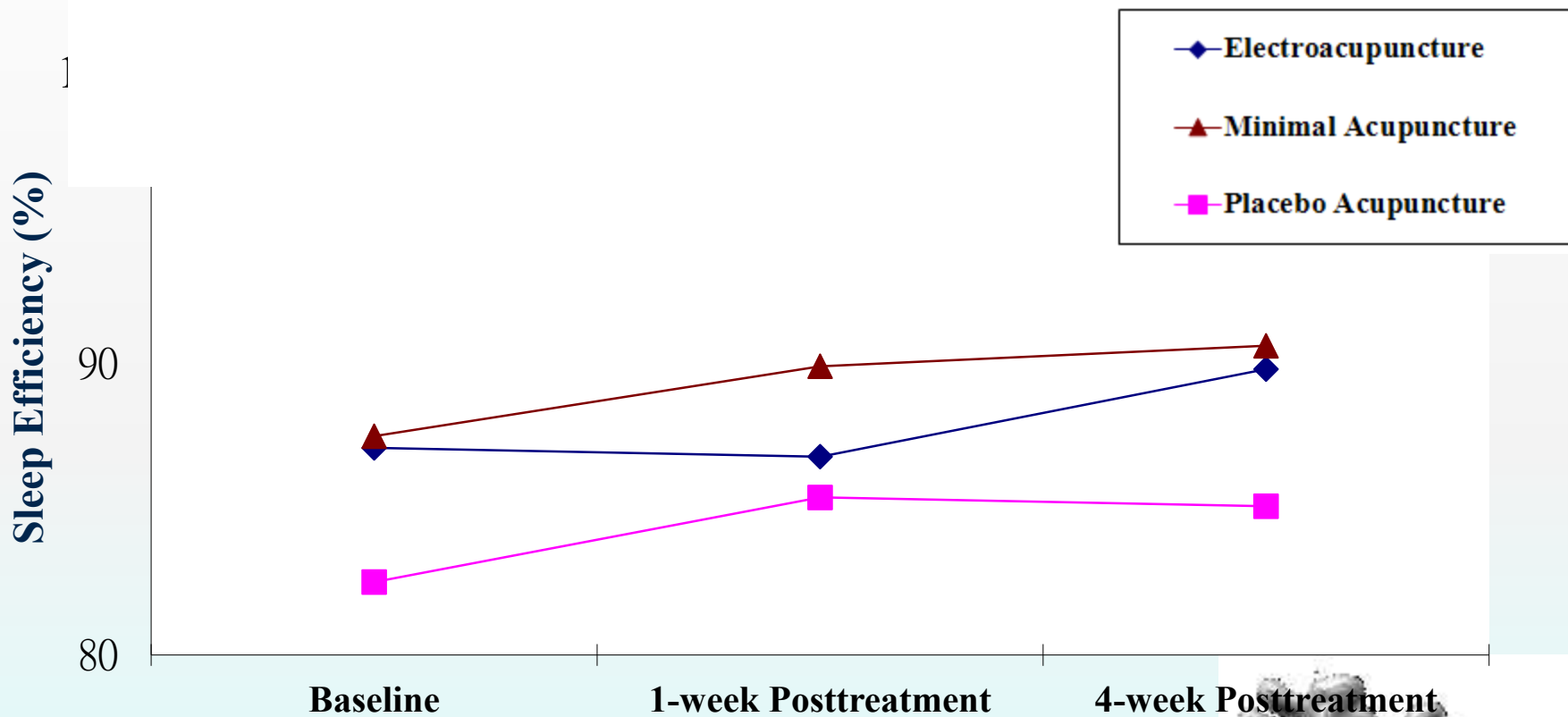


\* Minimal Acupuncture groups showed a significantly greater SE when compared with the Placebo Acupuncture group (Mixed effects model,  $P=0.01$ )



# Sleep Efficiency Measured by Actigraphy

## 腕動計量度的睡眠效率



No significant difference between the Electroacupuncture, Minimal Acupuncture, and Placebo Acupuncture groups (Mixed effects model,  $P > 0.05$ )

# Conclusion

## 結論

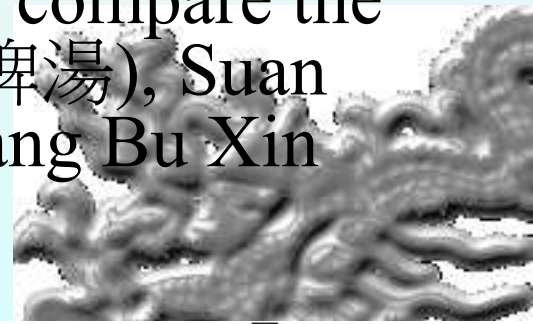
- ◆ Electroacupuncture and minimal acupuncture were more effective than placebo acupuncture in treating insomnia.
- ◆ There were no significant differences between electroacupuncture and minimal acupuncture in all outcome measures.
- ◆ Adverse events related to acupuncture were mild in severity.



# Other Completed / Ongoing / Planned studies

## 其他已完成/進行中/計劃中的研究

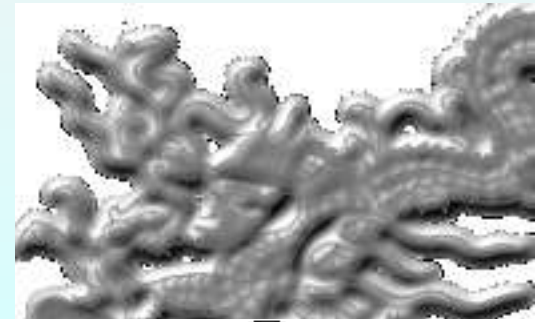
- ◆ Systematic review on the classification of insomnia using the TCM system
- ◆ Systematic review on pattern-based TCM treatment of insomnia
- ◆ Randomized placebo-controlled trial to compare traditional and minimal acupuncture that used “compatible” acupuncture sites
- ◆ Randomized placebo-controlled trial to compare the efficacy and safety of Gui Pi Tang (歸脾湯), Suan Zao Ren Tang (酸棗仁湯) and Tian Wang Bu Xin Dan (天王補心丹) for insomnia



# Future studies

## 今後研究

- ◆ Pragmatic clinical trial to compare individualized therapist-prescribed pattern-based acupuncture (醫師辨證取穴) vs. standardized acupuncture (標準統一取穴) for insomnia







## Acknowledgement 致謝

- ◆ Dr. Jerry WF Yeung 楊穎輝醫師/博士
- ◆ Dr. SP Zhang 張世平醫師/博士
- ◆ Dr. ZJ Zhang 張樟進醫師/博士