Auricular therapy and insomnia in the elderly

Suen Kwai Ping Lorna

This thesis is submitted for the

Degree of Doctor of Philosophy

at

The Hong Kong Polytechnic University

(June 2001)

ACKNOWLEDGEMENT

I would like to express my deepest gratitude to my academic supervisor, Professor Thomas K.S. Wong, for providing constant inspiration during my study. This research would never have been possible without his scholarly advice, tremendous support and encouragement.

I am also very grateful to my co-supervisor, Dr. Albert W.N. Leung. His advice, enthusiasm and unfailing help were all invaluable and essential during the research process.

I would like to express my sincere thanks to Dr. Shi Yan, a practitioner of Chinese medicine of the Hong Kong Baptist University, for offering his generous assistance in performing the traditional Chinese diagnosis on insomnia for the participants; as well as to Dr. Y.L. Yip, President of the Auricular Acupuncture Association, for his valuable contribution in conducting the interrater reliability on the location of acupoints.

Special thanks are due to Mr. Joseph Chai for his assistance on data entry; to Dr. Carol MacLennan and Dr. Sima Sengupta for their linguistic advice during the final stage of preparation of this thesis. In addition, my heartfelt thanks are extended to the superintendents and staff in the twelve hostels for the elderly for their support and assistance during the data collection period; as well as the volunteers for their participation and cooperation

during the process. Without their involvement, there would be no thesis.

The encouragement and advice given by many colleagues and friends throughout the research process must be acknowledged, though I cannot name all of them here! Last but by no means the least, I wish to thank my husband and my parents for their never-ending love, tireless support, care and encouragement.

Suffice it to say that without help from the people I have mentioned above, my study would not have been conducted so smoothly. I would like to express my appreciation again and show that I treasure all their kindness and support.

DECLARATION

I declare that this study represents my own work, except where due acknowledgement is made. The ideas in this dissertation have not been previously included in any thesis, dissertation or report submitted to this University or to any other institution for a degree, diploma or other qualification.

SUEN Kwai Ping Lorna

Abstract of thesis entitled 'Auricular therapy and insomnia in the elderly'
submitted by SUEN Kwai Ping Lorna
for the degree of Doctor of Philosophy
at the Hong Kong Polytechnic University in June 2001

ABSTRACT

Sleep disturbances are a particularly common problem in the elderly. According to the principles of traditional Chinese diagnosis, insomnia can be deficient or excessive in nature. Sleep efficiency declines with an increase in time spent in bed and a decrease in the total time spent asleep in people with insomnia. Medication such as hypnotics has been widely adopted by the elderly to overcome their sleeping problems; however the adverse effects of these drugs such as decreased reaction time and withdrawal insomnia will further compound the sleeping problems of the elderly. The purpose of this study is to examine the effectiveness of auricular therapy on sleep behaviours in the elderly. One hundred and twenty participants of 60 or above and have sleep disturbances were invited to participate in this study. Eligible participants were randomly assigned to receive auricular therapy using Junci Medulla (Group A=30), Semen Vaccariae (Group B=30) or magnetic pearls (Group C=60). Group A and Group B were the control groups, while Group C being the experimental group. Seven auricular points which are thought to have an effect on promoting sleep were selected. Junci Medulla/Semen Vaccariae/Magnetic

pearls were replaced every three to four days to avoid the possibility of local irritation of auricular points under treatment. The total treatment course lasted for three weeks (21 days). Objective measurement using actigraphic monitoring was performed before the therapy commenced, in the middle period of the therapy, and within one week after the therapy has been completed. After the therapy, there were significant differences among the three groups in terms of the nocturnal sleep time (NST) ($F_{2, 117}$ =6.84, p<0.05) and sleep efficiency (SE) ($F_{2, 117}$ =7.69, p<0.05). Significant improvement in the sleep behaviours was observed in the experimental group using magnetic pearls. No significant difference in the therapeutic effect on sleep could be found between clients with 'excessive' and 'deficiency' syndrome even when the treatment protocol was standardized. In a backward multiple regression, the effect of auricular therapy on sleep efficiency after allowing for age in female participants is of high statistical significance ($F_{3, 106}$ =9.04, p<0.001). It is argued that auricular therapy using magnetic pearls is an effective means towards improving the quantity and quality of sleep in the elderly, and is recommended that nurses should incorporate this in their nursing therapeutics for improvement of clients' sleep.

TABLE OF CONTENTS

APPENDICES

LIST OF TABLES

LIST OF FIGURES

PUBLICATIONS AND

CONFERENCE PRESENTATION

The list of publications and potential deliverables associated with this study include:

(A) Refereed journals

SUEN, L.K.P., WONG, T.K.S. & LEUNG, A.W.N. 'Is there a place for auricular therapy in the realm of nursing?' Complementary Therapies in Nursing and Midwifery, vol. 7, no.3, pp. 132-139 (2001).

SUEN, L.K.P., WONG, T.K.S. & LEUNG, A.W.N. Effectiveness of auricular therapy on sleep promotion in the elderly. The American Journal of Chinese Medicine (Submitted, October 2001).

SUEN, L.K.P., WONG, T.K.S. & LEUNG, A.W.N. Auricular therapy using magnetic pearls on sleep : a standardized protocol for the elderly with diverse traditional Chinese diagnosis on insomnia. Clinical Acupuncture and Oriental Medicine (Submitted, October 2001).

SUEN, L.K.P., WONG, T.K.S. & LEUNG, A.W.N. The long-term effect of auricular therapy using magnetic pearls on sleep promotion in the elderly. The Journal of Chinese Medicine (Submitted, October 2001).

SUEN, L.K.P., WONG, T.K.S. & LEUNG, A.W.N. Auricular therapy as energy healing in Rogers's conceptual model. Nursing Science Quarterly (in preparation).

孫桂萍，汪國成，梁榮能。磁珠貼壓耳穴對各種中醫分型之失眠的療效。中華護理雜誌。(準備中)

孫桂萍，汪國成，梁榮能。耳穴療法與老人失眠症之療效分析。中國針灸。(準備中)

(B) Conference presentations

孫桂萍，汪國成，梁榮能。耳穴療法與老人失眠症。中國睡眠研究會第二屆學術年會。天津：中國睡眠研究會，天津醫科大學總醫院。[論著匯編，第 92 頁] (2001 年 4 月 20-24 日) 。

SUEN, L.K.P., WONG, T.K.S. & LEUNG, A.W.N. Auricular therapy and insomnia in the elderly. International Scholarly Conference of China. Tianjian, China: Chinese Sleep Research Society, p.92, 20-24 April 2001.

孫桂萍，汪國成，梁榮能。 探討耳穴療法對老人失眠症之療效。2001 年亞洲護理學術大會。海南島海口市。[論著匯編，第 18-19 頁]。(2001 年 12 月 2-7 日) 。

SUEN, L.K.P., WONG, T.K.S. & LEUNG, A.W.N. The effectiveness of a clinical trial using auricular therapy on insomnia in the elderly. 2001 Asian Studies Conference. Heinam Province Heihau City, China, pp.18-19, 2-7 December 2001.

SUEN, L.K.P., WONG, T.K.S. & LEUNG, A.W.N. Auricular therapy and insomnia in the elderly. The 5th East Asian Forum of Nursing Scholars (EAFONS): Searching for Excellence: Doctoral Nursing Programs in Asia. Taipei, Taiwan, ROC: School and Graduate Institute of Nursing, National Taiwan University, 20-22 February 2002. (Accepted for presentation)

CHAPTER 1

INTRODUCTION

1.1 General introduction

Many people suffer from various degree of sleep disorders of different kinds. In the elderly, sleep disturbances are a particularly common problem. This may be due to the changes in sleep architecture indicating that sleep in the elderly differs both in terms of quantity and quality from sleep in younger persons. According to the principles of traditional Chinese diagnosis, insomnia can be due to 'deficient syndrome' or 'excessive syndrome'. In people with insomnia, sleep efficiency declines with an increase in time spent in bed and a decrease in the total time spent asleep.

Medication, such as hypnotics, has been widely used by the elderly to overcome their sleeping problems. However the adverse effects of these drugs have further compounded the sleeping problems of the elderly. Therefore complementary approaches for correcting sleep disturbances in the elderly should be explored. Auricular therapy, one of the approaches in traditional Chinese medicine (TCM), is a therapeutic method by which specific points on the auricle are stimulated to treat various disorders of the body. Many anecdotal reports have demonstrated the desirable effects of auricular therapy on patients with sleep disturbances. However empirical

evidence based on scientific investigation of the therapeutic effectiveness of auricular therapy on sleep improvement is scarce and yet to be explored. The purpose of this study is to examine the effectiveness of auricular therapy on sleep improvement in the elderly population.

1.2 Background to the study

1.2.1 Sleep disorders of the elderly

Sleep disturbances in the elderly are common, and affect over 50% of community-residing elderly, and close to 70% of persons in long-term care facilities (National Institutes of Health, 1991 in Johnston, 1994). Nearly half of all hypnotic prescriptions ordered are for persons over 65 years old (Johnston, 1994). The adverse effects of drugs that are used to induce sleep are well documented. Some of the key side effects are decreased reaction time and withdrawal insomnia (Castor, Woods, Pigott & Hemmes, 1991) that negatively affect respiration during sleep, and impair daytime alertness (Reynolds, Kupfer, Hoch & Sewitch, 1985). These side effects, to an extent, compound the sleep-related problems that many elderly people face. Therefore, it is essential to explore complementary approaches for sleep improvement in the elderly that are safe and cause fewer side effects.

1.2.2 Complementary therapies and nursing

The issue of whether complementary therapies should be included more frequently in the medical or nursing sector will continue to be hotly debated by health professionals. There does seem to be a place for some of these therapies, with their accentuation on the whole patient and their relatively cheap, low technology interventions, within the health delivery system (Shuttleworth, 1989). Florence Nightingale believed that the goal of nursing was to 'put the patient into the best condition for nature to act upon him' (Mantle, 1996). So indeed nursing would comply with these values and beliefs through the use of complementary therapies which could be incorporated into our nursing care.

Complementary therapies have gained widespread acceptance and many doctors are prepared to refer patients to alternative practitioners for conditions resisting successful treatment by orthodox medical treatment (Perkin, 1994). Complementary therapies include a wide range of caring approaches such as therapeutic touch, massage, shiatsu, aromatherapy, reflex zone therapy, acupuncture etc. The focus of complementary therapies is upon the holistic care of the individual (Norton, 1995). Nursing theories, such as those proposed by Rogers (1970), Levine (1971), Roy (1984) and Neuman (1989), also reflect the importance of holistic approaches to health care. The word 'holistic' is derived from the Greek 'holos', meaning a whole and refers to the fact that the whole is greater than the sum of its parts. In nursing, 'holistic' is concerned with all aspects of

life, that is the interactions between the chemical, physiological, biological and social functions of humans in their environment (Penson & Holloway, 1989).

The focus of modern medicine is on disease and its effects on the various parts of the body, with goals aimed at investigating and treating disease through diagnosis and appropriate treatment (Norton, 1995). Traditional Chinese medicine is based on the fundamental theory of balance among *Yin* and *Yang*, five basic phases, and a relationship between humans and nature (Sherwin, 1992). It is thought that disease is caused by an imbalance in a person's energy, *Qi*, and that resuming a balance will help people heal themselves (Mantle, 1996). TCM also recognizes that body, mind, emotions and spirit all need to be looked at, if healing is to take place (Penson & Holloway, 1989). Therefore incorporating TCM into nursing can assist nurses in the provision of holistic care which includes attending to a person's body, mind and spirit.

Many complementary therapies have been widely used as nursing therapeutics in certain nursing specialties and settings, including intensive care, elderly care, health visiting, neonatal intensive care and learning disabilities (Ace & Okubadejo, 1996). Recently, nurses in the United States and Great Britain have also begun the process of extending nursing practice to include the use of therapies which have not generally been considered to be within the scope of normal practice (McCabe, 1996). The

World Health Organisation also encourages the preservation and expansion of traditional medicine in the Third World (Penson & Holloway, 1989).

The role of such therapy is increasingly recognized by professional nursing education. The School of Health Studies at the University of Portsmouth has previously run a module in complementary therapies for students on its pre-registration diploma in nursing course to prepare them for future practice, and the evaluations have been positive. Some students, after completing the module, have successfully undertaken recognized training courses in a variety of complementary therapies and intend to use these within their clinical areas (Ace & Okubadejo, 1996).

Energy healing, including acupuncture and balancing the *Yin* and *Yang*, is a complementary therapy that has historical roots and scientific evidence to support its increasing availability and use by clients for various conditions (Starn, 1998). Therapeutic touch (TT) or noncontact therapeutic touch (NCTT) are other forms of energy healing that are becoming accepted in the nursing discipline (Bronstein, 1996; Meehan, 1993; Mulloney & Wells-Federman, 1996; Steckel & King, 1996; Wirth, Richardson, Eidelman & O'Malley, 1993). These therapies have been found to increase human hemoglobin level (Krieger, 1990), accelerate rate of wound healing (Kenosian, 1995; Wirth et al., 1993), and decrease state anxiety (Heidt, 1981; Quinn & Strelkauskas, 1993). Since people are open systems of

energy, thus allowing energy exchange between the client and the nurse during TT (Quinn, 1984).

It is essential that nurses explore the possibility for developing more complementary therapies in the realm of nursing therapeutics, which may enhance the holistic care of their clients, and make a more effective contribution to primary health care.

1.2.3 Local development of traditional Chinese medicine (TCM)

Hong Kong was administered by the British government over the past century, and during that time, the health care service in Hong Kong adopted the national health system of the United Kingdom. Therefore the hospitals in Hong Kong practiced Western medicine exclusively. Traditional Chinese medicine has started to carve out a place in the development phase after the handover of Hong Kong to China in 1997. According to the Basic Law for the Hong Kong Special Administrative Region of China, it is stipulated that Hong Kong shall formulate its own policy to develop both Western and Chinese medicine (Wong, 1998).

To meet the changing direction of the health care system, the Hong Kong Chinese University and the Baptist University both now have full-time programs in Chinese medicine to prepare graduates in this area (Lam, 1999). The Chief Executive Tung Chee-hwa also expressed his intention to develop Hong Kong as a world-class Chinese medicine centre, stating

that the government was examining options that included setting up an institute for Chinese medicine or TCM departments in hospitals (Lee, 1999). The Chinese Medicine Council has been set up to enforce standards of training, examination and qualification in practicing Chinese medicine. A proposal to set up a 'herbalport' has also given impetus to calls for TCM to be incorporated into the local public health system (Benitez, 1999). As the traditional medicine starts to be included in this developmental wave, many people are directing their attention to promoting rejuvenation or restoration of health through traditional exercises, such as *Qigong* (氣功) and *Tai Chi* (太極). Many local doctors are seeking to unveil the mysterious power of *Tai Chi* which is believed to improve the health of devotees ("Academics studying tai chi", 1999), and more research using research-based, scientific methods is being conducted locally to test the effects of conventional therapies.

To encourage the atmosphere of integration between Western and Chinese perspectives in medicine, nurses, as health care professionals, need to familiarize themselves with the development of TCM to meet future needs. Substantial, well-documented studies in TCM must be carried out before the Chinese method of treatment can attain total acceptance by the public and the world.

1.3 Theoretical rationale of study

In TCM, *Yin*, *Yang*, *Qi* (vital energy) and blood are seen as materials produced by the *Zang Fu* organs. These organs are distributed to all parts of the body via the channels and vessels to nourish the tissues and organs. *Qi* pervades the living body as a sort of intangible force and is of utmost importance to the functions of the body (Liu & Liu, 1989). It has four basic patterns of motions: ascending, descending, entering, and exiting. These motions maintain the "harmony of opposites" in the *Zang Fu* organs. The disruption of these basic patterns of motion will end up in different types of pathological changes of the body (Liu, 1995). This accords with the concepts of Rogers's Science of Unitary Human Beings (SUHB) that the energy flow is obstructed, disordered or depleted in times of illness (Starn, 1998a). This disturbance process is defined as a disruption of energy surrounding a person, resulting in a disharmony of the body, mind, or spirit (Starn, 1998b).

The focus of modern medicine is on disease and its effects on the various parts of the body, with goals aimed at investigating and treating disease through diagnosis and appropriate treatment, whereas the focus of complementary therapies is upon the holistic care of the individual (Norton, 1995). Alternative practitioners emphasize a 'holistic approach' that the patient should not be regarded as a set of symptoms to be resolved, but as a whole organism (Hillman, 1986). Complementary therapy addresses the whole client, acknowledging that symptoms are the body's signals

indicating that the mind and the spirit are in need of change. In TCM, it is thought that disease is caused by an imbalance in a person's energy, *Qi*, and that resuming a balance will help people heal themselves (Mantle, 1996). TCM also recognizes that body, mind, emotions and spirit all need to be looked at, if healing is to take place (Penson & Holloway, 1989). The principles of homeodynamics under SUHB are related to viewing human beings in their wholeness (Falco & Lobo, 1995). It focuses on the total individual during the caring process and is strongly based in general system theory. Therefore incorporating TCM into nursing can assist nurses in the provision of holistic care which includes attending to a person's body, mind and spirit.

The essential components of primary health care emphasize that care should be available, affordable, accessible, acceptable and appropriate (Candlin, 1997; Krebs, 1983). Auricular therapy, thought to be cost-effective, widely accepted, and applicable for treating many disorders, therefore seems to be desirable for treating insomnia in the elderly. Auricular therapy can activate meridians and collaterals, regulate the *Qi* and blood, help to achieve the balance between *Yin* and *Yang* status of internal organs, and is therefore suitable for treating many disorders of the body (Li & Tan, 1998, p.174). By using the theory of 'Five Phases' which are interacting, overacting and counteracting among the *Zang Fu* organs (Zhang & Wu, 1991, p.7), together with the existence of the bi-directional regulatory mechanism of the acupoint (Wu, 1998a), it is thought that the

Zang Fu organs create a state of unity of balance and coordination. The selected acupoints in this study may help to regulate the functions of the body and promote a better quality of sleep for clients with any type of insomnia.

Two common approaches in auricular therapy are acupuncture and pressing therapies, both of which are problematic for different reasons. Traditionally, auricular acupuncture employs needles as a source of stimulation (Feng, Bai & Du, 1994, p.61 & p.75; Margolin, Chang, Avants & Kosten, 1993), but this procedure perhaps may not be widely accepted by clients. Inflammation of the auricular points may occur if aseptic techniques are not strictly observed. When using pressing therapies, such as those using imbedded Semen Vaccariae, participants need to be reminded to press on the adhered pills regularly to achieve a better therapeutic effect (Zhou et al., 1991). Therefore bias in the results may arise if individual clients fail to perform this action adequately during the treatment period. Using magnetic pearls as auricular therapy is in comparison less traumatic and does not require pressing if the effect of magnetotherapy is present.

Since present understanding of the effect of magnetotherapy is limited and controversial (Low & Reed, 1992, p.255), the therapeutic effect of using magnetic pearls in auricular therapy for treating insomnia merits further study. The inconsistency in the treatment protocols used in previous

studies, and the use of combined therapies make it impossible to draw a strong causal relationship between auricular therapy and its treatment effect, thus making replication of existing studies difficult. It is only with the implementation of substantial, well-documented studies in TCM that the Chinese method of treatment can attain acceptance by the public and the world. A randomized clinical trial (RCT) is therefore the strongest study design to discern the efficacy of auricular therapy in improving sleep in the elderly.

The theory of SUHB based on the assumptions that the individual and the environment are characterized as open systems, and are continuously exchanging matter and energy with each other (Falco & Lobo, 1995). The properties of the energy fields as described by Rogers are having no boundaries, indivisible, extend to infinity, dynamic, and with a pattern of nonlinear domain (pandimensionality) that is not bounded by space or time (Falco & Lobo, 1995). The mode of action of static magnetic fields is said to be similar to pulsed shortwave (Haye, 1989 cited in Low & Reed, 1992). The effect of the magnetic pearls being used in the experimental group of this study formulate part of the client's environment, and this environmental energy is thought to have similar properties as the energy fields described above. On the other hand, human energy field is fundamental to the person's survival and is in fact a field which interacts and repatterns itself continuously in response to the environmental energy field surrounding it (Daley, 1997).

The mechanisms for the interaction of magnetic fields with biological tissues resulting in functional changes may be due to some underlying principles of physics. A physics principle known as Faraday's law states that a magnetic field will exert a force on a moving ionic current, such as the electrically charged ions of blood (Ramey, 1998). Furthermore, an extension of Faraday's law, the Hall effect, explains that when a magnet is placed over flowing blood in which ionic charges (such as Na^+ and Cl^-) exist, some force will be exerted on the ions. The separation of ionic charges will produce an *electromotive* force and which in turn produces a very small amount of heat. These existing physical effects may account for the purported effects of static magnetic field therapy (Ramey, 1998). According to the above principles, auricular therapy using magnetic pearls might promote the circulation of *Qi* and blood in the meridians, regulate functions of the *Zang Fu* organs, thus obviously improving the physiological functions of the body.

Auricular therapy based on the philosophy of TCM have greater potential for usefulness with Rogers's framework because they tend to reflect a more unitary view of the individual through the provision of holistic care which includes attending to a person's body, mind and spirit.

1.4 Significance of the study

Since many elderly people suffer from sleeping problem to some degree, it is hoped that the findings of this study can provide systematic evidence to demonstrate the effectiveness / lack of effectiveness of auricular therapy for sleep improvement in the elderly.

It is expected that the use of magnetic pearls for auricular therapy will be less traumatic, more hygienic and convenient, and more easily accepted by the clients than many other approaches of auricular therapy.

Further investigations into the relationship between the function of auricular points and their regulatory mechanism related to different parts of the body will help to clarify the effects of auricular therapy and its mechanism of action. By using the theory of 'Five Phases' which are interacting, overacting and counteracting among the *Zang Fu* organs (Zhang & Wu, 1991, p.7), together with the existence of the bi-directional regulatory mechanism of the acupoint (Wu, 1998a), it is believed that the *Zang Fu* organs create a state of unity of balance and coordination. Based on this assumption, the selected acupoints in this study may help to regulate the functions of the body and promote a better quality of sleep for clients with any type of insomnia.

The findings of this study may also encourage nurses to consider incorporating this complementary therapy as a nursing therapeutic to

improve the quantity as well as quality of clients' sleep. Since the essential components of primary health care emphasize that care should be available, affordable, accessible, acceptable and appropriate (Candlin 1997, Krebs 1983), the adoption of the auricular therapy could enable nurses to make a more effective contribution to primary health care. The standardization of the treatment protocol can facilitate the replication of this study and can increase the applicability of incorporating this practice as a therapeutic in the nursing domain.

1.5 The research questions

1. What are the effects of auricular therapy using
   a) Junci Medulla
   b) Semen Vaccariae (with no pressing)
   c) Magnetic pearls (with no pressing)
   on sleep * of the elderly who are 60 or above?
   (* Sleep parameters collected by actigraphic monitoring included NBT, NSP, NST, SL, TWT, WASO, MSA, and SE).

2. Are there any differences in effect on sleep if the treatment protocol of auricular therapy using magnetic pearls is standardized for the elderly:
   - having insomnia due to either 'Excessive' or 'Deficiency' syndrome?
   - of different age groups (60-80, 81-100)?
   - having different number of years of insomnia (0-10, 11 or above)?
   - treatment commenced on either left or right ears?

1.6 Research hypotheses

1. The effects of auricular therapy when using Junci Medulla [Group A] on sleep of the elderly are less evident than when using magnetic pearls [Group C] on sleep improvement measured by actigraphic monitoring.

2. The effects of auricular therapy when using Semen Vaccariae [Group B] on sleep of the elderly is less evident than when using magnetic pearls [Group C] on sleep improvement measured by actigraphic monitoring.

3. There are no significance differences in the effects on sleep improvement measured by actigraphic monitoring between auricular therapy using Junci Medulla [Group A] and Semen Vaccariae [Group B].

4. There are no significant differences in the sleep parameters measured by actigraphic monitoring before, during and after the auricular therapy in participants using Junci Medulla [Group A].

5. There are no significant differences in the sleep parameters measured by actigraphic monitoring before, during and after the auricular therapy in participants using Semen Vaccariae [Group B].

6. There are significant differences in the sleep parameters measured by actigraphic monitoring before, during and after the auricular therapy in participants using magnetic pearls [Group C].

7. There are no differences in the treatment effects on sleep if the treatment protocol of auricular therapy using magnetic pearls is standardized for the elderly:
   - having insomnia due to either 'Excessive' or 'Deficiency' syndrome
   - of different age groups (60-80, 81-100)
   - having different number of years of insomnia (0-10, 11 or above)
   - treatment commenced on either left or right ears

1.7 Definition of terms

Operational definitions of individual terms used in this study are provided below:

Complementary therapies

Complementary therapies are those therapies that work in conjunction with orthodox western medicine, rather than a replacement for orthodox western medicine for the well-being of the clients. Complementary therapies have the potential to complement and enhance current nursing and medicine practice to nurse the spirit, mind and body of patients in a holistic manner (Rankin-box, 1988; Sherwin, 1992). Examples are massage [按摩], shiatsu [指壓], reflex zone therapy [反射區療法], auricular therapy [耳穴療法], acupuncture and moxibustion [針灸療法], traditional chinese herbalism [中草葯療法], and *Qigong* [氣功]. The nursing therapeutic being discussed in this study is auricular therapy [耳穴療法].

Auricular therapy

Auricular therapy is one of the approaches in traditional Chinese medicine. It is a therapeutic method by which specific points on the auricle are punctured or pressed (Suen, Wong & Leung, 2001). It is widely believed that auricular therapy can activate meridians and collaterals, regulate the *Qi* and blood, help to achieve the balance between the *Yin* and *Yang* status of internal organs, and is therefore suitable for treating many disorders of the body.

Nocturnal bedtime (NBT)

Nocturnal bedtime is the total amount of time the participants spend in bed at night.

Nocturnal sleep period (NSP)

Nocturnal sleep period is the period of time measured from sleep onset during nighttime to the final awakening. In addition to nocturnal sleep time (NST), this includes the time taken for arousal and movement time until full awakening.

Nocturnal sleep time (NST)

Nocturnal sleep time is the total amount of time that the participant sleeps at night.

Sleep latency (SL)

Sleep latency measures the period of time from which a person attempts to sleep until the commencement of sleep.

Total wake time (TWT)

Total wake time is the total amount of time that the participant remains awake during time in bed. This includes sleep latency and the period of time spent awake during a sleep period.

Wake after sleep onset (WASO)

Wake after sleep onset is the period of time spent awake since after the sleep onset.

Midsleep awakening(s) (MSA)

Midsleep awakenings is the number of awakenings during a sleep period.

Sleep efficiency (%) (SE)

Sleep efficiency is an index calculated by dividing total sleep time (at night) by total time in bed (at night) multiplied by 100%.

Qi (氣) / Vital energy

Qi is considered to be the basic substance constituting the human body. In TCM, *Qi* has two connotations. One is the refined and nutritious substances flowing in the body, such as the *Qi* of water and food, the *Qi* of breathing or breathing nutrients. Another connotes the vital functions of various organs and tissues of the body, such as the *Qi* of internal organs and *Qi* of the meridians (Liu & Akira, 1998, p.34; Zhang & Wu, 1991, p.50).

Yin & Yang (陰 陽)

Yin & *Yang* are two opposite principles within the natural world. The theory of *Yin Yang* holds that normal physiological functioning of the human body is generated from the harmonious opposition of *Yin* & *Yang* to achieve bio-tendency, so diseases resulting from malfunctioning of the organs as interpreted and attributed to disturbances of *Yin* & *Yang*. *Yin* & *Yang* therefore plays an important role in Chinese medicine guiding the method of differential diagnosis in TCM and effective therapy (Liu & Liu, 1989, pp.1-2).

Jing Luo (經 絡) / Meridians and Collaterals

Jing Luo is the principal pathway for the flow of *Qi* (氣) and blood throughout the human body. It is composed of two parts – meridians (經 脉) and collaterals (絡 脉). The ones running longitudinally are termed meridians; while the ones branching out of the meridians and connecting all portions of the body are termed collaterals (Liu & Liu, 1989; Shi & Zhang, 1998).

Zang Fu (臟 腑)

The Chinese medical term for defining the viscera and the internal organs as two categories are: *Zang* (臟) and *Fu* (腑). *Zang* has five organs, including the heart, liver, spleen, lungs and kidneys, hence the term *Wu Zang* (五 臟). The *Fu* are six in number, embracing the following internal organs : gallbladder, stomach, small intestines, large intestine, urinary bladder and *San Jiao* (三 焦),

thus forming the *Liu Fu* (六 腑) (Liu & Liu, 1989; Shi & Zhang, 1998).

Five Phases (五 行)

The Five Phases are : metal, wood, water, fire and earth. In application, the lungs, skin, body hair, and nose are symbolized by "metal"; the liver, tendons and ligaments, and eyes by "wood"; kidneys, bones, and ears by "water"; the heart, blood-vessels, and tongue by "fire"; the spleen, flesh (muscles) and mouth by "earth". The physiological and pathological relationships of all internal organs rest upon the interaction of these five phases, with the law of interpromoting, interacting, overacting and counteracting, bringing about harmony (health) or disharmony (illness) in the body (Liu & Liu, 1989, p.2; Zhang & Wu, 1991, pp.25-26).

***San Jiao* (三 焦) / Triple *Jiao* / Triple heater / Triple warmer**

San Jiao is the three-specialized grouping of the internal organs specifically related to fluid-transport in the living body. The upper *Jiao* is the upper portion of the triple *Jiao* corresponding to the body cavity above the diaphragm where the heart and lungs are located. The middle *Jiao*, corresponds to the body cavity below the diaphragm and above the level of the umbilicus, where the stomach and spleen are situated. The lower *Jiao*, corresponds to the body cavity below the level of the umbilicus, and includes the functions of the small and large intestines, kidneys and the bladder (Liu & Liu, 1989, p.29; Zhang & Wu, 1991, p.42).

1.8 Organization of thesis

This thesis contains eight chapters. Apart from the introductory part of this thesis and the theoretical rationale of the study that is presented in the first chapter, the remainder of this thesis is organized as follows. Chapter 2 presents a literature review of the underlying theories of auricular therapy, its clinical applications, and the gaps of knowledge identified in previous research. The framework of the research process is also included. Chapter 3 describes in detail the methodology and procedures followed in this randomized controlled trial of auricular therapy in the elderly with insomnia. Chapter 4 delineates the findings and implications of the pilot study. Chapter 5 shows the first part of the main study results. It focuses on reporting the socio-demographic characteristics and sleep behaviours of the participants (n=120) in 12 hostels for the elderly. Comparisons of the treatment effects on sleep among the three types of intervention were made. The second part of the study results are reported in Chapter 6 in which the relationship between the therapeutic effects in the experimental group and other variables such as age group, gender, number of years of having suffered from insomnia, or side of the ears where treatment commenced were explored. The long-term effect of auricular therapy using magnetic pearls was also evaluated. Chapter 7 contains the discussion of the findings, while the final chapter (Chapter 8) addresses the limitations of the current study and suggests directions for future studies.

CHAPTER 2

LITERATURE REVIEW

2.1 Introduction

A thorough review of the literature related to this topic was carried out to provide a general framework for this study. This chapter starts by describing the different stages of normal sleep patterns, and how these patterns are disrupted in people with insomnia. It also highlights the sleep problems that are commonly found in the elderly, and describes in detail the types of insomnia differentiated by traditional Chinese diagnosis from the TCM perspectives.

This review also discusses how and why complementary therapies have been adopted as nursing therapeutics in recent decades. Since the main focus of this study is on the effectiveness of auricular therapy, the history and development, underlying theories, types and clinical applications of this therapy have been explored. Previous research studies using this therapy were critically reviewed, and gaps in knowledge arising from these studies were identified.

As the effects of applying magnetic pearls were evaluated in this study, the review moves on to discuss the effects of magnetotherapy, its clinical

applications, and controversial findings regarding its effects as noted in previous studies.

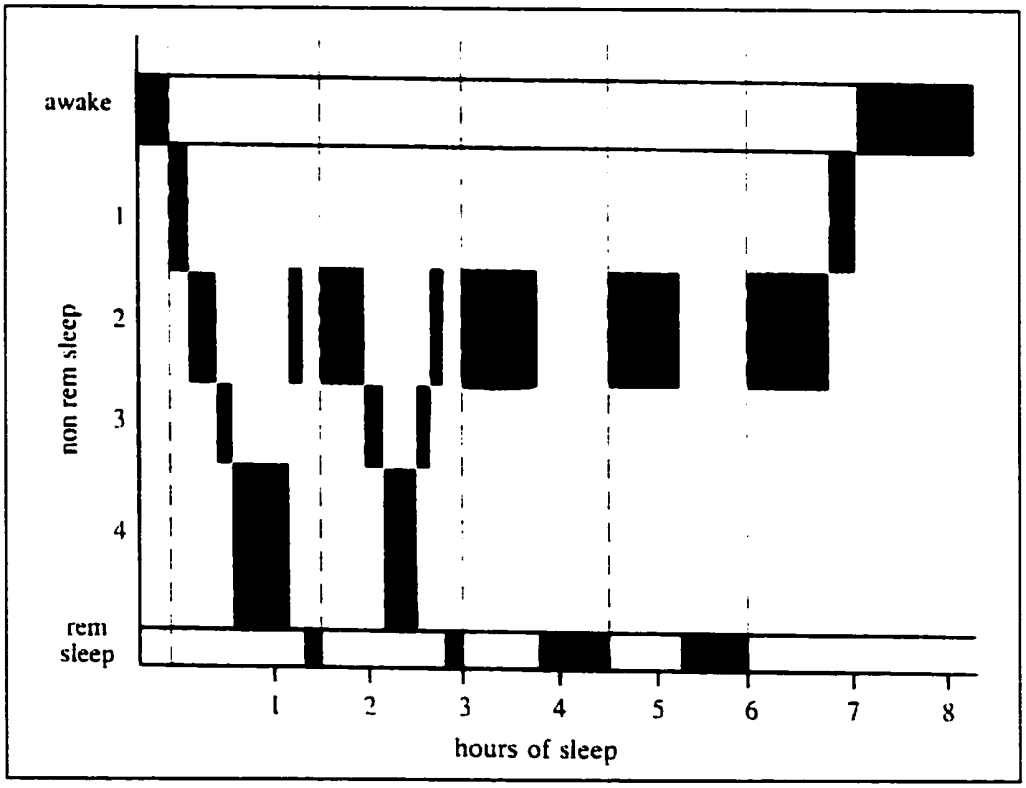
Instruments for sleep measurement are discussed and compared, and reasons why actigraphic monitoring was adopted as an objective measurement in this study are justified. Lastly, a summary of the review is provided, and the framework of the research process for this study is established.

2.2 The physiology of sleep

Life consists of three relatively distinct states: wakefulness, rapid eye movement (REM) sleep, and non-rapid eye movement (NREM) sleep (Irwin, 1992) (Figure 2.1).

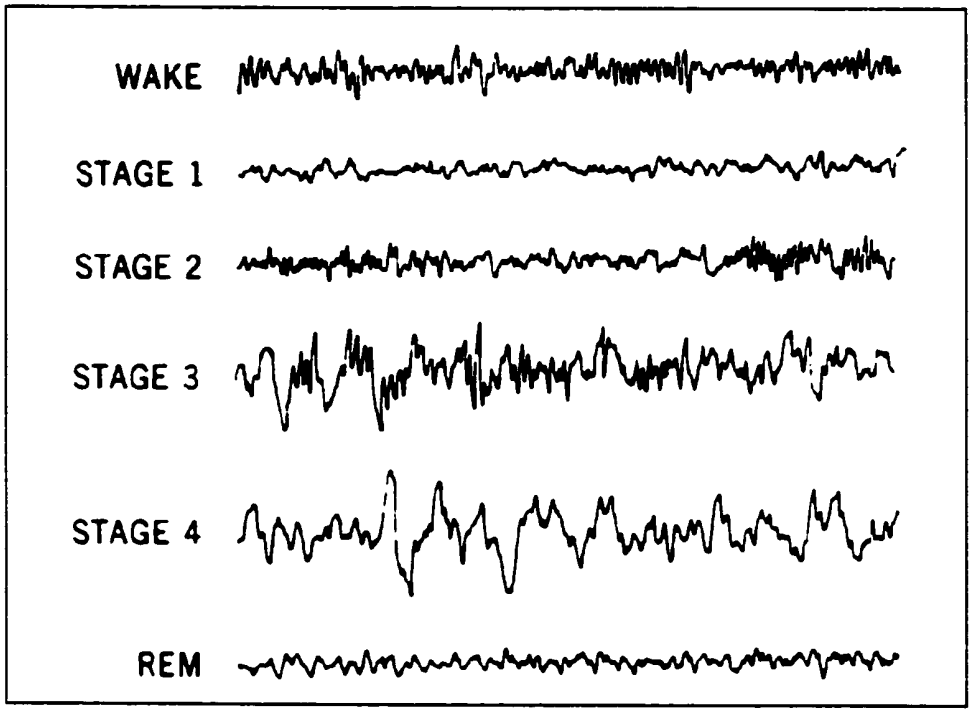
NREM sleep is also known as synchronized (S) sleep, quiet sleep or 'orthodox' sleep. During this time, the sleeper descends from stage 1 to stage 4. The electroencephalography (EEG) of different sleep stages is displayed in Figure 2.2.

Figure 2. 1 The pattern of sleep during the night for adults (Irwin, 1992).



(shaded areas indicate the duration in each sleep stages)

Figure 2.2 The EEG of wakefulness, REM sleep, and the four stages of NREM sleep (Orr, Altshuler & Stahl, 1982).



The EEG of different sleep stages are briefly described as follows:

Wakening

The waking EEG is represented by alpha waves (8-12 cycles per second) and low voltage activity of mixed frequency (Hartmann, 1973).

Stage 1 NREM Sleep

This is a brief transitional phase bridging the gap between wakefulness and the onset of sleep. The sleep is very light and the arousal threshold is relatively low. This stage only lasts for about 5 minutes and does not

normally reappear during subsequent sleep cycles (Morin, 1993). It is characterized by a reduction in autonomic activities such as heart rate, blood pressure and sweating (Duxbury, 1994). The EEG of this stage displays low voltage, regular 4-6 cycles per second (Hartmann, 1973); and mixed frequency activity with less than 50% alpha activity (8-12 Hz), and irregular theta waves (4-7 Hz) predominating (Orr et al., 1982).

Stage 2 NREM Sleep

This stage follows Stage 1 sleep, and makes up 45% of the total sleep time (Horne, 1988 in Irwin, 1992). Lasting between 10 and 20 minutes during the initial cycle, the EEG of Stage 2 sleep is characterized by larger waves than Stage 1 sleep, with rapid sleep spindles, occasional large slow waves, and high-voltage spikes known as K-complexes (Irwin, 1992; Orr et al., 1982). It contains an activity pattern of 13-15 cycles per second (Hartmann, 1973). In the first cycle of sleep, Stage 2 sleep lasts a few minutes, but during a whole night's sleep, it contains an increasing proportion of each cycle, and becomes the beginning of each subsequent sleep cycle (Irwin, 1992).

Stage 3 and 4 NREM Sleep

These two stages also called Slow Wave Sleep (SWS) (sometimes called Deep sleep, or Delta sleep), are the deepest stages of sleep (Dorociak, 1990; Morin, 1993; Orr et al., 1982). The arousal threshold is highest during this phase, which may last between 20 and 40 minutes in the first

sleep cycle, and is halved in the second. SWS does not reappear in the sleep cycles in the latter part of the night. Higher-voltage activity, characterized by 20% to 50% delta waves in Stage 3, and over 50% delta waves in Stage 4, becomes apparent. There is a decrease in physiological reactivity to external stimuli and it is said to make up 13% of total sleep (Irwin, 1992). Moreover, hormonal changes occur during SWS, for example, secretion of human growth hormone (Duxbury, 1994; Irwin, 1992). The initial sequence is followed by a return from Stage 4 to Stage 3 and Stage 2, leading to the first REM episode (Morin, 1993).

REM Sleep

REM sleep is also called fifth stage, desynchronized sleep, active sleep, or 'paradoxical' sleep. REM sleep is associated with rapid eye movements, total muscle relaxation, irregular breathing, and increased blood pressure and heart rate (Irwin, 1992). Penile erections have been found to be associated with this sleep stage in males; and increased blood flow to the vagina in females (Morin, 1993). REM sleep lasts only a few minutes in the first sleep cycle but increases in duration with each cycle. The sleeper is very difficult to arouse during this stage. After each period of REM sleep, a new sleep cycle begins with Stage 2 sleep. Each sleep cycle lasts approximately 90 minutes, and appears four to five times per night. Past evidence has demonstrated that dreaming occurs in all stages of the sleep cycle, but dreams in REM sleep are often more vivid, particularly later

in the night, than those in other sleep stages (Irwin, 1992). As SWS appears in the first third of the night, REM sleep is more predominant in the last third (Orr et al., 1982).

After having some ideas on the normal physiology of sleep and EEG patterns that mentioned in the above paragraphs, it is easy to understand how the sleeping patterns deviate from normal when one is suffering from sleep deprivation.

2.3 Effects of sleep deprivation on the sleep cycle

Traditionally, it is claimed that sleep is a time of restoration and preparation for the next period of wakefulness (Duxbury, 1994). NREM sleep is considered to be directly related to the restoration of physical energy, whereas REM sleep plays a greater role in cognitive functions, and performs a functional role in retention of newly learned material during wakefulness (Duxbury, 1994; Morin, 1993).

People with regular sleeping patterns feel that they have had a more beneficial sleep and they function better during the day than those with variable sleep patterns (Dorociak, 1990). A survey of the health and lifestyle over one million people conducted by Kripke et al. (1979, quoted in Morin, 1993) suggests that sleep length correlates with longevity; with the longest life expectancy associated with sleep duration between 7 and 7.9 hours. These authors also found that people who sleep for a significantly shorter duration (4 hours) or a longer duration (10 hours) have a higher incidence of heart disease and stroke. However, the results of this survey are just correlational, and do not imply any causal relationship.

If a person is awakened from any sleep stages, he/she must start again from Stage 1, so interrupted sleep can lead to deprivation of SWS and REM sleep (Dorociak, 1990). Sleep-deprived individuals begin to have microsleeps - the same very short periods of sleep typically found in the elderly (Orr et al., 1982).

Persistent sleep disruption not only causes daytime sleepiness, an increase in accidents, and impaired performance in individuals (Johnston, 1994; Orr et al., 1982), but can also lead to irritability, anxiety, apathy, fatigue, depression, lower alertness, difficulty in concentrating, increased sensitivity to pain and discomfort, confusion, aggression, disorientation and eventual mental illness (McIntosh, 1989).

It has been suggested that only the first few cycles (5.5 - 6 hours) of sleep are the necessary 'core' of sleep, the remaining sleep being 'optional' (Dorociak, 1990; Horne, 1988 in Irwin, 1992). Therefore nurses should strive to allow patients to have uninterrupted sleep, particularly during the first few hours of sleep.

2.4 Sleep disorders of the elderly

2.4.1 Usual sleeping patterns of the elderly

Sleep disturbances in the elderly are a common problem, affecting over 50% of the elderly residing in the community, and nearly 70% of residents in long-term care agencies in the United States (National Institutes of Health, 1991 in Johnston, 1994). A recent local survey on 1,034 elderly people aged 70 or above also indicates that nearly 40% of the elderly in Hong Kong suffer from the problem of insomnia to some degree ("Forty percent of the elderly", 1999). Caffeine and dairy products may either promote or interfere with sleep. Persistent insomnia was reported by old people who have high tea consumption (Curless, French, James & Wynne, 1993). It is suggested that hot milky drinks before bedtime could promote sleep (Ferrer, Bisson & French, 1995). Sleep problems may be associated with emotional problems such as stress, depression and anxiety (Fordham, 1991; Hooyman & Kiyak, 1993). There are strong objective and subjective data demonstrating that sleep disturbances in depressed elderly is common (Knowles & MacLean, 1990; Livingstone, Blizard & Mann, 1993; Waxman, McCreary, Weinrit & Carner, 1985).

Sleep architecture undergoes certain changes in the elderly. The amount and amplitude of slow-wave sleep decreases. Spindles, the characteristic feature of stage 2 sleep, is abnormal or 'degraded'. During REM sleep, eye movements decrease. Sleep efficiency declines with an increase in

time spent in bed and a decrease in the total time spent asleep. The number and duration of periods of wakefulness, together with the number of shifts from one stage of sleep to another increases. The arousal threshold for noise and the time from the onset of sleep to REM sleep decreases. Daytime napping is more pronounced particularly among men and the frequency increases with age (Swift & Shapiro, 1993).

Hypnotic prescriptions ordered for the elderly are common. However it was found that the sleep-promoting properties of most hypnotic drugs are lost after 14-28 days. The adverse effects of these drugs such as decreased reaction time and withdrawal insomnia (Castor et al., 1991) will compound the sleeping problems of the elderly to some extent.

2.4.2 Traditional Chinese diagnosis on insomnia

According to the principles of traditional Chinese diagnosis, insomnia can be deficient or excessive in nature (Wang, 1996, p.109). The "Excessive syndrome" mainly refers to the excess of pathogenic factors. In this situation, pathogenic factors and *Qi* grow vigorously in strength and result in intense conflict between the two. This may be due to the stagnation of phlegm, food, water, and blood within the body. The "Deficiency syndrome" refers to pathological changes associated with a deficiency of *Qi*. When *Qi* is comparatively weak, it will lower the resistance to pathogenic factors. Therefore the conflict and reaction of *Qi* is less intense. This syndrome is usually found when patients are of weak constitution, in later

stages of disease, in chronic situations or when diseases are not properly treated (Liu & Akira, 1998, p.132).

The etiology, manifestations, and principles of treatment for different types of insomnia differentiated by traditional Chinese diagnosis are summarized as follows (Liu, 1995, pp.330-334; Wang, 1996, pp.109-114; Xie, Dai & Zhuang, 1988, p.177[37]; Yu, 1993, pp.72-73[42]):

(A) Insomnia due to the "Excessive syndrome"

(1) Liver *Qi*-stagnation turning into fire [肝郁化火] :

Etiology

Emotional upsets impair the renal function and cause the stagnation of liver-*Qi*, which then turns into fire. Deficiency of *Yin* leads to hyperactivity of *Yang*, which interferes with the mind resulting in insomnia.

Analysis

Anger damages the liver and causes liver *Qi*-stagnation, which then turns into fire to disturb the heart and mind, and ends up causing insomnia. If the stomach is attacked by liver-*Qi*, poor appetite will follow. Stagnation of liver-*Qi* converts into fire and attacks the stomach resulting in thirst and a desire to drink. Hyperactive liver fire causes irritability. Upward disturbance of fire and heat lead to red eyes and a bitter taste in the mouth. Deep yellow urine, constipation, a red tongue with yellow coating and a taut and thready pulse all indicate the existence of heat syndrome inside the body.

Manifestations

Irritability, insomnia, red eyes, thirst, a bitter taste in the mouth, poor appetite, deep yellow urine, constipation, a red tongue with yellow coating, a taut and

rapid pulse.

Principle of treatment

To soothe a depressed liver, disperse heat and calm the mind.

(2) Disturbance of stomach-*Qi*, Internal disturbance of phlegm-heat [胃氣不和，痰熱內擾]:

Etiology

Improper diet damages the intestines and stomach, and causes retention of food, which produces phlegm-heat. Retained phlegm-heat in the middle *Jiao* disturbs stomach-*Qi*, resulting in insomnia.

Analysis

Phlegm-dampness caused by food retention produces heat which disturbs the upper part of the body, resulting in restlessness and insomnia. The phlegm-dampness that is retained in the middle *Jiao* causes chest stuffiness. Hindrance of clear *Yang* leads to a heavy sensation in the head and blurred vision. Food retention blocks *Qi* circulation and impairs the normal function of the stomach, and causes anorexia, belching and nausea. A sticky and yellow tongue coating, and a smooth and rapid pulse are signs of phlegm-heat and retention of phlegm-heat.

Manifestations

Restlessness, insomnia, a heavy sensation in the head, blurred vision, profuse sputum, stuffiness in the chest, anorexia, belching, acid regurgitation, nausea, a bitter taste in the mouth, a sticky and yellow tongue coating, a slippery and rapid pulse.

Principle of treatment

To resolve phlegm, disperse heat, harmonize the middle *Jiao* and calm the mind.

(B) Insomnia due to "Deficiency syndrome "

(1) Cardiac and splenic deficiency [心脾兩虛] :

Etiology

Damage of the heart causes the consumption of *Yin* blood, resulting in wandering of the mind. Damage of the spleen affects the appetite, and thus the heart is deprived of nourishment, and insomnia ensues. Mental strain, chronic illness, frailness and old age may cause insufficiency of vital energy and blood.

Analysis

Deficiency of both the heart and spleen deprives the heart of nourishment, and causes wandering mind. As a result, dream-disturbed sleep, shallow sleep, poor memory and palpitations appear. *Qi* and blood deficiency deprive the brain of nourishment, that leads to dizziness and blurred vision. Blood deficiency leads to a pale complexion and a pale tongue. The spleen's failure to transport the nutrients results in a lack of taste. Lack of blood and *Qi* causes lassitude and a thready and weak pulse.

Manifestations

Insomnia, excessive dreaming during sleep, shallow sleep and tendency to wake up, palpitations, poor memory, dizziness, blurred vision, lassitude, lack of taste, pale complexion, a pale tongue with thin coating, and a thready and weak pulse.

Principle of treatment

To fortify the spleen and heart, and produce *Qi* and blood.

(2) Disharmony between the heart and kidneys [心腎不交] :

Etiology

With congenitally weak people and those who have suffered a prolonged illness, kidney *Yin* is too deficient to nourish the heart. Therefore the heart

fire or heart *Yang* becomes hyperactive. Emotional upsets directly lead to hyperactivity of heart fire, which cannot coordinate with kidney water. Hyperactive heart fire caused by the disharmony between the heart and kidneys interferes with the mind and results in insomnia.

Analysis

Yin-deficiency of the kidneys leads to hyperactivity of heart and liver fire, which disturbs the mind and results in insomnia, restlessness and palpitation. Consumption of renal essence leads to dizziness, tinnitus and poor memory. Insufficient nourishment in the lumbar region leads to soreness. The disharmony between the heart and kidneys weakens the gate of essence, resulting in nocturnal emission. Thirst, lack of saliva, a hot sensation in the palms, soles and chest, a red tongue and a thready and rapid pulse all indicate hyperactivity of fire due to the *Yin* deficiency.

Manifestations

Insomnia, restlessness, palpitation, dizziness, tinnitus, poor memory, lumbar soreness, nocturnal emission, a hot sensation in the palms, soles and chest, thirst, lack of saliva, a red tongue, and a thready and rapid pulse.

Principle of treatment

To replenish *Yin*, reduce fire, nourish the heart and calm the mind.

(3) *Qi* deficiency of the heart and gallbladder [心胆氣虛] :

Etiology

Being timid, indecisive, and easily frightened can all lead to insomnia. Additionally, nervousness induced by a sudden fright can also gradually develop into insomnia.

Analysis

Cardiac deficiency can lead to restlessness, while gallbladder deficiency

makes one easily frightened. Consequently, symptoms such as dream-disturbed sleep, shallow sleep, palpitation, and being easily frightened will appear. Shortness of breath, lassitude and profuse clear urine all indicate *Qi* deficiency. A pale tongue, and a taut and thready pulse are due to the *Qi* and blood deficiency.

Manifestations

Insomnia, excessive dreaming during sleep, shallow sleep, timidity, palpitation, being easily frightened, shortness of breath, lassitude, profuse clear urine, pale tongue, and a taut and thready pulse.

Principle of treatment

To benefit *Qi*, soothe the heart, calm the mind and tranquilize the emotions.

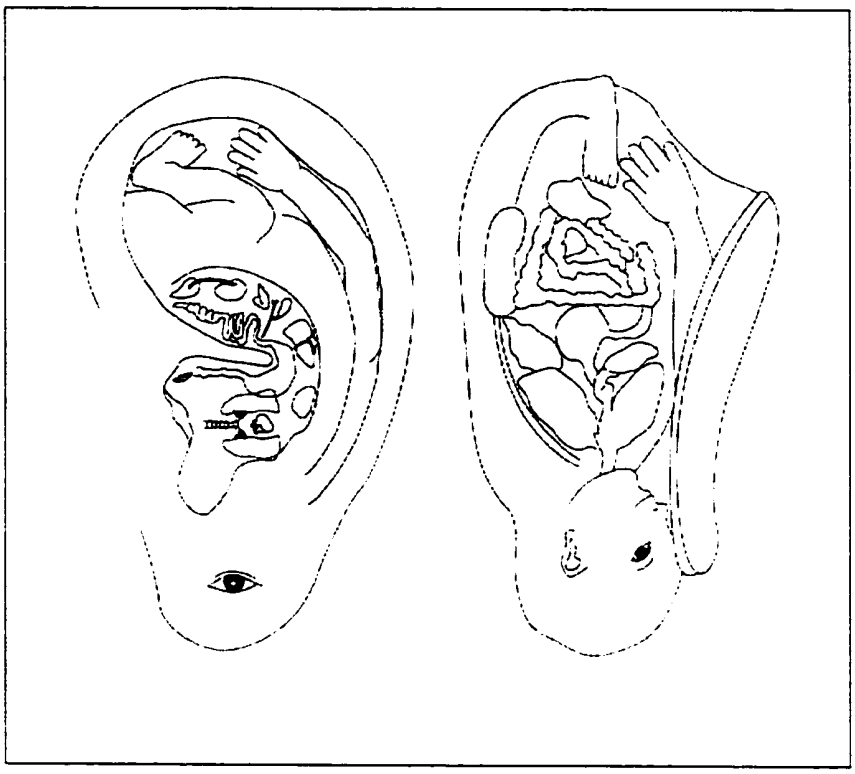
The etiology of different types of insomnia differentiated by traditional Chinese diagnosis mentioned above indicates that sleep, from the Chinese perspective, is controlled by many major viscera of the body such as the kidney, liver, heart and spleen. Many vital organs of the body degenerate as a consequence of ageing (Gardner-Abbate, 2000); therefore this can explain why sleep disturbances are so common in the elderly. Therefore only when the functions of the *Zang Fu* organs are regulated, can the root cause of insomnia be treated. The background information on the different types of insomnia also helps to justify why certain auricular points that correspond to the vital organs of the body were selected in this study for promoting sleep.

2.5 Auricular therapy

2.5.1 History and development of auricular therapy

The ear is first mentioned in the earliest Chinese medical book, Yellow Emperor's Classics of Internal Medicine [黃帝內經], published more than 2,000 years ago. It states that the ear is related to all parts of the human body and internal organs, and that all meridians converge at the ear (Chan, 1981, pp.13-14; Huang, 1995, p.3[14]). In 1957, Dr. Paul Nogier, a well-known French neurosurgeon, made a careful study of the ear and found that the ear is thought to simulate an inverted fetus within the womb (Figure 2.3). Acupoints on the ear lobe correspond to the head and facial region; acupoints on the scapha correspond to the upper limbs; acupoints on the antihelix correspond to the trunk of the body; acupoints on the superior and inferior crura of antihelix correspond to the lower limbs; and those on the superior and inferior concha correspond to the internal organs (Ming & Yang, 1997, p.164).

Figure 2.3 The ear represents a simulation of an inverted fetus within the womb (Suen, Wong & Leung, 2001).



Many research studies and clinical experiences on using auricular therapy have been recorded unsystematically, and 284 auricular points had already been named before 1972 (Chen, 1991; Chen, 1993). Confusion of names and locations of auricular points has seriously hindered the development of auricular therapy. To have a common language for study and exchange of ideas, the Chinese Association of Acupuncture and Moxibustion, was entrusted by the World Health Organization Western Pacific Regional Office, to call meetings among experts several times since 1982. The "Scheme of

Standardization of Auriculo-acupoints" [耳穴標準化方案] (acupoints mainly represented by specific points) was later published in June 1987 for the purpose of nation-wide unification and popularization (Chen, 1991; Huang, 1995, p.10[14]). In May 1993, the "Chinese Standard Ear-Acupoints" [中國標準耳穴] which consists of 91 acupoints (acupoints mainly represented by zones) was established and widely adopted in China (Guan, Li, Guan & Guan, 1994, p.3[7]). The Chinese Standard Ear-Acupoints Chart [標準耳穴定位示意圖] (English version and Chinese version) are displayed in Appendix 1 and 2. The anatomical nomenclature of the auricle (frontal surface) is displayed in Appendix 3.

2.5.2 Underlying theories of auricular therapy

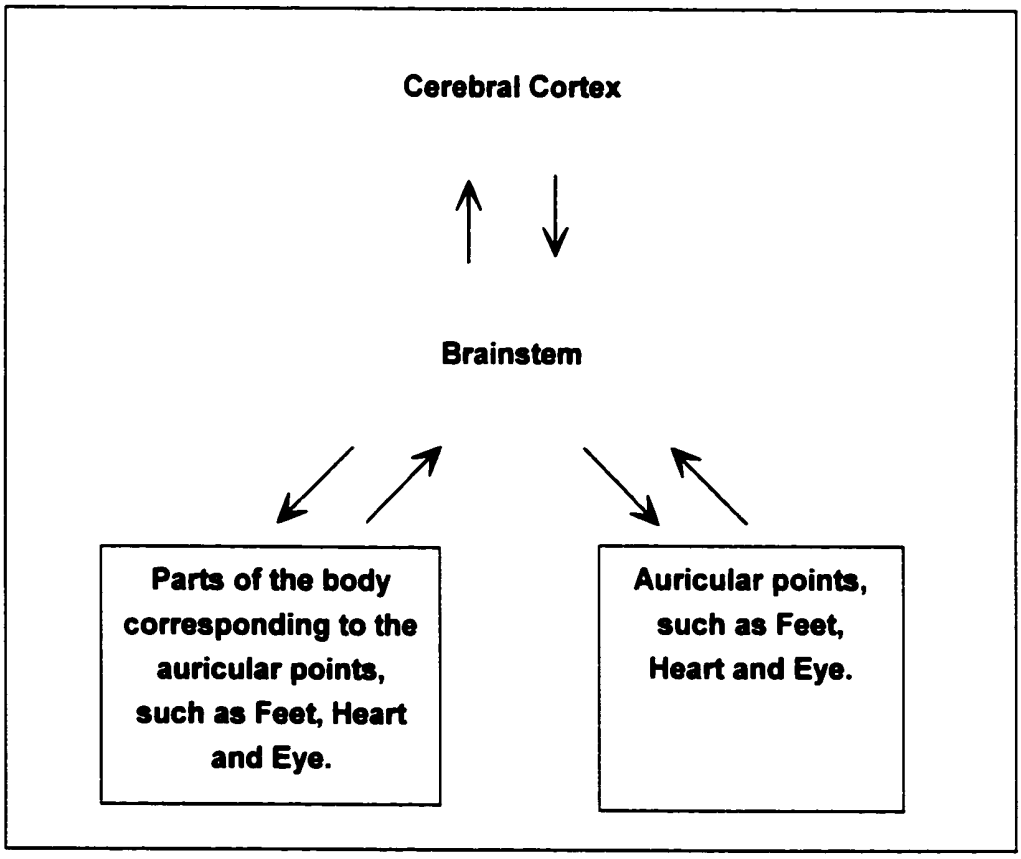
Auricular therapy has demonstrated its effectiveness in the diagnosis and treatment of a number of diseases and disorders, and theories like the 'Homuncular reflex theory', 'Delta reflex theory', and 'Meridian theory' are widely accepted (Feng et al., 1994).

a) Homuncular Reflex Theory [全息反射說] :

Based on the neuro-embryal theory, Dr. Paul Nogier came to view the auricle as a homunculus of the human body similar in shape to an inverted fetus, with the head located on the lower lobe, the feet at the upper rim of the ear, and the body in the middle. Homuncular reflex theory helps to

explain the somatotopic relationship between the ear and the body. In the homuncular reflex arc, the homuncularly related neurons in the brain are the center of the reflex arc, located centrally in the brainstem. A bi-directional transfer of message is found among auricular points, homuncularly related neurons, and parts of the body corresponding to the auricular points (Feng et al., 1994, pp.11-12).

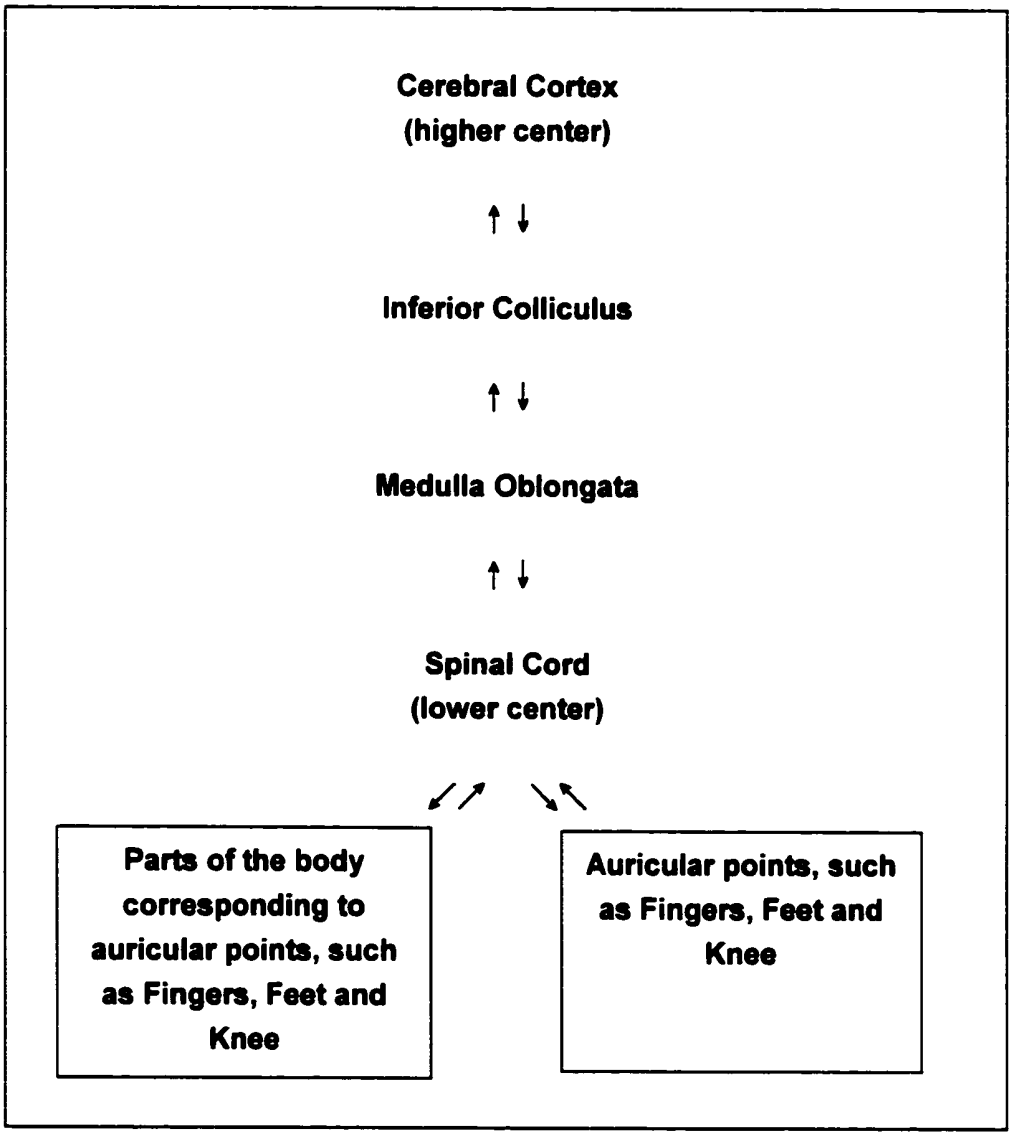
Figure 2.4 Diagram demonstrating the pathway of the Homuncular reflex arc between the ear and the body (Feng et al., 1994, p.13).



b) Delta Reflex Theory [德爾他反射說]:

This theory was put forward by a Korean-American, Dr. M.H. Cho, in the 1970's. The detector of an electric thermometer was taped to various auricular points, such as Fingers, Feet, and Knee, one point at a time. After the indicator of the thermometer was stabilized, the parts of the body corresponding to the auricular points were stimulated by cold, heat, or acupuncture. After 10 to 15 seconds, a 1.0 to 5.5℃ increase in the temperature of the auricular points corresponding to the stimulated body parts was noted. Conversely, when the auricular points were stimulated, there was also an increase in the temperature of the related parts of the body. Dr. Cho named this phenomenon Delta reflex because the pathway of the reflex arc is triangular in shape (Feng et al., 1994; Wang, Yu & Wang, 1993, p.10[33]).

Figure 2.5 Diagram demonstrating the pathway of the Delta reflex (Feng et al., 1994, p.14).



c) Meridian Theory [經絡學說]:

Traditional Chinese medicine (TCM) holds that the five viscera (*Wu Zang* 五臟) and six bowels (*Liu Fu* 六腑), the nine body orifices (*Jiu Qiao* 九竅), four extremities (*Si Zhi* 四肢) and all bones of the body (*Bai Hai* 百骸) are closely linked with the ears through the channels and collaterals (*Jing Luo* 經絡). According to *LingShu* (靈樞經) which was written in 475-221 B.C., "the ears are the confluence of the channels". This implies that the ears, through the channels and collaterals, are related to the internal organs as well (Xu & Fei, 1985). Chan (1981, p.24) also states that the ear is directly or indirectly related to the 12 main pairs of meridians that run over the body. They are the *Yang* Meridians (陽經) which consist of the large intestine, stomach, small intestine, bladder, *San Jiao*, and gallbladder; and *Yin* Meridians (陰經) which are comprised of lung, spleen, heart, kidney, pericardium and liver.

2.5.3 Types of auricular therapy

The most commonly used type of stimulation of ear auricular points is needle insertion. For auricular acupuncture, there are several types of needles: (1) regular half-inch and one-inch, (2) press needles, and (3) interdermal needles. The latter two types of needles are imbedded into the skin and taped in place. The needles are imbedded in order to provide continuous stimulation. Other auricular stimulation could be obtained by using staple-puncture, applying magnetic beads, ultrasound, bloodletting,

laser irradiation, aqua-puncture, moxibustion, electrical treatment and pressing therapy (Chan, 1981, p.15; Chen, 1993). Auricular pressing therapy or auricular taping refers to the taping of small, round, hard, smooth objects which are of the appropriate size for stimulating the auricular points. The objects chosen should have no toxic properties or side effects. Semen Vaccariae (王不留行籽), Semen Impatients (急性子), mung beans (綠豆), Liushen pills (六神丸), or magnetic pearls (磁珠) are all suitable for use in auricular taping (Li & Tan, 1998, p.170).

Even though there are many approaches to the stimulation of the ear acupoints for achieving therapeutic effects, not all of them are safe and highly accepted by the clients. For example, inflammation of the auricle may arise due to puncturing if the aseptic technique is not closely observed (Keane, Ahmadi & Gruen, 1993); and the therapeutic effects cannot be guaranteed if the participants fail to perform the manoeuvre of pressing on the beans or semens. Examples of previous studies using these substances and limitations of their approaches are critically evaluated in the section of 2.5.5.

2.5.4 Clinical applications and research on auricular therapy

Much research on auricular therapy has been conducted in recent decades with desirable results. Auricular pressing therapy can activate meridians and collaterals, regulate the *Qi* and blood, help to achieve the balance between *Yin* and *Yang* status of internal organs, and is therefore suitable for treating many disorders of the body (Li & Tan, 1998, p.174). Successful weight reduction after employing auricular acupuncture was widely reported (Alkaysi, Leindler, Bajusz, Szarvas & Karacsonyi, 1991; Cox, 1975; Dung, 1986; Soong, 1975; Xu & Fei, 1985). Auriculo-acupoint pressing therapy has also demonstrated its effectiveness for the control of hypertension, and the stability of the therapeutic effect was found to be better in patients receiving auricular therapy than those receiving Western medicine (Zhou et al., 1991). Auricular acupuncture is gradually becoming a popular intervention for the treatment of cocaine addiction in the United States (Margolin, Chang, Avants & Kosten, 1993). In addition, many studies have shown that auricular therapy is an effective pain killer as it can increase the body's pain threshold (Kitade & Hyodo, 1979; Li et al., 1994; Xu, 1992).

2.5.5 Previous studies using auricular therapy for clients with insomnia

Many studies which were conducted in China Mainland have reported desirable effects of auricular therapy on patients with insomnia. Participants receiving auricular pressing therapy achieved a significantly better therapeutic effect than those receiving Western medication such as tranquillisers for treating insomnia (Gao, 1995[9]; Lian & Yan, 1990). Seed pressing therapy using Semen Vaccariae [Vaccaria 王不留行籽] has been popular over the past decades. Other seed-like substances used for auricular therapies, such as Fright-Wind Pill [*Jing-Feng* Pill 驚風丸] (Du, 1996[3]), Alpinia Oxyphyllae Fructus [Alpinia 益智仁] (Wang, Y., 1998[32]), and Borneolum [Borneol 冰片] (Wu & Tian, 1998[36]) have been adopted in other studies for patients with insomnia. Some researchers also combined Semen Vaccariae with other Chinese herbal medicines such as Moschus [Musk 麝香] (Shang, 1997[26]; Wu, 1998a[34]; Wu, 1998b[35]), Rhizoma [Rhubarb 大黃], Radix Polygalae [Polygala 遠志], Fried Semen Ziziphi Sprinosae [Spiny Jujube 酸棗仁] and Borneolum [Borneol 冰片] (Yang, 1988) in order to strengthen the therapeutic effects for treating insomnia.

Participants were usually instructed by the researchers to apply additional stimulation to the ear acupoints by pressing regularly on the semen to achieve a better therapeutic effect. However the frequency, timing and duration of applying such pressure varies among studies. Frequency for pressing the semens varies from 2-3 times per day (Gao, 1995[9]), 3-4 times per day (Guo, 1996[10]; Gao & Sun, 1996[8]; Shang, 1996[27]), to 6-10 times

daily (Dang, 1995[2]; Tang, 1997[29]). Many authors emphasize that the pills adhered to the acupoints should be massaged every night before sleep (Huang, Yuan, Yuan & Li, 1996[13]; Lian & Yan, 1990; Yang, 1988), whereas Zhang (1997[43]) asserts that pressing should not be done within four hours before bedtime. There is also a wide discrepancy in terms of the duration for each pressing, ranging from 1-2 minutes (Gao & Sun, 1996[8]), 3-5 minutes (Gao, 1995[9]; Shang, 1996[27]; Yang & Zhang, 1998[40]) to 10-15 minutes each time (Shang, 1996[27]). More importantly, it was difficult to monitor whether the participants have performed the manoeuvre of pressing and the intensity of pressing the semens. One study that attempted to ensure that pressing was performed regularly involved nurses helping to monitor the process and offering assistance when the clients were unable to conduct the pressing (Li, 1997[18]), but such intervention can only be possible for inpatient cases. In unsupervised situations, injury to the auricle leading to local infection may result if the rubbing is performed incorrectly (Li & Tan, 1998, p.172).

Additionally, the duration of each course of auricular therapy differed among studies, from the minimum of 6 days (Wu, 1998a[34]) to a maximum of 35 days (Dang, 1995[2]). Selection of auricular acupoints for treatment were not standardized. In fact in most situations, five to seven main points were selected in addition to one to three adjuvant points adopted according to different types of insomnia differentiated by the traditional Chinese diagnosis (Guo, 1996[10], Ju, 1997[16], Liu, 1998[20], Qiu, 1996[23], Wang, S.Y.,

1998[31]). Dang (1995[2]) also applied auricular blood-letting by puncturing the Apex of the Ear to promote the therapeutic effect on his patients. It is believed that blood-letting by puncturing of the Apex of Ear is useful for heat and pain relief, wind elimination, and tranquilizing the mind, etc. and is widely used in clinical practice such as fever, hypertension and insomnia (Feng et al., 1994, p.61, p.75). However auricular infections due to the puncturing may result if the aseptic technique is not closely observed.

To avoid the 'overstrain' of the selected acupoints and avoid the possibility of local irritation on unilateral ear, both ears are treated alternately and the semens replaced regularly. However the frequency of changing differ among studies. Many authors changed the semens every 2-3 days (Huang et al., 1996[13]; Li, 1997[18]; Shang, 1995[25]; Zhu, 1998[46]), but some kept them unchanged for 5-7 days (Dang, 1995[2]; Guo, 1996[10]; Ju, 1997[16]). Du (1996[3]) even applied the pills on both ears of the participants to increase stimulation and effectiveness.

Certain studies adopted a combined therapeutic approach by using both auricular pressing therapy together with other therapies, such as acupuncture (Feng, 1998[6]; Xu, 1998[39]; Yang, 1997[41]) or Chinese herbal medicines (Xing & Tang, 1996[38]). In such cases, the single effect of auricular therapy on treating insomnia cannot be assessed if other therapies are adopted simultaneously.

The effect of this therapy on the elderly was not clearly illustrated. Only two authors reported that they had 9% (n = 3) (Shang, 1995[25]) or 29% (n = 18) (Xu, 1998[39]) of participants aged above 60 in their study; the overall effect of the therapy on all participants was reported without considering whether there were any differences in the effects between the younger and the older participants.

In all the studies mentioned above, only individual participants subjectively reported the improvement of the sleep quality after the therapy. None of these studies adopted a scientific approach to the investigation of the therapeutic effectiveness of auricular therapy on sleep using objective measurements on sleep parameters.

To conclude, the effect of auricular therapy on the majority of cases with insomnia has been clearly stated. However the inconsistency in the treatment protocol among studies, the use of combined therapies and the lack of objective measurements make it impossible to draw a strong causal relationship between treatment and effect of auricular therapy on insomnia, and also make replication of studies difficult.

2.6 Effect of magnetotherapy and its clinical applications

"Magnetization of acupoints is a therapeutic method in which a magnetic field acts on certain acupoints to treat diseases" (Li & Tan, 1998, p.207). Early in 1871, the *Ben Cao Gang Mu* (本草綱目) which was compiled by Li Shi-shen (李時珍) of the Ming Dynasty, has reported that putting a magnet in the ear canal can treat deafness (Qi, 1999, p.95[22]).

It is reported that magnetization of acupoints has the function of disperse swelling, relieve itching, control diarrhoea and dyspnoea (Li & Tan, 1998, p.207). Furthermore, acupoint magnetotherapy could accelerate the blood circulation by dilating blood capillaries, treating diseases through applying a magnetic field to human *Jing Luo* (main and collateral channels), and producing sedative, analgesic and antiinflammative effects (Chen, Zhou & Hu,1998, p.53[1]). It is thought that magnets can increase the energy (*Qi*) flow along the meridian and can be used for treating various disorders (Magnetech, no date).

Using magnetic pearls as auricular therapy in the clinical treatment of diseases has been widely reported. Successful examples using magnetic pearls on certain otopoints as a single treatment included the prevention of drug reaction of the gastrointestinal tract (Mao & Gong, 1994[21]); infection of cartilage of pinna (Guo, 1997[11]), and headaches (Zhao, 1996[44]). Jiang et al. (1995[15]) demonstrated, in their study, that magnetic pearls applied to the auricle can be an effective anaesthesia for the operation of the thyroid

because of its pain relieving properties. Vallbona, Hazlewood and Jurida (1997) also show that the application of a device delivering static magnetic fields of 300 to 500 Gauss over a pain trigger point results in significant and prompt relief of pain in postpolio subjects under their double-blind pilot study.

Various studies (Li et al.,1995[17]; Shen, Zheng & Pan, 1997[28]; Wan, 1998[30]) illustrate that magnetic treatment when combined with other therapies such as low voltage electric current, can be used successfully in cases with gallstones. Other studies using a combined approach of auricular magnetotherapy with other therapies, such as auricular tapping for mumps (Fei, 1996, p.60[5]); acupuncture for cerebral palsy (Fan & Wang, 1996[4]); Chinese herbal medicines for allergic rhinitis (Liu & Ni, 1997[19]); low-voltage electric current for pseudocyst of the pinna (Zhu & Cao, 1998[45]), also showed a positive effect in treatment. Chen et al. (1998, p.126[1]) report a successful experience of helping a person who had suffered from insomnia for three years to resume normal sleep by applying magnetic pearls (@ 300 Gauss) to three auricular acupoints: shenmen, subcortex and kidney.

Although many studies have demonstrated a positive clinical effect for magnetotherapy, the way in which magnetic fields react with living tissue is quite uncertain (Low & Reed, 1992, p.255). The actual effect of magnetotherapy is widely debated. Ramey (1998) emphasizes that explanations claiming magnetic fields 'increase circulation', 'reduce

inflammation', or 'speed recovery from injuries' are simplistic and are not supported by experimental evidence. Hong et al. (1982) even failed to support that the Japanese TDK magnetic necklace has any significant therapeutic effect on chronic neck and shoulder pain and stiffness. A significant placebo effect may be responsible for decreasing the intensity or frequency of pain in subjects. However Valbona et al. (1997) argue that the failure to find evidence of effect in the study of Hong et al. may be due to the small amount of magnetic intensity delivered by the device which was not directly applied over specific pain trigger points. Finegold (1999) stresses that magnets marketed to improve the appearance of the face by wearing a mask containing magnets work no better than a 'placebo' effect, and that the effectiveness of magnets has yet to be justified in other studies.

2.7 Instruments for sleep measurement

To distinguish sleep and wake phases, many sleep measuring tools have been developed to monitor activity during sleep. The most commonly used instruments are sleep diaries, wrist actigraphy (also referred to as actometer or actimeter), polysomnography (PSG), and electroencephalographic (EEG) recordings.

Though PSG is claimed to be the 'gold standard' in sleep research, it is not convenient and acceptable to clients who need to undergo a lengthy period of data collection within which their sleeping patterns have to be monitored. Chambers (1994) points out that PSG is an expensive procedure and its use may not be financially practical in many cases involving insomnia. On the other hand, wrist actigraphy is widely believed to provide simple, inexpensive and rather accurate measurement of sleep-wake activity. A significant correlation coefficient of $r = 0.82$ ($p < 0.0001$) for total sleep time (TST) between actigraphy and PSG among people with insomnia has been reported (Jean-Louis, Zizi, Spielman, Hauri & Taub, 1997a) (Figure 2.6). Most current wrist actigraphs consist of a movement detector and considerable memory storage that are packed into a small box that can be worn on the wrist like a watch. The data are stored in the internal memory of the device throughout the night until the stored information is downloaded to a computer (Figure 2.7).

It has been demonstrated that actigraph placements on dominant and non-

dominant wrist yield identical movement patterns, and there may not be a first-night effect associated with actigraphy as is found with PSG (Jean-Louis, Zizi, Spielman, Hauri & Taub, 1997b). The type of information generated from a sleep diary and the actigraph are essentially the same (i.e. rough estimates of sleep time but no data concerning sleep stages), therefore using actigraphic monitoring can facilitate later comparison of the sleep parameters between these tools.

Figure 2.6 Correspondence between polysomnography and actigraphy for one night using total sleep time as an index of comparison (Jean-Louis, et al., 1997a).

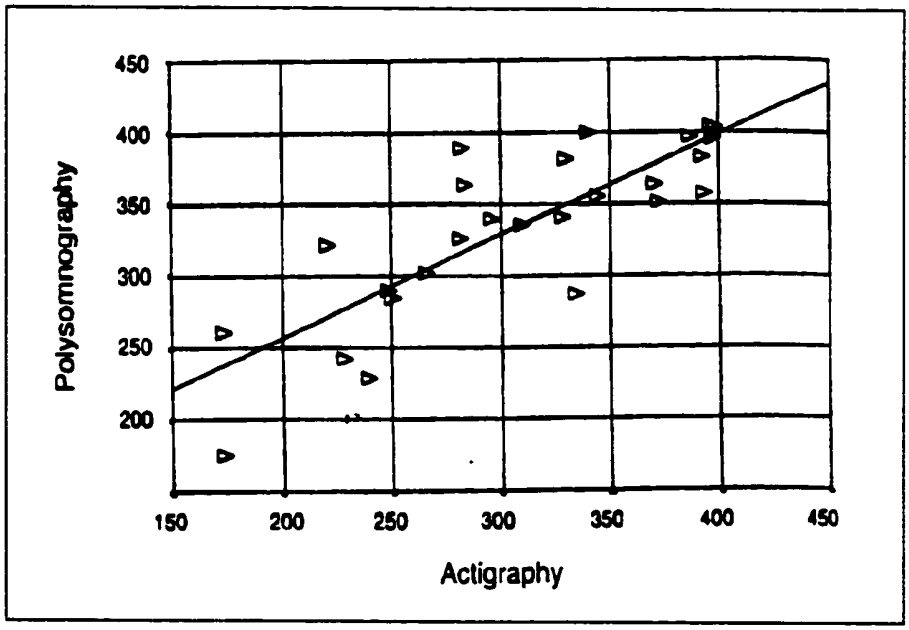


Figure 2.7 The devices for actigraphic monitoring.

2.8 Summary of review

Sleep disturbance in the elderly is a particularly common problem. Persistent sleep disruption affects both the physical status and emotional responses of an individual. Using hypnotic prescriptions for insomnia only further compound the sleeping problems of the elderly due to the side effects of drugs. Auricular therapy can activate meridians and collaterals, regulate the *Qi* and blood, help to achieve the balance between the *Yin* and *Yang* status of internal organs, and is therefore suitable for treating many disorders of the body. Many studies being conducted in China Mainland have reported desirable effects of auricular therapy on patients with various disorders, including insomnia. However the inconsistency in the treatment protocol among studies, the use of combined therapies, and controversial views regarding the effect of magnetotherapy make it impossible to draw a strong causal relationship between auricular therapy and its treatment effect. To draw a more valid causal inference, clinical trials using randomization method and objective measurements are necessary to determine the therapeutic effect of auricular therapy. The participation of nurses in such trials is advised so as to enhance the holistic care of patients, at the same time as contributing to more standardized research practices with sufficient autonomy to carry out their new role in primary health care.

2.9 Framework of the research process

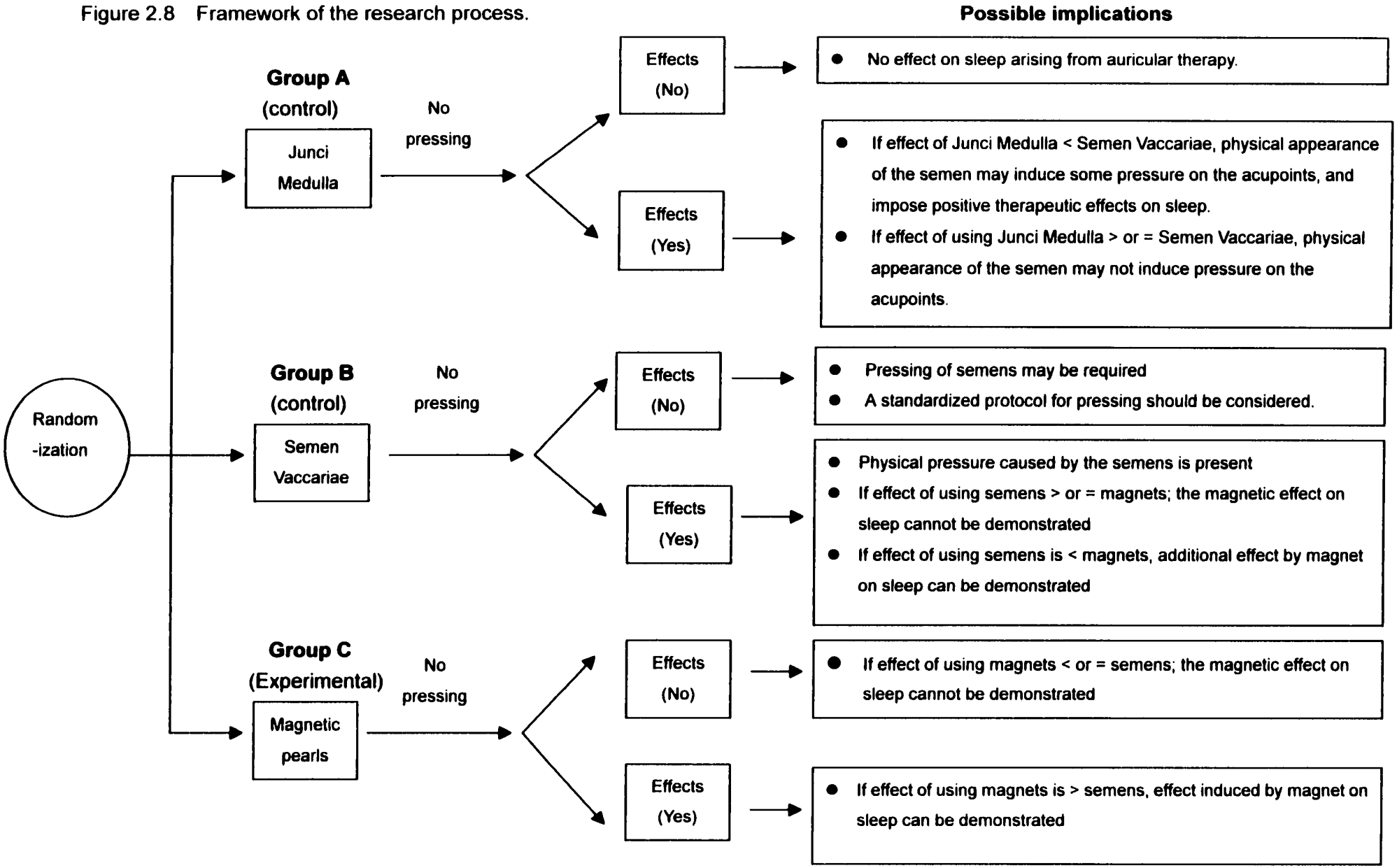
The framework of the research process was based on the literature review and gaps of knowledge identified from previous studies. According to the literature, auricular acupuncture employing needles as a source of stimulation may not be widely accepted by the clients. Inflammation of the auricular points may result if aseptic techniques are not strictly observed. When using pressing therapies, such as those using imbedded Semen Vaccariae, participants should be reminded to press on the adhered pills regularly to achieve a better therapeutic effect. Therefore bias of the results may arise if individual clients fail to perform this action during the treatment period. It is expected that the use of magnetic pearls for auricular therapy will be less traumatic, more hygienic and convenient, and more easily accepted by the clients than many other approaches to auricular therapy. Since present understandings of the effect of magnetotherapy are limited and controversial, the therapeutic effect of using magnetic pearls as an auricular therapy on many disorders merits further study. For these reasons, this study consisted of two controls groups and one experimental group so that a comprehensive picture of auricular therapy using different objects for acupoints stimulation could be seen.

Using subjects receiving Semen Vaccariae in one control group (Group B) [王不流行籽] provide better insight as to whether a therapeutic effect can be

achieved if no additional pressure is applied to the semens, and this can also serve as a referent group when the effect of magnetic pearls [磁珠] (Group C) is observed. Moreover, whether the physical appearance of the semen induced pressure on the acupoints can thus lead to sleep improvement can be determined when the therapeutic effect between another control group using Junci Medulla [燈芯] (Group A) is compared with the group receiving Semen Vaccariae [王不流行籽] (Group B).

This clinical trial adopted a scientific approach in which objective measurement using actigraphic monitoring was used to evaluate the treatment effects arising from the therapy. Diagrammatic presentation of the framework of the research process is displayed in Figure 2.8.

Figure 2.8 Framework of the research process.



PS: Significant therapeutic effects are determined by the between-group and within-group comparisons of objective data (sleep parameters) collected by actigraphic monitoring.

CHAPTER 3

METHODOLOGY

3.1 Introduction

In this chapter, the methodology of this clinical trial is described. This includes the criteria used for selecting the participants to take part in the study, as well as the description of the subjective and objective instruments used for evaluating the therapeutic effects of auricular therapy. The procedures of the therapy which include the assessment of the traditional Chinese diagnosis on insomnia for the participants by an experienced TCM practitioner are explicitly stated. Lastly, the ethical considerations and methods of data analyses related to this study are explained.

3.2 Study design and selection of participants

A randomized controlled trial using a pretest-posttest control group design was used. As was discussed in the framework of the research process in Chapter 2, there were two control groups and one experimental group.

The three groups were:

Group A (control group) : Using Junci Medulla [燈芯] (n = 30)

Group B (control group): Using Semen Vaccariae [王不流行籽] (n = 30)

Group C (experimental group): Using magnetic pearls [磁珠] (n = 60)

Twelve hostels for the elderly were contacted for the purpose of recruiting potential participants. The contexts of these hostels are homogenous in terms of their environmental settings, staff:resident ratio and admission criteria. Participants of 60 or above who were suffering from sleep disturbances were invited to participate in this study. Volunteers were accepted after a preliminary screening only if they reported sleeping poorly on at least three nights per week and if their insomnia had lasted for a minimum of six months. A sleep questionnaire (details in section 3.3.1) was used for screening purposes. In addition, actigraphic monitoring was used to distinguish participants with clinically impaired sleep from normal sleep by a typical cutoff score of sleep efficiency of 85% (Morin, Colecchi, Stone, Sood & Brink, 1999). The sleep efficiency is expressed in percentage and is calculated by dividing nocturnal sleep time by nocturnal bedtime. Therefore the higher the sleep efficiency, the better the quantity and quality of sleep of a person. A low sleep efficiency index (e.g. below 85%) implies that a person has short nocturnal sleep time that may be due to long sleep latency, frequent midsleep awakenings, and long waking time after sleep onset.

Eligible participants were randomly assigned by drawing cards indicating group assignments and which side of the ear where treatment was commenced. The sample size of each group was determined when the effect size was identified after the pilot study (details of sample size estimation are described in Chapter 4 of this thesis). It was decided that

an effect size of f=0.40 with 93% power at α_2 = .05 would be appropriate for this study (Portney & Watkins, 1993, p.663).

Owing to the effects on sleep, potential participants with serious physical and psychological illnesses were not invited to join the study. To avoid the 'masking' effect of other interventions on sleep, participants were instructed not to take any sleeping pills during the study period when receiving the therapy. Participation in the study was on a voluntary basis, and all potential participants were informed and assured that they had the right to refuse or withdraw from the study at any time.

Exclusion criteria

- Serious physical and psychological illnesses, such as stroke, mental illness, dementia, major depression, and impairment such as being bedridden.
- Sleep apnea
- Regular use of a hypnotic medication or other psychotropic medication with an inability or unwillingness to discontinue medication
- Wearing a pacemaker, or implanted electrical device – this is to avoid possible interaction between the pacemaker and the magnetic pearls if participants were randomly allocated to the experimental group.
- Those who have a sleep partner : this is to minimize the artifact due to movement by partner during the time when the participant received actigraphic monitoring.
- Infection or abscess of external ear; or absence of ear(s).

3.3 Instruments and materials

3.3.1 Sleep questionnaire

An already established questionnaire designed by the research team of the sleep laboratory of The Hong Kong Polytechnic University and was having a content validity index (CVI) (0.92) and coefficient of reliability (0.87) respectively was adopted for use in this study (Sleep research team of NHS, 1997a). Minor modifications to the questionnaire have been made to meet the objectives of this study. The revised questionnaire was sent to three experts who are experienced in sleep or geriatric studies for validation, and the content validity index of 92% (0.92) was achieved. The English and Chinese versions of the revised questionnaire are in Appendix 4 and Appendix 5. The sleep parameters being investigated included the usual bedtime, sleep latency, waking after sleep onset, awakening time, arising time and satisfactory sleep level etc. Factors relating to daily habits such as alcohol consumption, smoking, use of medications, exercise, outdoor activities and bedtime snacks were also included.

3.3.2 Wrist actigraphy

To supplement the information obtained from the sleep diary, wrist actigraphy (Basic Mini-Motionlogger Actigraph™) was used to record the activity of the participant during sleep (Figure 3.1). The wrist actigraphy could help monitor the nocturnal sleep behaviours and the participants were told to wear the actigraph during sleep at night. Since it has been

demonstrated that actigraph placements on dominant and non-dominant wrist placements yield identical movement patterns (Jean-Louis, Zizi, Spielman, Hauri & Taub, 1997b), the participant could choose to wear the actigraph on either hand that she/he felt convenient. They were instructed to press the 'event button' of the actigraph when they intended to sleep at night and when they woke up in the morning. The time when the 'event button' was pressed could serve as an indicator to validate the sleep/wake time subjectively reported by the participants in the sleep diary.

Computerized sleep scoring programmes were used: the ACT 2000™ (Beta version 1.43.01) was used to initialize the actigraphs and for data downloading; and the ACTION™ programme (version 1.32) was used for analysis of sleep parameters. Sleep parameters collected by the actigraph including NBT (Nocturnal bedtime), NSP (Nocturnal sleep period), NST (Nocturnal sleep time), SL (Sleep latency), TWT (Total wake time), WASO (Wake after sleep onset), MSA (Number of midsleep awakenings), and SE (Sleep efficiency). An example of the actigraphic output is shown in Figure 3.2.

3.3.3 Sleep diary

The sleep diary was formerly designed by the research team of the sleep laboratory of The Hong Kong Polytechnic University (Sleep research team of NHS, 1997b). Four more items relevant to auricular therapy were added in the last section of the diary (Appendix 6 and Appendix 7). During

the time when the participants received actigraphic monitoring, the staff in the hostels for the elderly made a daily inquiry using the sleep diary in order to understand the sleep behaviours and related activities of the participants over the past 24 hours. Using the staff of the hostels to collect the information on the sleep diary, made it possible for the researcher to minimize bias, since when both the staff and the participants were blinded to the type of interventions that were given by the researcher. Briefing to the staff in filling in the sleep diary was conducted so that the reliability of the findings derived from the diary was empirically valid. The data collected by the sleep diary were used to compare with the data derived from the actigraphs to see if there was any discrepancy in the sleep parameters between the actigraphs and those subjectively reported by the participants, and to validate the sleeping time and arising time as indicated by the event button markings on the actigraphic record.

Figure 3.1 A wrist actigraph.

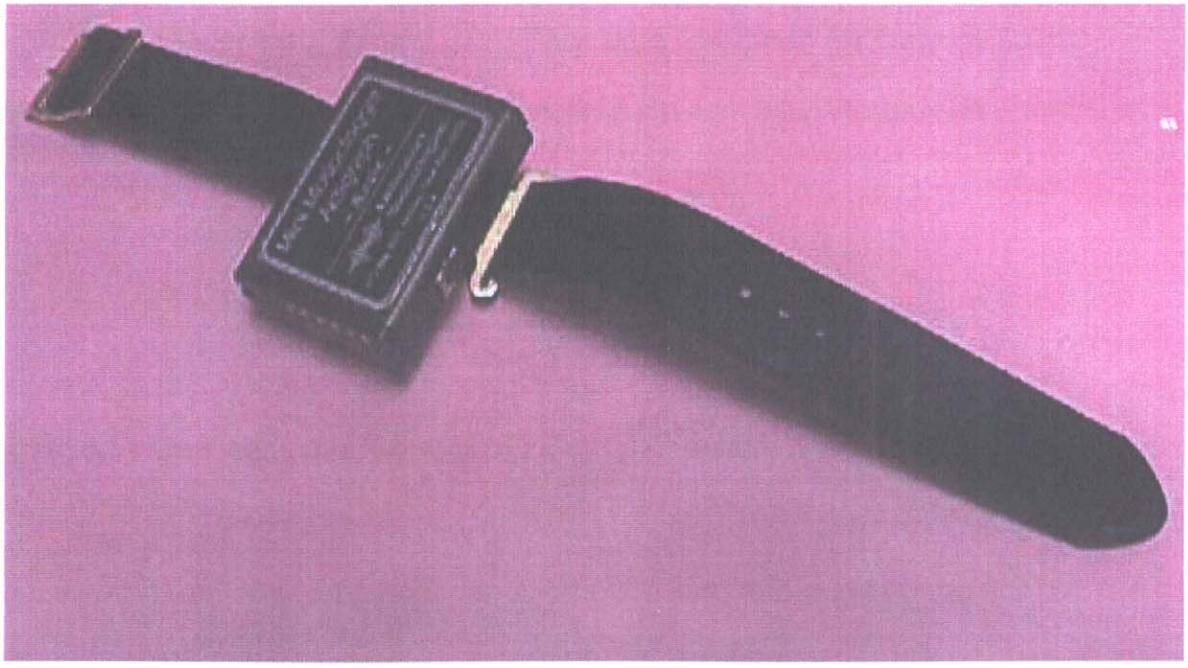


Figure 3.2 An example of the actigraphic output.

```
                    INTERVAL STATISTICS

      Interval: 2   Start: 20:13:30/340     End:05:31:30/341

                              Activity

Epochs in Interval:   1116          Minimum:              0.00
Epoch Length(secs):    30.00        Maximum:            158.00
Mean activity:         18.96        25 Percentile:        0
Std Dev:               39.79        50 Percentile:        0
                                    75 Percentile:       10

                               Sleep
       Total Interval                    Onset - Offset
Total Minutes Scored: 558.00        First Sleep Onset: 20:34:00/340
Sleep (minutes):      415.00        Last Sleep Offset: 05:13:00/341
       percent:        74.37           Duration (min):    519.50
Wake (minutes):       143.00        Sleep (minutes):      415.00
       percent:        25.63              percent:        79.88
Total Awakenings:     20            Wake (minutes):       104.50
      Avg length:      5.22              percent:        20.12
Sleep/Wake ratio:      2.90         Sleep latency (min):   20.50

      PgDn:Next Interval   PgUp: Previous Interval   ESC:Quit
```

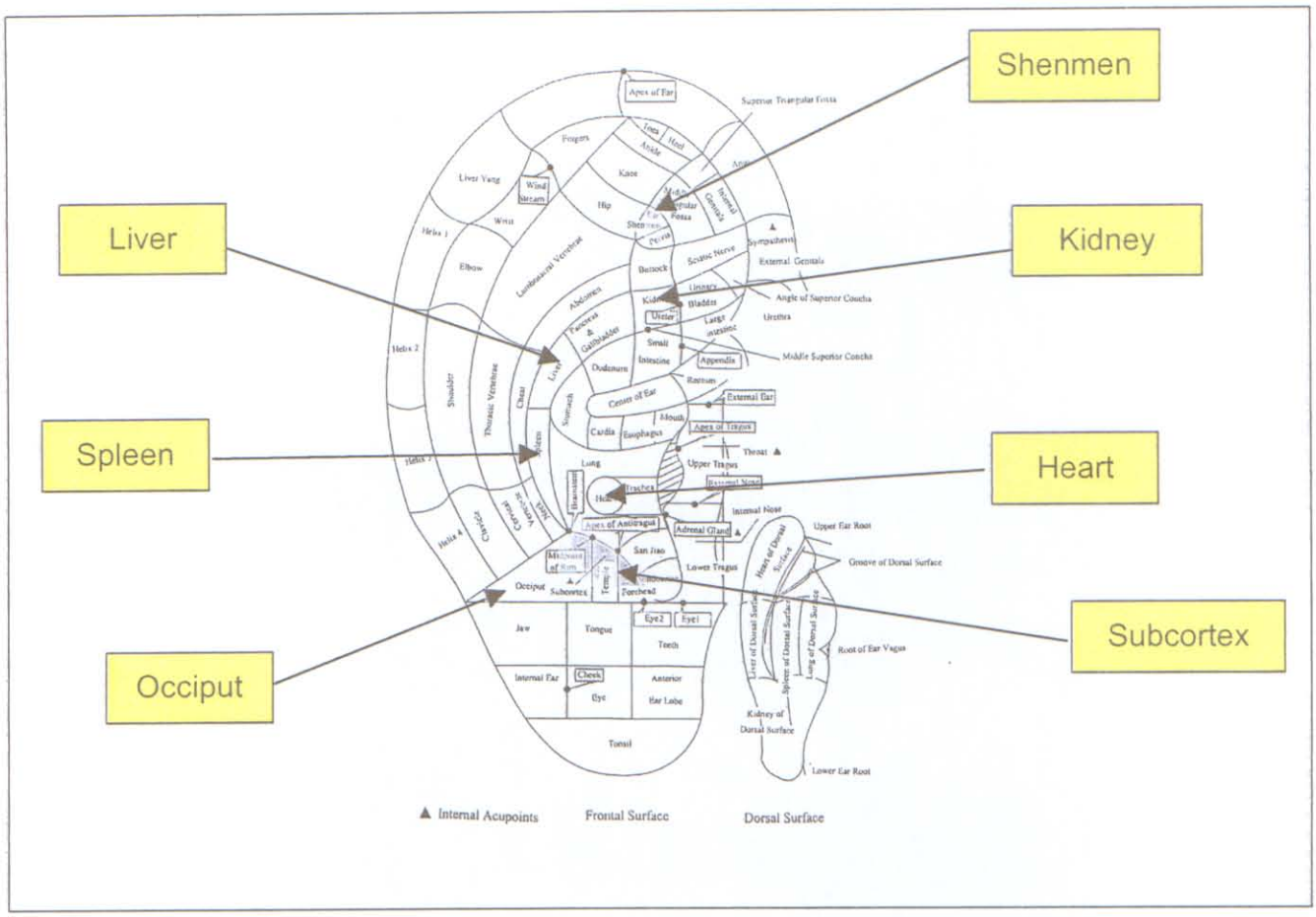
3.4 Justification of the selection of acupoints

Seven auricular points which were thought to have an effect on promoting sleep were selected (Figure 3.3). They were Shenmen (or Gate of Spirit) [神 門], Heart [心], Kidney [腎], Liver [肝], Spleen [脾], Occiput [枕], and Subcortex [皮 質 下].

Points selection was based on the "organ" theory of Chinese medicine. According to the principles of TCM, the mind resides in the heart, so treating 'Heart' can calm the mind; kidneys can restore essence, so treating 'Kidney' can tonify the essence (Feng et al., 1994, pp.67-70). The acupoint 'Liver' was used as it can soothe the liver and regulate the flow of *Qi* especially when insomnia is caused by stagnation of liver-*Qi;* and stimulating the 'Spleen' can promote digestion and fluid drainage (Feng et al., 1994, p.103; Zhang & Wu, 1991, pp.36-37).

Besides, 'Shenmen' and 'Occiput' are believed to tranquilize the mind, the latter is also effective in treating headaches and dizziness; while the 'Subcortex' can harmonize excitement and inhibition of the cortex (Feng et al., 1994, p.103; Yang, 1988). Both the occiput and subcortex are also organs belonging to the neurological system that may have an effect on sleep improvement.

Figure 3.3 Selected acupoints for auricular therapy for sleep improvement.



Anatomical location of each acupoint (definitions directly quoted from Feng et al., 1994, p.31, pp.35-398):

Shenmen [神 門]	On the triangular fossa superior to the origin of the superior and inferior crus of the helix.
Heart [心]	On the centre of the inferior concha.
Kidney [腎]	On the superior concha inferior to the origin of the superior and inferior crus of the antihelix.
Liver [肝]	On the posterio-superior portion of the superior concha.
Spleen [脾]	On the posterio-superior portion of the inferior concha.
Occiput [枕]	On the posterio-superior portion of the external side of the antitragus.
Subcortex [皮 質 下]	On the medial side of the antitragus.

3.5 Procedures

Participants were randomly selected to receive auricular therapy using Junci Medulla, Semen Vaccariae or magnetic pearls.

Group A (Control group): Using Junci Medulla

Junci Medulla is the dried stem of perennial plant Juncus effusus L. (Juncaceae) (Yuan, Ren, Huang & Gao, 1996, p.414). It is soft in texture, and will not induce any physical pressure on the acupoints of the ear. It is assumed to have no therapeutic effect when using it as an auricular therapy for sleep improvement (Figure 3.4).

Group B (Control group): Using Semen Vaccariae

Semen Vaccariae is a small round seed which is commonly used for auricular taping (Figure 3.5). The diameter of each semen is ~ 0.13cm (Figure 3.7).

Group C: Using magnetic pearls

The magnetic pearls used in this study were randomly checked by the Teslameter located at the Department of Applied Physics (Figure 3.6). This Teslameter can give digital readings of magnetic flux densities ranging from 0.01 mT to 2 T (i.e. 0.1 Gauss to 20,000 Gauss). Each magnetic pearl that was used in this study contained an average of –6.58 mT (~66 Gauss/pearl) magnetic flux densities (Figure 3.8). The diameter of each magnetic pearl was similar to that of Semen Vaccariae and was also ~ 0.13cm (Figure 3.7).

Figure 3.4 Junci Medulla.

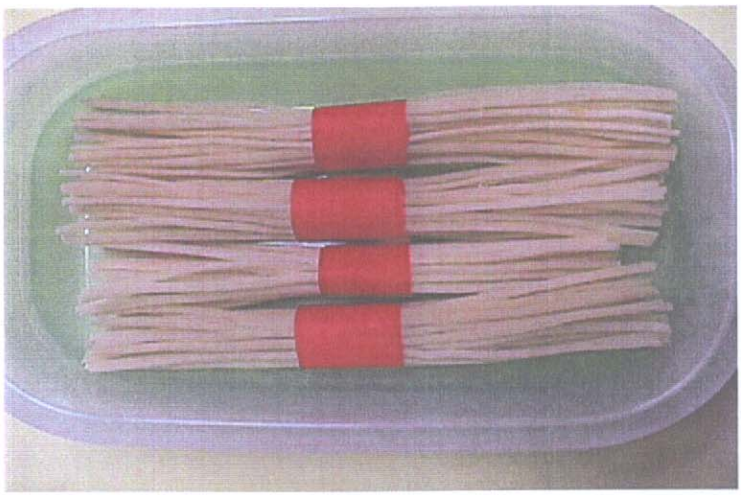


Figure 3.5 Semen Vaccariae.

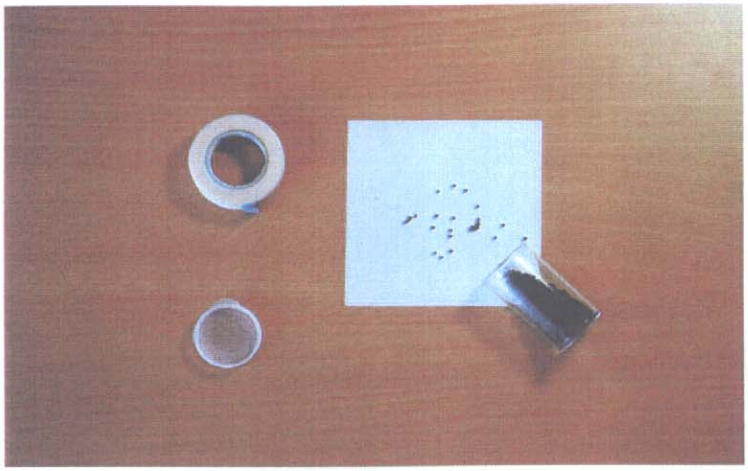


Figure 3.6 Magnetic pearls.

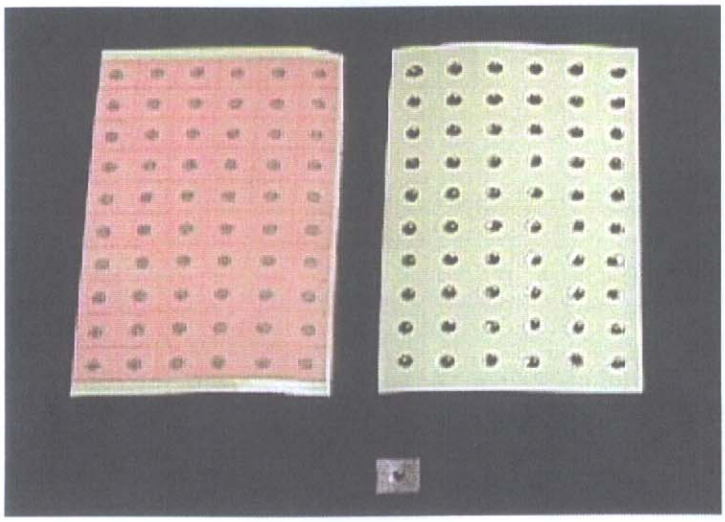


Figure 3.7 The diameter of a Semen Vaccariae and a magnetic pearl.

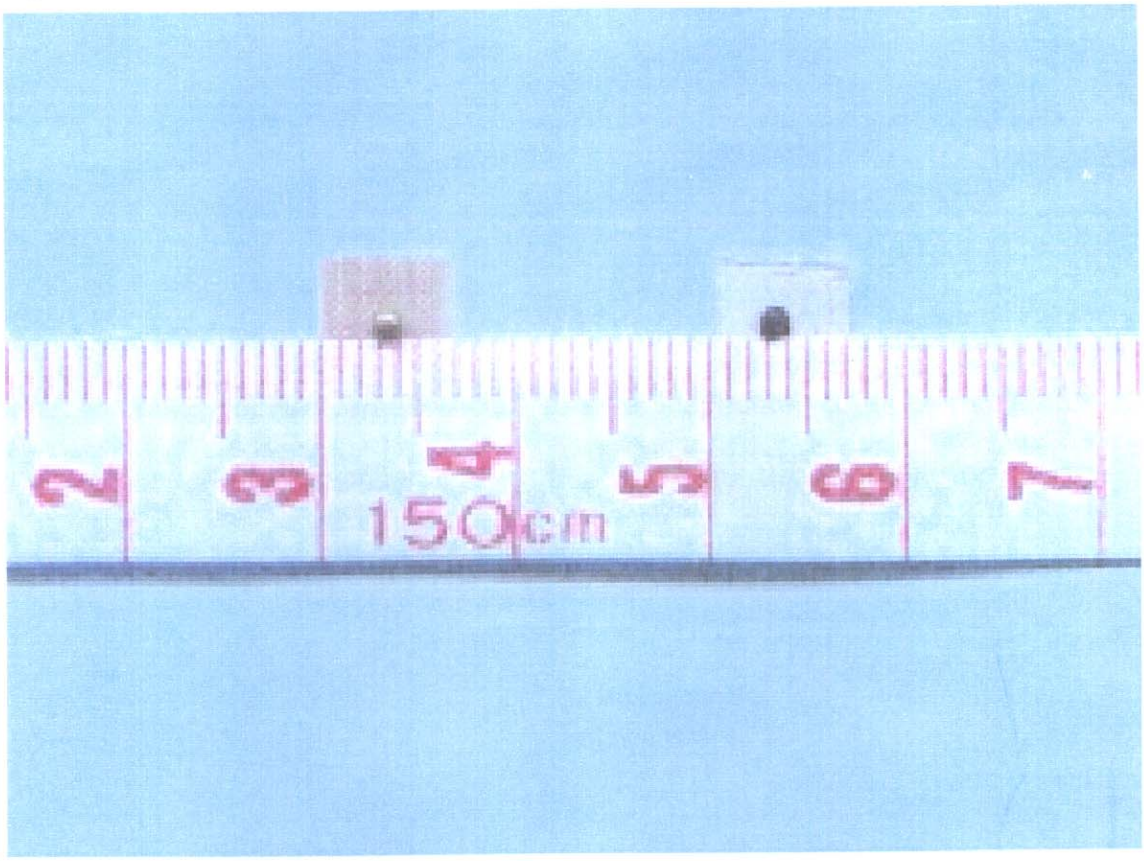
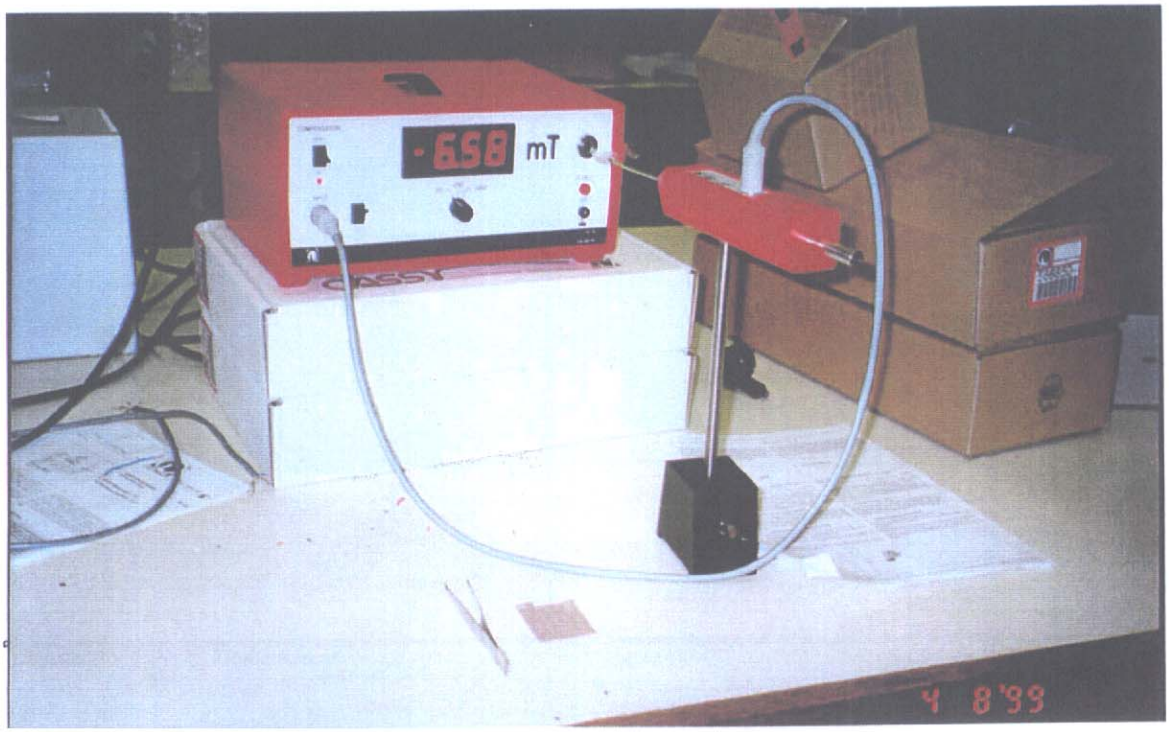


Figure 3.8 Teslameter for measuring the magnetic flux densities of the magnetic bead.



Briefing sessions were provided for the participants by the researcher prior to the commencement of the study. Each volunteer was asked to fill in a sleep questionnaire at the initial stage to provide information related to their usual sleep behaviours and factors related to sleep. Before the commencement of the therapy, the traditional Chinese diagnosis on insomnia was identified after assessment of the participant via medical history taking, pulse palpation and tongue inspection conducted by an experienced TCM practitioner (Figure 3.9). The assessment form (in Chinese) that served this purpose is displayed in Appendix 8.

Figure 3.9 Performing the traditional Chinese diagnosis on insomnia for the participants by an experienced TCM practitioner.

The inter-rater reliability between the TCM practitioner and the researcher on assessing the traditional Chinese diagnosis on insomnia for the participants was conducted on 23% (n=27) of the total participants, and the agreement was 81.5% (Figure 3.10).

Figure 3.10 Inter-rater reliability conducted between the TCM practitioner and the researcher on assessing the traditional Chinese diagnosis on insomnia.

The auricle of the participant was sterilized with 75% alcohol prior to the administration of the therapy (Figure 3.11). Participants were also randomly assigned to receive therapy commencing on either the left or right ear so as to identify any differences in effect between the two kinds of approach. Junci Medulla, Semen Vaccariae or magnetic pearls were applied to the most sensitive area of each selected auricular point. The sensitive point was detected by means of an Electrical detector (Potentiometer) (Pointer Plus™) to measure auricular electrical resistance (Figure 3.12 & Figure 3.13). When disease or disorder is present in the body, the electrical resistance in the corresponding auricular points will decrease obviously; and areas where the electrical resistance is lower than the standard are claimed as positive, or highly conductive, electrical resistance points (Feng et al., 1994, pp.52-53). Once the detector had identified a sensitive point, the indicator light flashed. Many previous studies (Ju, 1997[16]; Li, 1997[18]; Shang, 1995[25]; Tang, 1997[29]) also identified the positive electrical resistance points for treatment in order to achieve a more favourable effect. Both ears were treated alternately. Junci Medulla / Semen Vaccariae / Magnetic pearls were replaced every three to four days to avoid the possibility of local irritation of auricular points under treatment (Figure 3.14).

Figure 3.11 Accessories for sterilization of auricle before therapy.

Figure 3.12 Electrical detector (Potentiometer / Pointer Plus™).

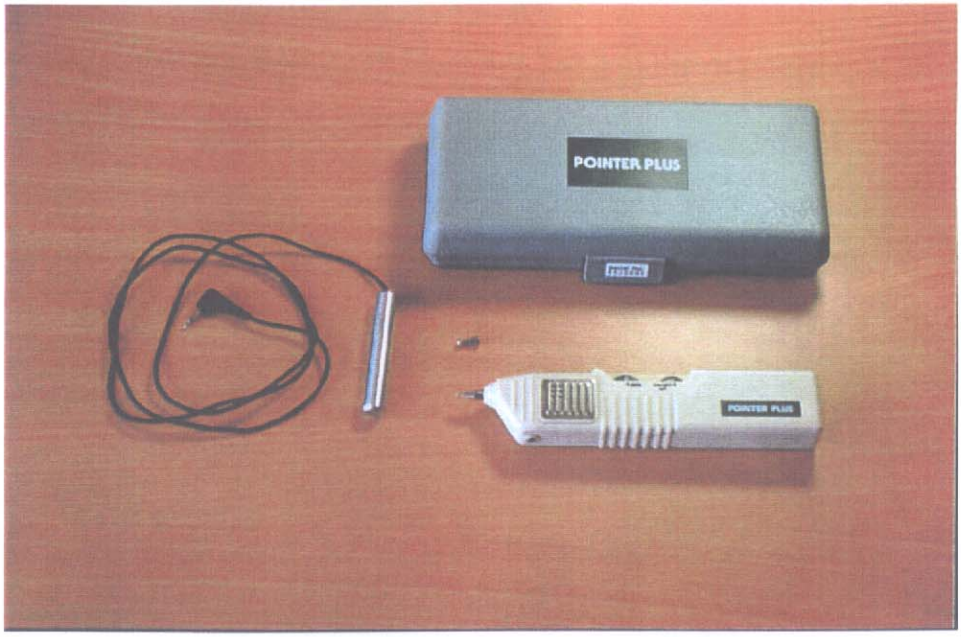


Figure 3.13 Using electrical detector for measuring the auricular electrical resistance of each acupoint.

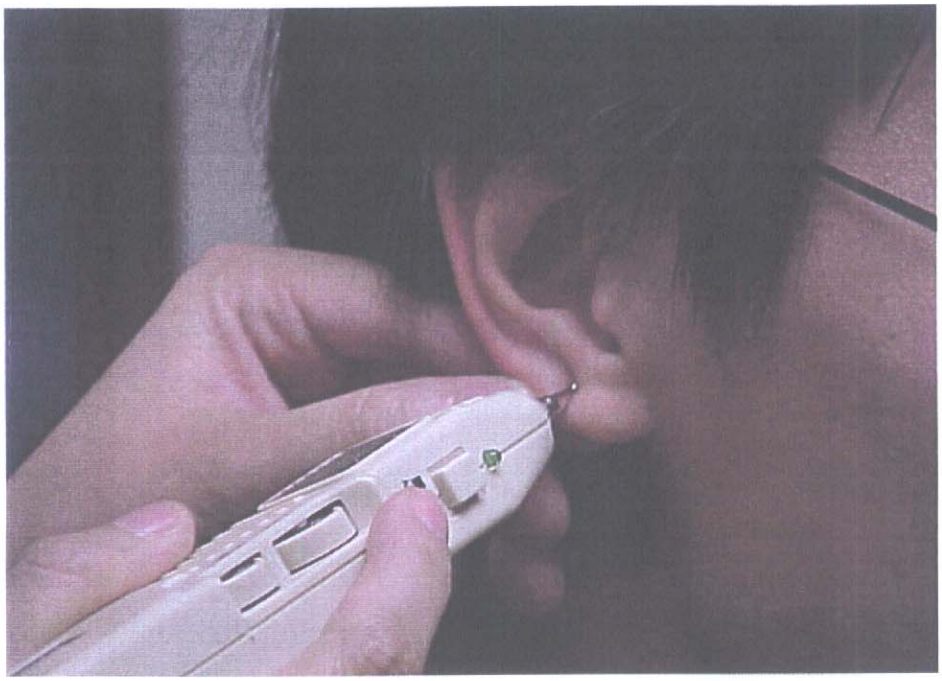
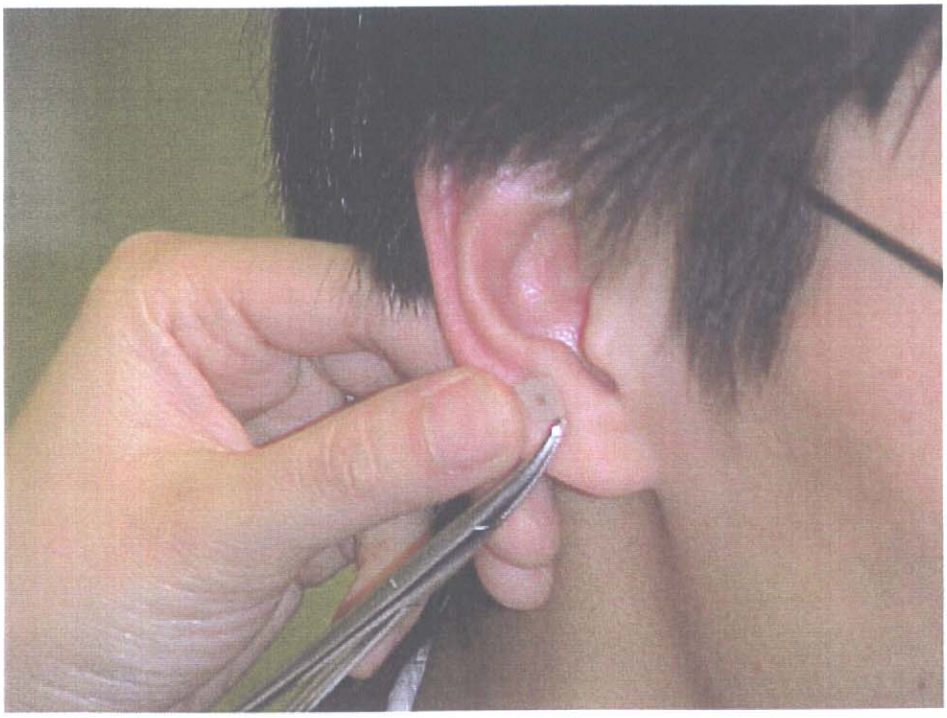


Figure 3.14 Application of magnetic pearl to the auricular acupoint.



The treatment protocol consisted of three days of baseline measurement, three weeks of auricular therapy, and three days of post treatment monitoring (Table 3.1). Before the commencement of the therapy, the sleep questionnaire was used to collect information on the socio-demographic data and usual sleep behaviours of the participants. In addition, objective sleep parameters using actigraphic monitoring were collected before therapy as baseline data. These parameters included NBT, NSP, NST, SL, TWT, WASO, MSA, and SE. During the time when the participants received actigraphic monitoring, the staff in the hostels for the elderly made a daily inquiry using the sleep diary in order to understand the sleep behaviours and related activities of the participants over the past 24 hours. Data collection using actigraphic monitoring and sleep diary were repeated for three days during the period of the therapy, and for three days after the therapy was completed.

Table 3.1 Treatment protocol.

Day	Intervention (Group A, B or C)	Data collected		
		Sleep Questionnaire	Sleep Diary	Actigraphic Monitoring
Three days before treatment commenced	—	✔	✔	✔
Treatment period Day 1 – Day 10	✔	—	—	—
Treatment period Day 11 – Day 13	✔	—	✔	✔
Treatment period Day 14 – Day 21	✔	—	—	—
Within three days after therapy	—	—	✔	✔

3.6 Data analyses

Data derived from actigraphic monitorings were obtained using the ACT 2000™ (Beta version 1.43.01) and the ACTION™ programme (version 1.32). These epoch-by-epoch samples were stored in the internal memory of the device throughout the night until the stored information could be downloaded to a computer.

The quantitative data were analyzed by the statistical package SPSS™ version 9.0. Descriptive statistics were applied to data collected by the sleep questionnaire examining the factors related to sleep of the participants. Data collected by sleep diaries were analyzed to determine the quality of sleep as subjectively reported by the participants during the study period. To cross-validate the estimates of various sleep parameters and to determine whether there was any over- or under-reporting of effects of the therapies, the subjective data collected by sleep diaries were compared to the actigraphic recordings.

One-way analysis of variance (ANOVA) procedures were used to evaluate between-group differences in the sleep parameters at baseline, during and after therapy. The hypothesis which examined whether the mean of the sleep parameters of individual groups shows significant differences before, during, and after the 3-week therapy were further investigated by repeated measures analysis of variance (RANOVA). Alternate criteria for evaluation

of therapeutic effects using the categories of markedly effective, moderately effective, slightly effective, and ineffective in NST or SE improvement were used (Table 3.2). An increase in NST and/or SE indicates that both the sleep quality and sleep quantity of the participants were improved if the therapy was found effective on sleep improvement.

Besides using descriptive statistical analysis, *t*-tests were conducted to determine the difference in effect on the sleep parameters of clients with different types of insomnia ('Excessive' or 'Deficient'). The therapeutic effects in terms of the sleep efficiency (SE) of participants in the experimental group (a) in different age groups (60-80, 81-100), (b) having suffered insomnia for a different number of years (0-10, 11 or above), and (c) commencing treatment on different ears were evaluated using *t*-tests. Multiple regression analysis was conducted to examine whether the sleep efficiency of the participants was affected by the therapy after allowing for a myriad of possible predictors.

Table 3.2 Criteria for evaluation of therapeutic effects

Category	Effective criteria of NST	Effective criteria of SE
Markedly effective	improved NST > 10%	improved SE > 10%
Moderately effective	improved NST 6%-10%	improved SE 6%-10%
Slightly effective	improved NST 1%-5%	improved SE 1%-5%
Ineffective	improved NST ≤ 0%	improved SE ≤ 0%

3.7 Ethical considerations

The researcher was governed by the regulations of The Hong Kong Polytechnic University in protecting the human rights of participants involved. The research proposal was submitted to the Ethics Committee of The Hong Kong Polytechnic University. After approval was granted by the Ethics Committee and the selected hostels for the elderly, data collection commenced.

The identified volunteers were requested to sign a consent form before they began the program of auricular therapy (Appendix 11 and Appendix 12). The researcher explained the nature and purposes of the study carefully to the participants. All potential participants were informed and assured that they had the right to refuse or withdraw from the study at any time. Clarification of any queries or misconceptions about the therapy could be made during the briefing session. In addition, the name and contact telephone number of the researcher were given to each participant to enable subsequent inquiry about the study.

The foreseeable risk was minimal in this study, since no invasive technology was involved during data collection. However, wearing the watch-like wrist actigraph during sleep might cause a slight sense of discomfort to individual participants. The materials that were used for auricular therapy in this study (Junci Medulla, Semen Vaccariae, and magnetic pearls) are less traumatic, more hygienic and convenient than

many other approaches of auricular therapies, such as auricular acupuncture. Side effects arising from this therapy are rare. Normal reactions to auricular pressing therapy that might appear include localized sensations of pain, heat, numbness, and distention (Feng et al., 1994, p.57; Li & Tan, 1998, p.170). However abnormal phenomena such as fainting during or after taping, allergic reactions to the adhesive tape or infection of the auricle may be possible. In severe situation(s), the participant could peel off the semens / pearls and such adverse reaction(s) would diminish very quickly.

The researcher developed an information sheet (English and Chinese versions) to make sure that adequate information was given to participants and for their later reference (Appendix 11 and Appendix 12). Participation in the study was on a voluntary basis. Personal information and data remained confidential and anonymous. Collected data could only be accessed by the researcher and her supervisors.

CHAPTER 4

THE PILOT STUDY

4.1 Aims of the pilot study

A pilot study prior to the main study was conducted on fifteen participants from March to April 2001. The aims of the pilot study were:

1) to test out the feasibility of the data collection procedure;
2) to identify the effect size of the therapy for determining appropriate sample size for the main study;
3) to determine the interrater reliability index on the accuracy of the acupoint locations.

4.2 Method

4.2.1 Sampling

The criteria for recruiting participants for the pilot study were exactly the same as in the main study. Health talks on introducing auricular therapy were delivered to the clients in two hostels prior to the recruitment of participants. A total of 14 females (93%) and one male (7%) were recruited from two hostels for the elderly.

4.2.2 Procedures

A randomized controlled trial using pretest-posttest control group design was adopted. Fifteen eligible participants were randomly selected to receive auricular therapy using Junci Medulla [Group A: control group, *n*=5], Semen Vaccariae [Group B: control group, *n*=5] or magnetic pearls [Group C: experimental group, *n*=5].

Briefing sessions were organized for the participants by the researcher prior to the commencement of the study and written consents were sought. Each volunteer was asked to fill in a sleep questionnaire at the initial stage to provide information related to their usual sleep behaviours and factors related to sleep. The types of insomnia differentiated by traditional Chinese diagnosis were identified after assessment of the participant by an experienced TCM practitioner.

Participants were also randomly allocated to have the treatment commence on either left or right ear. Junci Medulla, Semen Vaccariae or magnetic pearls were applied to the most sensitive area of each selected auricular point detected by an electrical detector. Auricular points that were identical to those in the main study and were expected to have an effect on promoting sleep were selected. Both sides of the ears were treated alternately. The Junci Medulla / Semen Vaccariae / magnetic pearls were replaced every three to four days to avoid the possibility of local irritation of auricular points.

Similar to the treatment protocol in the main study, the treatment protocol consisted of three days of baseline measurement, three weeks of auricular therapy, and three days of post treatment monitoring. During the research process, an objective measurement using actigraphic monitoring was used within three days before the therapy commenced, three days during the therapy, and within three days after the therapy was completed. Briefing to the staff in the hostels was given so that they could understand how to fill in the sleep diary during the period when the participants received actigraphic monitoring.

4.3 Results

Since the number of participants is small in the pilot study, therefore only descriptive statistics were used to evaluate the therapeutic effect of the therapy.

4.3.1 Demographic characteristics and sleep behaviours of participants

The mean age of the participants was 81.33 (SD=5.05), and the average number of years residing in the hostels was 4.44 (SD=3.26). Generally, all participants in the pilot study reported having an acceptable (n=11) or good (n=4) health status. The duration of having insomnia among the participants in this study ranged from six months to 20 years. The average number of days/week of sleep disturbance was 5.47 (SD=1.87, mode=7), with 80% (n=12) of participants reporting that they had poor or very poor sleep.

4.3.2 Treatment effect evaluation

Before the therapy commenced, the differences in the sleep parameters among the three groups were minimal, except a slightly higher NBT, NSP, NST and WASO were observed in Group C (Table 4.1). During the therapy, participants in the experimental group demonstrated gradual improvement in their sleep in terms of NST and SE (Table 4.2). Further improvement in sleep of the experimental group compared with the two control groups could be seen when the therapy was completed (Table 4.3).

When the NST and SE before, during and after the therapy were compared for individual groups, significant improvement in these parameters could be observed in the experimental group during and after the therapy. It is interesting to note that even though a gradual improvement in NST in the experimental group was observed throughout the therapy (Table 4.4), the SE at the halfway and at the end of the treatment protocol show no difference (Table 4.5).

Among the fifteen participants, nine had insomnia due to 'excessive syndrome', while the cause for the remaining participants was 'deficiency syndrome' (Table 4.6). No participant in the pilot study demonstrated marked improvement in SE after the therapy, but participants (n=2) who showed moderate improvement in SE belonged to the experimental group, with one having treatment commencing on right ear, and the other one on the left (Table 4.7).

Table 4.1 Comparison of sleep parameters of the three groups before therapy in the pilot study.

	NBT (minute)	NSP (minute)	NST (minute)	S.L. (minute)	TWT (minute)	WASO (minute)	MSA (no.)	SE (%)
	mean (sd)	mean (sd)	mean (sd)	mean (sd)	mean (sd)	mean (sd)	mean (sd)	mean (sd)
Group A (Junci Medulla) (*n*=5)	518.60 (49.31)	485.60 (46.83)	394.40 (39.05)	30.80 (20.87)	124.20 (39.71)	81.20 (33.42)	16.60 (8.44)	76.00 (6.36)
Group B (Semen Vaccariae) (*n*=5)	545.20 (18.02)	515.80 (20.14)	413.40 (41.91)	23.00 (5.66)	131.80 (55.48)	102.40 (55.04)	16.80 (10.23)	75.80 (9.55)
Group C (Magnetic pearls) (*n*=5)	580.00 (17.22)	540.20 (15.48)	430.60 (25.49)	37.20 (23.27)	149.40 (36.02)	109.60 (28.95)	20.60 (5.59)	74.40 (5.68)

Sleep parameters (abbreviation):

NBT (Nocturnal bedtime), NSP (Nocturnal sleep period), NST (Nocturnal sleep time), SL (Sleep latency), TWT (Total wake time), WASO (Wake after sleep onset), MSA (Number of midsleep awakenings), SE (Sleep efficiency).

Table 4.2 Comparison of sleep parameters of the three groups during therapy in the pilot study.

	NBT (minute)	NSP (minute)	NST (minute)	S.L. (minute)	TWT (minute)	WASO (minute)	MSA (no.)	SE (%)
	mean (sd)	mean (sd)	mean (sd)	mean (sd)	mean (sd)	mean (sd)	mean (sd)	mean (sd)
Group A (Junci Medulla) (*n*=5)	541.00 (40.23)	509.40 (39.51)	390.60 (37.10)	21.20 (5.17)	150.40 (47.03)	118.80 (44.24)	25.80 (9.76)	72.40 (7.70)
Group B (Semen Vaccariae) (*n*=5)	550.60 (35.03)	507.60 (32.24)	415.40 (29.29)	29.80 (13.97)	120.00 (45.90)	91.40 (51.96)	20.60 (8.59)	75.60 (8.41)
Group C (Magnetic pearls) (*n*=5)	561.20 (30.87)	515.80 (36.34)	440.20 (42.98)	27.20 (10.11)	121.00 (24.83)	75.60 (33.19)	18.20 (7.79)	78.40 (4.83)

Sleep parameters (abbreviation): as shown in Table 4.1.

Table 4.3 Comparison of sleep parameters of the three groups after therapy in the pilot study.

	NBT (minute)	NSP (minute)	NST (minute)	S.L. (minute)	TWT (minute)	WASO (minute)	MSA (no.)	SE (%)
	mean (sd)	mean (sd)	mean (sd)	mean (sd)	mean (sd)	mean (sd)	mean (sd)	mean (sd)
Group A (Junci Medulla) (*n*=5)	548.60 (44.20)	514.40 (46.23)	386.60 (55.01)	21.00 (7.78)	162.00 (14.44)	127.80 (15.29)	28.80 (7.19)	70.20 (4.55)
Group B (Semen Vaccariae) (*n*=5)	556.80 (31.89)	513.80 (25.56)	409.60 (43.43)	22.40 (8.85)	147.20 (68.62)	104.00 (62.17)	22.20 (8.93)	74.00 (10.89)
Group C (Magnetic pearls) (*n*=5)	572.20 (51.95)	542.40 (42.05)	450.00 (70.33)	23.60 (14.17)	122.20 (33.63)	92.20 (46.85)	21.40 (5.37)	78.40 (7.02)

Sleep parameters (abbreviation): as shown in Table 4.1.

Table 4.4 Comparison of 'Nocturnal sleep time' (NST) (minutes) of the three groups before, during and after therapy in the pilot study.

	Before therapy	During therapy	After therapy
Group A (Junci Medulla) (*n*=5)	394.40 (39.05)	390.60 (37.10)	386.60 (55.01)
Group B (Semen Vaccariae) (*n*=5)	413.40 (41.91)	415.40 (29.29)	409.60 (43.43)
Group C (Magnetic pearls) (*n*=5)	430.60 (25.49)	440.20 (42.98)	450.00 (70.33)

Table 4.5 Comparison of 'Sleep efficiency' (SE) (%) of the three groups before, during and after therapy in the pilot study.

	Before therapy	During therapy	After therapy
Group A (Junci Medulla) (*n*=5)	76.00 (6.36)	72.40 (7.70)	70.20 (4.55)
Group B (Semen Vaccariae) (*n*=5)	75.80 (9.55)	75.60 (8.41)	74.00 (10.89)
Group C (Magnetic pearls) (*n*=5)	74.40 (5.68)	78.40 (4.83)	78.40 (7.02)

Table 4.6 Traditional Chinese diagnosis on insomnia of three groups of participants in the pilot study.

	Group A (Junci Medulla) (*n*=5)	Group B (Semen Vaccariae) (*n*=5)	Group C (Magnetic pearls) (*n*=5)	Total (*n*=15)
Insomnia due to 'Excessive syndrome'				
Liver *Qi*-stagnation turning into fire	2	1	3	6
Disturbance of stomach-*Qi*	0	2	1	3
Internal disturbance of phlegm-heat	0	0	0	0
Total	2	3	4	9
Insomnia due to 'Deficiency syndrome'				
Cardiac and splenic deficiency	1	1	0	2
Disharmony between the heart and kidneys	0	1	0	1
Qi-deficiency of the heart and gallbladder	2	0	1	3
Total	3	2	1	6

Table 4.7 Evaluation of therapeutic effects of participants' sleep efficiency (SE) (%) where treatment commenced on different ears in the pilot study.

		Group A (Junci Medulla) (*n*=5)	Group B (Semen Vaccariae) (*n*=5)	Group C (Magnetic pearls) (*n*=5)	Total (*n*=15)
Markedly effective (improved SE > 10%)	Right side	0	0	0	0
	Left side	0	0	0	0
Total		0	0	0	0
Moderately effective (improved SE 6%-10%)	Right side	0	0	1	1
	Left side	0	0	1	1
Total		0	0	2	2
Slightly effective (improved SE 1%-5%)	Right side	0	1	2	3
	Left side	1	1	0	2
Total		1	2	2	5
Ineffective (improved SE ≤ 0%)	Right side	2	2	0	4
	Left side	2	1	1	4
Total		4	3	1	8

4.4 Implications of the pilot study for the main study

4.4.1 Implications arising from the procedures and study results

The subjective and objective instruments that were used in this study were appropriate and no further modifications of the tools were made. The procedures of the research protocol were smooth. Some participants expressed having difficulty using the conventional straps to fasten the actigraphs on their wrists, therefore one-piece velcro wrist straps were also used in the main study for ease of manipulation.

Using a health talk in the hostels for the elderly seemed to be an effective way to recruit the participants. Support from the superintendents and the staff in the hostels was very positive, and it was estimated that an average of 7-10 participants could be recruited in each institution for the main study. In view of the relatively lower number of male participants in many hostels, it was also envisaged that not many males could be recruited into the study.

Although only descriptive statistics were used in the pilot study, the preliminary results showed that participants in the experimental group had demonstrated greater sleep improvement in terms of NST or SE than those in the control groups. It was decided that these two sleep parameters could serve as indicators of sleep improvement when the effectiveness of the therapy was evaluated in the main study. A longer follow up period of up to six months after completion of the therapy in the main study was

suggested for selected participants only if they demonstrated positive responses to the therapy in the experimental group and were willing to continue participating in the study, so that the long-term effects of the magnetic therapy could be monitored.

Due to the small sample size in the pilot study, the differences in the treatment effects for participants with diverse traditional Chinese diagnosis on insomnia, and with treatment commencing on different ears could not be identified. Therefore further analyses in the main study were to be undertaken in order to examine whether these variables were associated with the treatment effect.

4.4.2 Sample size determination

One of the purposes of the pilot study was to identify the effect size to determine a suitable sample size for the main study. Calculation of the effect size was based on the following formula (Portney & Watkins, 1993, p.655):

$$f = \frac{s_m}{s}$$

f = the effect size index

s_m = the standard deviation of the k sample means around the grand mean

s = the common standard deviation for each of the k distribution of scores

With equal sample sizes, the standard deviation of the means is given by:

$$s_m = \sqrt{\frac{\Sigma(\bar{X}_i - \bar{X}_G)^2}{k}}$$

where $(\bar{X}_i - \bar{X}_G)$ represents the deviation of each individual mean $(\bar{X}_i)$ from the grand mean $(\bar{X}_G)$.

The means of post sleep efficiency of the three groups were:

Group A = 70.20 (SD=4.55, variance=20.70)

Group B = 74.00 (SD=10.89, variance=118.50)

Group C = 78.40 (SD=7.02, variance=49.30)

Common SD (Pooled SD) = $\sqrt{(S_1^2 + S_2^2 + S_3^2)/3}$

$= \sqrt{(20.7+118.50+49.30)/3} \quad = 7.92$

The means of the three groups = 74.20; common standard deviation = 7.92

Therefore, $\sum(\overline{X}_i - \overline{X}_G)^2$ = (70.20-74.20)+(74.00-74.20)+(78.40-74.20)

= 33.68

$S_m = \sqrt{33.68 / 3} \quad = 3.35$

$f = 3.35 / 7.92 \quad = 0.42$

Since f (0.42) is close to the conventional large effect size value (f = 0.40) suggested by Cohen (Portney & Watkins, 1993, p.656), the sample size of the main study was calculated on the basis of a large effect size. It was decided that an effect size of f = 0.40 with 93% power at α_2 = .05 (Portney & Watkins, 1993, p.663) was taken. The sample size of each group should be 30. Since a larger sample size in the experimental group could facilitate the comparison of effects in people with diverse traditional Chinese diagnosis on insomnia, the final sample size for each group was as follows:

Group A = 30

Group B = 30

Group C = 60

Thus, the total number of participants in the main study was 120.

4.4.3 Interrater reliability on the location of acupoints

For the purpose of conducting this study using auricular therapy, the researcher completed a number of courses on complementary therapies (including auricular therapy) at outside institutions (Appendix 13). To ensure the accuracy of identification of acupoints by the researcher in the main study, the inter-rater reliability on the locations of acupoints between the President of the Auricular Acupuncture Association, Dr. Y.L. Yip, and the researcher was conducted on the participants (n=15) in the pilot study. An agreement of 99% was reached (Figure 4.1).

Figure 4.1 Inter-rater reliability on the identification of acupoints.

4.5 Summary

The aims of the pilot study were all satisfactorily achieved. The instruments being used in this study and the procedures for the treatment protocol were found to be appropriate. Preliminary findings from the pilot study also demonstrated that using magnetic pearls as auricular therapy had a better effect on sleep improvement than using Junci Medulla or Semen Vaccariae. However due to the limited sample size in the pilot study, no causal relationship could be established at this stage. The effect size of the therapy for sample size determination for the main study was calculated based on the findings of the pilot study, and it was decided that 120 participants were to be recruited into the main study. An interrater reliability index on the accuracy of the acupoint locations was conducted, and a high agreement index of 99% was reached.

CHAPTER 5

RESULTS OF THE MAIN STUDY (PART I)

This chapter contains the first part of the main study results, and focuses on reporting the socio-demographic characteristics and sleep behaviours of the participants (n=120) in twelve hostels for the elderly. All the data in the main study was collected from May 2000 to April 2001. Comparisons of the treatment effects on sleep among the three types of intervention were made. In addition, this chapter includes the analysis for evaluating the effectiveness of therapy in participants with different traditional Chinese diagnosis on insomnia.

5.1 Descriptions of characteristics of participants

As was determined by the pilot study, the total number of participants required by the main study should be 120 (Group A =30, Group B=30, Group C=60). The dropout rates were low: 18% in two control groups (n=11), and 13% in the experimental group (n=8). The reasons for withdrawal from the therapy were due to home leave (n=8), refusal to wear an actigraph as a monitoring device (n=3), admission to hospital (n=2), being treated for influenza (n=3) or unreported reasons (n=3). The participants who dropped out from the study were replaced until the estimated sample size was achieved, and 12 hostels for the elderly were

contacted for recruitment purposes.

All participants were from a Chinese origin. Overall, 92% of subjects were female (n=110) and 8% were male (n=10). The number of females outnumbered males in this study mainly because there were not many male residents in the majority of the hostels. It was also found that the male:female ratio (1:10) in this study was similar to the ratio of residents in most of the hostels participating in this study. The mean age of the participants was 81.66 (SD=5.80), and the average number of years they had resided in the hostels was 6.87 (SD=3.55).

Generally, the health status of the participants was relatively stable, with 96% of residents reported having good or acceptable health condition (Appendix 4, Q4). The most commonly reported disorders among them were diabetes mellitus and hypertension both under control by regular treatment in most cases. Only one out of 120 participants reported smoking, and none of them consumed alcohol. Half of them consumed caffeinated food/ drink daily (n=60), and many clients in the nursing homes consumed regular dairy products such as breakfast or bedtime snacks. The participants among the three groups have similar exercising level (mode=0.5 hrs). Sleep disturbance may be associated with emotional problems such as stress, depression and anxiety (Fordham, 1991; Hooyman & Kiyak, 1993), and thus these factors were examined. It was found that there was no notable difference among the participants in the

three groups in terms of their level of anxiety or depression. Details of the socio-demographic characteristics of the participants are displayed in Table 5.1.

Table 5.1 Socio-demographic characteristics of participants.

	Group A (Junci Medulla) (*n*=30)	Group B (Semen Vaccariae) (*n*=30)	Group C (Magnetic pearls) (*n*=60)	All Participants (*n*=120)
Gender				
Male	4 (13%)	3 (10%)	3 (5%)	10 (8%)
Female	26 (87%)	27 (90%)	57 (95%)	110 (92%)
Ethnicity				
Chinese	30 (100%)	30 (100%)	60 (100%)	120 (100%)
Age	79.63	81.90	82.55	81.66
mean (sd)	(5.22)	(5.37)	(6.11)	(5.80)
Health status				
Good	8 (27%)	10 (33%)	14 (23%)	32 (27%)
Acceptable	21 (70%)	17 (57%)	45 (75%)	83 (69%)
Poor	1 (3%)	3 (10%)	1 (2%)	5 (4%)
Years of residency in hostel Mean (sd)	6.70 (3.25)	7.00 (3.69)	6.67 (3.65)	6.87 (3.55)
Smoking				
Yes	0 (0%)	0 (0%)	1 (2%)	1 (1%)
No	30 (100%)	30 (100%)	59 (98%)	119 (99%)
Alcohol				
Yes	0 (0%)	0 (0%)	0 (0%)	0 (0%)
No	30 (100%)	30 (100%)	60 (100%)	120 (100%)
Caffeinated food/drink				
Yes	17 (57%)	14 (46%)	29 (48%)	60 (50%)
No	13 (43%)	16 (53%)	31 (52%)	60 (50%)

(To be continued)

(con't Table 5.1)

	Group A (Junci Medulla) (*n*=30)	Group B (Semen Vaccariae) (*n*=30)	Group C (Magnetic pearls) (*n*=60)	All Participants (*n*=120)
Dairy consumption				
Yes	21 (70%)	16 (53%)	42 (70%)	79 (66%)
No	9 (30%)	14 (47%)	18 (30%)	41 (34%)
Daily exercise				
Yes	28 (93%)	23 (77%)	53 (88%)	104 (87%)
No	2 (7%)	7 (23%)	7 (12%)	16 (13%)
Bedtime snack				
Yes	16 (53%)	13 (43%)	29 (48%)	58 (48%)
No	14 (47%)	17 (57%)	31 (52%)	62 (52%)
Worry/Anxiety in the last 6 months				
Yes	9 (30%)	11 (37%)	17 (28%)	31 (31%)
No	21 (70%)	19 (63%)	43 (72%)	83 (69%)
Bothered by depressed mood for the past couple of years				
Frequently	3 (10%)	5 (17%)	11 (18%)	19 (16%)
Sometimes	6 (20%)	7 (23%)	9 (15%)	22 (18%)
Rarely	2 (7%)	3 (10%)	6 (10%)	11 (9%)
Never	19 (63%)	15 (50%)	34 (57%)	68 (57%)

5.2 Sleep behaviours of participants

As detailed in the methods section (Chapter 3), volunteers were accepted into the study after a preliminary screening only if they reported sleeping poorly on at least three nights per week and if their insomnia had lasted for a minimum of six months. Participants were further screened by a typical cutoff score of sleep efficiency of 85% to determine whether they suffered from insomnia. The sleep behaviours of participants were subjectively reported by the clients using a sleep questionnaire (Appendix 4). The length of time the participants in this study had experienced insomnia ranged from six months to more than 20 years. The average number of days/week of sleep disturbance was 5.33 (SD=1.87), with 72% (n=86) of participants reporting that they had had poor or very poor sleep.

The usual bedtime for 85% (n=102) of the participants was between 7:30pm and 9:30pm. Though the majority of participants went to bed early, many reported having difficulty in falling asleep (mean minutes=144.60, SD=80.57). Even after falling asleep, many participants had frequent midsleep awakenings, possibly due to nocturia or unknown factors that exacerbate their sleep behaviours. Under these circumstances, many clients continued to rest in bed after toileting. The time for falling asleep again was usually long, and in 21% (n=25) of cases, it was impossible to sleep again once awoke.

The majority of the participants in the hostels rose early (mode: 6am), with an average of 1.19 hours (SD=1.08) remaining in bed from the time of final awakening before rising. Many clients felt tired and sleepy due to nocturnal sleep disturbance, and daytime sleep or dozing was common. Thirty-five percent of cases (*n*=42) reported having frequent or occasional headache/dizziness after rising (Table 5.2).

Table 5.2 Sleep behaviours of participants.

	Group A (Junci Medulla) (*n*=30)	Group B (Semen Vaccariae) (*n*=30)	Group C (Magnetic pearls) (*n*=60)	Total
Sleeping status at night				
Very good	0 (0%)	0 (0%)	0 (0%)	0 (0%)
Good	0 (0%)	0 (0%)	0 (0%)	0 (0%)
Acceptable	10 (33%)	13 (43%)	11 (18%)	34 (28%)
Poor	15 (50%)	13 (43%)	36 (60%)	64 (53%)
Very poor	5 (17%)	4 (14%)	13 (22%)	22 (19%)
Feeling upon arising				
Refreshed	0 (0%)	4 (13%)	2 (3%)	6 (5%)
Acceptable	3 (10%)	8 (27%)	14 (23%)	25 (21%)
Still tired	17 (57%)	10 (33%)	32 (54%)	59 (49%)
Sleepy	10 (33%)	8 (27%)	12 (20%)	30 (25%)
Years of having insomnia				
0-5 years	16 (53%)	18 (60%)	30 (50%)	64 (53%)
6-10 years	8 (27%)	7 (24%)	17 (29%)	32 (27%)
11-15 years	3 (10%)	1 (3%)	6 (11%)	10 (9%)
16-20 years	1 (3%)	3 (10%)	3 (5%)	7 (6%)
> 20 years	2 (7%)	1 (3%)	3 (5%)	6 (5%)
Factors that exacerbate sleep disturbance				
Go to toilet frequently	12 (40%)	14 (47%)	19 (32%)	45 (38%)
Too noisy	3 (10%)	0 (0%)	1 (2%)	4 (3%)
Physical discomfort	1 (3%)	1 (3%)	4 (6%)	6 (5%)
Don't know	12 (40%)	14 (47%)	33 (55%)	59 (49%)
Others	2 (7%)	1 (3%)	3 (5%)	6 (5%)

(To be continued)

(con'tTable 5.2)

	Group A (Junci Medulla) (*n*=30)	Group B (Semen Vaccariae) (*n*=30)	Group C (Magnetic pearls) (*n*=60)	Total
Time to fall asleep again after wake				
Fall asleep again immediately	0 (0%)	0 (0%)	1 (2%)	1 (1%)
A short period of time	0 (0%)	2 (7%)	4 (7%)	6 (5%)
A long period of time	6 (20%)	10 (33%)	18 (30%)	34 (28%)
A very long period of time	12 (40%)	9 (30%)	22 (36%)	43 (36%)
Once awake, can't fall asleep again	8 (27%)	6 (20%)	11 (18%)	25 (21%)
Don't know/No fixed mode	4 (13%)	3 (10%)	4 (7%)	11 (9%)
Things to do after midsleep awakenings				
Still rest on bed	1 (3%)	3 (10%)	6 (10%)	10 (8%)
Get up to do something till sleepy	1 (3%)	0 (0%)	3 (5%)	4 (3%)
Go to toilet, then rest on bed	28 (94%)	27 (90%)	50 (83%)	105 (88%)
Others	0 (0%)	0 (0%)	1 (2%)	1 (1%)
Feel headache/dizzy after arising	2 (7%)	4 (13%)	7 (12%)	13 (11%)
Most of the time	7 (23%)	3 (10%)	19 (32%)	29 (24%)
Yes, but not very frequent	21 (70%)	23 (77%)	34 (56%)	78 (65%)
No				
Dreams during sleep				
Frequently	4 (13%)	8 (27%)	16 (27%)	28 (23%)
Sometimes	12 (40%)	9 (30%)	10 (17%)	31 (26%)
Rarely	4 (13%)	3 (10%)	6 (10%)	13 (11%)
Never	10 (34%)	10 (33%)	28 (46%)	48 (40%)
Daytime sleep				
Frequently	8 (27%)	8 (27%)	20 (33%)	36 (30%)
Sometimes	5 (17%)	5 (17%)	6 (10%)	16 (13%)
Rarely	2 (6%)	3 (10%)	3 (5%)	8 (7%)
Never	15 (50%)	14 (46%)	31 (52%)	60 (50%)
Dozing during daytime				
Frequently	21 (70%)	12 (40%)	29 (48%)	62 (52%)
Sometimes	3 (10%)	8 (27%)	12 (20%)	23 (19%)
Rarely	4 (13%)	2 (6%)	5 (8%)	11 (9%)
Never	2 (7%)	8 (27%)	14 (24%)	24 (20%)
Pattern of dozing	(*n* =28)	(*n* =22)	(*n* =46)	(*n* =96)
A very short period of time	7 (25%)	3 (10%)	6 (13%)	16 (17%)
A short period of time	13 (46%)	15 (50%)	33 (71%)	60 (62%)
A long period of time	2 (7%)	1 (3%)	3 (7%)	7 (7%)
Don't know/No fixed mode	6 (22%)	5 (17%)	4 (9%)	13 (14%)

5.3 Measurement of sleep parameters.

Actigraphic monitoring was used as an objective measurement of sleep parameters in this study. The sleep parameters being measured by actigraphs included 'Nocturnal bedtime' (NBT), 'Nocturnal sleep period' (NSP), 'Nocturnal sleep time' (NST), 'Sleep latency' (SL), 'Total wake time' (TWT), 'Wake after sleep onset' (WASO), 'Number of midsleep awakenings' (MSA) and 'Sleep efficiency' (SE).

A discrepancy in certain sleep parameters which were collected before the commencement of the therapy was observed between actigraphic monitoring and those subjectively reported by all clients (n=120) in this study (Table 5.3). However the factors that cause the actigraph to overestimate or underestimate the sleep parameters are relatively consistent from one night to another. Therefore actigraphic monitoring is still a desirable measure in research when night-to-night variability of a change in the sleeping pattern of participants is monitored (Chambers, 1994; Hauri & Wisbey, 1992).

The distribution of data was examined by the plots using stem-and-leaf and by the Normality test. A low significance value ($p < 0.05$) in the Normality test means that the scores are not normally distributed (The Computing Services Centre, 1996, p.52). A low significance value ($p < 0.05$) is observed in the Normality test on several sleep parameters (SL, TWT, WASO and MSA) and the data were skewed. Since the logarithmic

transformation is used most often to normalize a skewed distribution (Portney & Watkins, 1993, p.670), the transformation of these variables was conducted. The transformed data rather than the original data were used in subsequent parametric analyses. The treatment effect was also evaluated by the change in either the 'Nocturnal sleep time' (NST) and/or the 'Sleep efficiency' (SE). It was expected that if the therapy was found to be effective, either NST or SE, or both parameters would be increased. The concurrent validity of these two indicators after the therapy was also established ($r=0.81$, $p<0.001$).

It is also possible that the effects of the therapy on the dependent variable was caused by Hawthorne effect due to the subjects awareness that they were participants under study (Polit & Hungler, 1997, p.458). Therefore whether the Hawthorne effect was present in this study was examined when the baseline of the sleep parameters in the three groups were compared to those after the therapy. It was found that a Hawthorne effect arising from the therapy occurred in around 10% ($n=13$) of all participants, because they stated that their sleep had improved although no evidence of improvement was shown in their SE or NST after the therapy.

Table 5.3 Discrepancy of sleep parameters between actigraphic findings and self report of 120 participants.

	Self report by participants Mean (sd)	Actigraphic findings Mean (sd)	Mean difference
Sleep latency (minutes)	144.60 (80.57)	25.16 (16.66)	119.44
Midsleep awakenings (number)	3.36 (1.79)	17.96 (6.32)	-14.6
Total sleep time (minutes)	191.25 (70.34)	402.03 (81.54)	-210.78

5.4 Treatment effect evaluation.

Before the therapy commenced, there were no significant differences in the sleep parameters (NBT, NSP, NST, SL, TWT, WASO, MSA, SE) among the three groups (Table 5.4). At the halfway of the 3-week therapy, participants in the experimental group demonstrated gradual improvement in their sleep, and significant differences among the groups could be found in TWT ($F_{2,117}$=4.03, p<0.05), WASO ($F_{2,117}$=3.72, p<0.05) and SE ($F_{2,117}$=3.70, p<0.05) (Table 5.5). Further improvement could be seen in the sleep of the experimental group when the 3-week therapy was completed, and significant differences in NST ($F_{2,117}$=6.84, p<0.001) and SE ($F_{2,117}$=9.58, p<0.001) were also recorded among the groups. Other parameters which also showed significant differences among the groups included SL, TWT, WASO and MSA. Indeed, further Bonferroni post-hoc analyses demonstrated that the experimental group had made significant improvement in these parameters when compared with the controls. However no significant differences in the sleep parameters as illustrated by the results of post-hoc analyses could be detected between the two control groups after the treatment course (Table 5.6).

The hypotheses of whether the sleep parameters had significant differences before, during, and after the 3-week therapy of individual groups were further tested by repeated measures analysis of variance (RANOVA) (Table 5.7 to Table 5.14). The degree of freedom of F ratio is evaluated by

Greenhouse-Geisser (G-G) as estimates of adjustment (epsilon), if Mauchly's test of sphericity is not assumed (p>0.05). Bonferroni multiple comparisons are given if the F ratio is statistically significant. Generally, the changes in the NBT and NSP among the three groups were not obvious before, during and after the therapy, except a gradual increase in NSP was found in the experimental group during the treatment period (Table 5.7 and Table 5.8). Significant differences before, during and after the 3-week therapy among the participants in the experimental group includes an increase in nocturnal sleep time (NST) ($F_{2,118}$=16.17, p<0.001) (Table 5.9), decrease in the time to fall asleep (SL) ($F_{2,118}$=6.81, p<0.01) (Table 5.10), decrease in wake up time in terms of TWT ($F_{2,118}$=18.81, p<0.001) and WASO ($F_{2,118}$=7.22, p<0.01) (Table 5.11 & Table 5.12), and sleep efficiency (SE) ($F_{2,118}$=27.50, p<0.001) (Table 5.14). Example of the actigraph data report of a participant receiving auricular therapy using magnetic pearls is displayed in Appendix 14. Gradual improvement in sleep could be seen in this participant as evidenced by an increase in the average SE (%) (64%, 71%, 73%) and average NST (minutes) (310, 343, 366) before, during and after the therapy (Appendix 14).

Though significant differences before, during and after the therapy could also be found in certain sleep parameters in the control groups, it could not be concluded that improvement in sleep had occurred. In some situations, the sleep behaviours after the therapy in the control groups were much worse compared with the conditions before the therapy had commenced

(Table 5.9, Table 5.11 & Table 5.14).

Alternate criteria for evaluation of therapeutic effects using the categories of markedly effective, moderately effective, slightly effective, and ineffective in NST or SE improvement were used (Table 5.15 & Table 5.16). The results indicated that there were no difference in the treatment effect between Group A and Group B. No participants in either groups demonstrated marked or moderate improvement in NST / SE after the therapy, and an equal number of participants in both groups demonstrated only slight improvement in their sleep (n=7), while some even found the treatment ineffective (n=23). On the other hand, 38% (n=23) participants in Group C showed marked or moderate improvement on these two parameters after the therapy.

Table 5.4 Comparison of sleep parameters of the three groups before the therapy.

	NBT (minute) mean (sd)	NSP (minute) mean (sd)	NST (minute) mean (sd)	S.L. (minute) mean (sd)	TWT (minute) mean (sd)	WASO (minute) mean (sd)	MSA (no.) mean (sd)	SE (%) mean (sd)
Group A (Junci Medulla)	572.90 (75.25)	517.17 (119.56)	404.73 (95.36)	25.47 (12.61)	166.67 (90.00)	130.13 (78.84)	19.40 (5.67)	71.23 (14.50)
Group B (Semen Vaccariae)	542.93 (74.44)	514.23 (72.84)	404.20 (75.92)	21.10 (10.63)	142.97 (85.48)	115.10 (79.21)	18.23 (7.52)	74.40 (12.49)
Group C (Magnetic pearls)	541.45 (78.20)	502.80 (74.25)	399.58 (78.08)	27.03 (20.35)	141.92 (76.90)	103.42 (57.13)	17.10 (6.00)	74.33 (11.97)
One-way ANOVA: $F_{2,117}$ (p value)	1.84 (p=0.16)	0.34 (p=0.72)	0.05 (p=0.95)	*1.06 (p=0.35)	*1.53 (p=0.22)	*1.95 (p=0.15)	*1.68 (p=0.72)	0.67 (p=0.51)

* calculation based on variables after logarithmic transformation.

Sleep parameters (abbreviation):

NBT (Nocturnal bedtime), NSP (Nocturnal sleep period), NST (Nocturnal sleep time), SL (Sleep latency), TWT (Total wake time), WASO (Wake after sleep onset), MSA (Number of midsleep awakenings), SE (Sleep efficiency).

Table 5.5 Comparison of sleep parameters of the three groups during therapy.

	NBT (minute)	NSP (minute)	NST (minute)	S.L. (minute)	TWT (minute)	WASO (minute)	MSA (no.)	SE (%)
	mean (sd)	mean (sd)	mean (sd)	mean (sd)	mean (sd)	mean (sd)	mean (sd)	mean (sd)
Group A (Junci Medulla)	564.50 (58.77)	532.03 (54.02)	395.03 (94.75)	26.73 (20.44)	169.37 (89.17)	134.47 (80.87)	20.70 (7.69)	70.23 (15.75)
Group B (Semen Vaccariae)	553.00 (54.55)	511.77 (59.18)	391.07 (76.68)	28.17 (14.81)	164.67 (87.95)	124.30 (78.23)	19.07 (7.69)	70.87 (13.36)
Group C (Magnetic pearls)	551.57 (73.72)	521.50 (74.45)	421.53 (71.70)	21.60 (20.64)	130.05 (70.43)	100.72 (57.31)	17.48 (5.54)	76.85 (10.52)
One-way ANOVA: $F_{2,117}$ (p value)	0.41 (p=0.67)	0.70 (p=0.50)	1.96 (p=0.15)	*3.18 (p=0.05)	*4.03 (p<0.05)	*3.72 (p<0.05)	*2.03 (p=0.14)	3.70 (p<0.05)
Bonferroni post-hoc analyses								
(Gp C & Gp A) p-value	---	---	---	0.42	0.06	<0.05	---	0.07
(Gp C & Gp B) p-value	---	---	---	0.05	0.08	0.25	---	0.11
(Gp A & Gp B) p-value	---	---	---	1.00	1.00	1.00	---	1.00

* calculation based on variables after logarithmic transformation.

Sleep parameters (abbreviation): as shown in Table 5.4

Table 5.6 Comparison of sleep parameters of the three groups after therapy.

	NBT (minute)	NSP (minute)	NST (minute)	S.L. (minute)	TWT (minute)	WASO (minute)	MSA (no.)	SE (%)
	mean (sd)	mean (sd)	mean (sd)	mean (sd)	mean (sd)	mean (sd)	mean (sd)	mean (sd)
Group A (Junci Medulla)	565.63 (59.78)	525.33 (55.05)	381.80 (86.56)	26.83 (14.99)	184.93 (90.74)	144.60 (76.07)	21.80 (7.29)	67.73 (15.04)
Group B (Semen Vaccariae)	546.23 (58.08)	514.20 (56.16)	387.20 (70.66)	21.47 (8.71)	159.13 (83.13)	127.30 (78.50)	19.27 (6.64)	71.63 (12.97)
Group C (Magnetic pearls)	550.83 (62.20)	524.17 (59.62)	434.50 (70.99)	19.42 (14.54)	116.18 (68.68)	89.62 (54.79)	16.55 (4.74)	79.28 (10.77)
One-way ANOVA: $F_{2,117}$ (p value)	0.88 (p=0.42)	0.37 (p=0.69)	6.84 (p<0.01)	*5.05 (p<0.01)	*11.96 (p<0.001)	*10.71 (p<0.001)	*6.46 (p<0.01)	9.58 (p<0.001)
Bonferroni post-hoc analyses								
(Gp C & Gp A) p-value	---	---	<0.01	<0.01	<0.001	<0.001	<0.01	<0.001
(Gp C & Gp B) p-value	---	---	<0.05	0.24	<0.01	<0.01	0.19	<0.05
(Gp A & Gp B) p-value	---	---	1.00	0.78	0.67	0.97	0.47	0.69

* calculation based on variables after logarithmic transformation.

Sleep parameters (abbreviation): as shown in Table 5.4

Table 5.7 Comparison of 'Nocturnal bedtime' (NBT) (minutes) of the three groups before, during and after therapy (Using RANOVA).

	Before therapy	During therapy	After therapy	Within-subject effects using F value (*p* value)	Sphericity test (df)
Group A (Junci Medulla) (*n*=30)	572.90 (75.25)	564.50 (58.77)	565.63 (59.78)	0.42 (*p*=0.66)	Mauchly's W (df=2, 58)
Group B (Semen Vaccariae) (*n*=30)	542.93 (74.44)	553.00 (54.55)	546.23 (58.08)	0.62 (*p*=0.54)	Mauchly's W (df=2, 58)
Group C (Magnetic pearls) (*n*=60)	541.45 (78.20)	551.57 (73.72)	550.83 (62.20)	1.27 (*p*=0.28)	Mauchly's W (df=2, 118)

Table 5.8 Comparison of 'Nocturnal sleep period' (NSP) (minutes) of the three groups before, during and after therapy (Using RANOVA).

	Before therapy (1) mean (sd)	During therapy (2) mean (sd)	After therapy (3) mean (sd)	Within-subject effects F value (p value)	∂ Sphericity test (df)
Group A (Junci Medulla) (n=30)	517.17 (119.56)	532.03 (54.02)	525.33 (55.05)	0.36 (p=0.61)	G-G (df=1.30, 37.77)
Group B (Semen Vaccariae) (n=30)	514.23 (72.84)	511.77 (59.18)	514.20 (56.16)	0.05 (p=0.96)	Mauchly's W (df=2, 58)
Group C (Magnetic pearls) (n=60)	502.80 (74.25)	521.50 (74.45)	524.17 (59.62)	4.97 (p<0.01) φ	Mauchly's W (df=2, 118)
	Bonferroni multiple comparisons Mean difference: (3) – (1) 21.37 (p<0.05) (3) – (2) 2.67 (p=1.000) (2) – (1) 18.70 (p<0.05)				

φ Bonferroni multiple comparisons are given for statistically significant F ratio.

∂ degree of freedom of F ratio is evaluated by Greenhouse-Geisser (G-G) as estimates of adjustment (epsilon), if Mauchly's test of sphericity is not assumed.

Table 5.9 Comparison of 'Nocturnal sleep time' (NST) (minutes) of the three groups before, during and after therapy (Using RANOVA).

	Before therapy (1) mean (sd)	During therapy (2) mean (sd)	After therapy (3) mean (sd)	Within-subject effects F value (p value)	∂ Sphericity test (df)
Group A (Junci Medulla) (n=30)	404.73 (95.36)	395.03 (94.75)	381.80 (86.56)	4.53 (p<0.05) φ	G-G (df=1.51, 43.69)
	Bonferroni multiple comparisons Mean difference: (3) – (1) -22.93 (p<0.05) (3) – (2) -13.23 (p=0.38) (2) – (1) -9.70 (p=0.22)				
Group B (Semen Vaccariae) (n=30)	404.20 (75.92)	391.07 (76.68)	387.20 (70.66)	2.17 (p=0.12)	Mauchly's W (df=2, 58)
Group C (Magnetic pearls) (n=60)	399.58 (78.08)	421.53 (71.70)	434.50 (70.99)	16.17 (p<0.001) φ	Mauchly's W (df=2, 118)
	Bonferroni multiple comparisons Mean difference: (3) – (1) 34.92 (p<0.001) (3)– (2) 12.97 (p=0.15) (2) – (1) 21.95 (p<0.001)				

φ Bonferroni multiple comparisons are given for statistically significant F ratio.

∂ degree of freedom of F ratio is evaluated by Greenhouse-Geisser (G-G) as estimates of adjustment (epsilon), if Mauchly's test of sphericity is not assumed.

Table 5.10 Comparison of 'Sleep latency' (SL)* (minutes) of the three groups before, during and after therapy (Using RANOVA).

		Before therapy (1) mean (sd)	During therapy (2) mean (sd)	After therapy (3) mean (sd)	Within-subject effects F value (*p* value)	Sphericity test (df)
Group A (Junci Medulla) (*n*=30)	A	25.47 (12.61)	26.73 (20.44)	26.83 (14.99)	0.27 (*p*=0.76)	Mauchly's W (df=2, 58)
	B	3.13 (0.46)	3.08 (0.65)	3.15 (0.54)		
Group B (Semen Vaccariae) (*n*=30)	A	21.10 (10.63)	28.17 (14.81)	21.47 (8.71)	2.99 (*p*=0.06)	Mauchly's W (df=2, 58)
	B	2.93 (0.51)	3.20 (0.55)	2.99 (0.39)		
Group C (Magnetic pearls) (*n*=60)	A	27.03 (20.35)	21.60 (20.64)	19.42 (14.54)	6.81 (*p*<0.01) φ	Mauchly's W (df=2, 118)
	B	3.08 (0.66)	2.89 (0.55)	2.78 (0.58)		
		Bonferroni multiple comparisons Mean difference: (3) – (1) -7.61 (*p*=0.05) (3) – (2) -2.18 (*p*=0.40) (2) – (1) -5.43 (*p*=0.11)				

* calculation based on variables after logarithmic transformation.

φ Bonferroni multiple comparisons are given for statistically significant F ratio.

A = original scores of SL (mean & sd)

B = logarithmic scores of SL (mean & sd)

Table 5.11 Comparison of 'Total wake time' (TWT)* (minutes) of the three groups before, during and after therapy (Using RANOVA).

		Before therapy (1) mean (sd)	During therapy (2) mean (sd)	After therapy (3) mean (sd)	Within-subject effects F value (p value)	∂ Sphericity test (df)
Group A (Junci Medulla) (n=30)	A	166.67 (90.00)	169.37 (89.17)	184.93 (90.74)	3.56 (p=0.04) φ	Mauchly's W (df=2, 58)
	B	5.01 (0.44)	5.01 (0.51)	5.12 (0.46)		
	Bonferroni multiple comparisons Mean difference: (3) – (1) 18.26 (p=0.07) (3) – (2) 15.56 (p=0.05) (1) – (2) 2.70 (p=1.00)					
Group B (Semen Vaccariae) (n=30)	A	142.97 (85.48)	164.67 (87.95)	159.13 (83.13)	4.72 (p<0.05) φ	G-G (df=1.63, 47.13)
	B	4.84 (0.47)	5.00 (0.46)	4.96 (0.46)		
	Bonferroni multiple comparisons Mean difference: (3) – (1) 16.16 (p<0.05) (3) – (2) -5.54 (p=1.000) (1) – (2) 21.70 (p<0.05)					
Group C (Magnetic pearls) (n=60)	A	141.92 (76.90)	130.05 (70.43)	116.18 (68.68)	18.81 (p<0.001) φ	Mauchly's W (df=2, 118)
	B	4.84 (0.46)	4.76 (0.44)	4.62 (0.51)		
	Bonferroni multiple comparisons Mean difference: (3) – (1) -25.74 (p<0.001) (3) – (2) -13.87 (p<0.01) (1) – (2)-11.87 (p<0.05)					

* calculation based on variables after logarithmic transformation.

φ Bonferroni multiple comparisons are given for statistically significant F ratio.

A = original scores of TWT (mean & sd)

B = logarithmic scores of TWT (mean & sd)

∂ degree of freedom of F ratio is evaluated by Greenhouse-Geisser (G-G) as estimates of adjustment (epsilon), if Mauchly's test of sphericity is not assumed.

Table 5.12 Comparison of the 'Wake after sleep onset' (WASO)* (minutes) of the three groups before, during and after therapy (Using RANOVA).

		Before therapy (1) mean (sd)	During therapy (2) mean (sd)	After therapy (3) mean (sd)	Within-subject effects F value (*p* value)	Sphericity test (df)
Group A (Junci Medulla) (*n*=30)	A	130.13 (78.84)	134.47 (80.87)	144.60 (76.07)	1.84 (*p*=0.17)	Mauchly's W (df=2, 58)
	B	4.73 (0.50)	4.78 (0.55)	4.85 (0.50)		
Group B (Semen Vaccariae) (*n*=30)	A	115.10 (79.21)	124.30 (78.23)	127.30 (78.50)	2.12 (*p*=0.13)	Mauchly's W (df=2, 58)
	B	4.60 (0.52)	4.68 (0.52)	4.71 (0.50)		
Group C (Magnetic pearls) (*n*=60)	A	103.42 (57.13)	100.72 (57.31)	89.62 (54.79)	7.22 (*p*<0.01) φ	Mauchly's W (df=2, 118)
	B	4.51 (0.50)	4.48 (0.51)	4.33 (0.58)		

Bonferroni multiple comparisons
Mean difference: (3) – (1) -13.80 (*p*<0.01)
(3) – (2) -11.10 (*p*<0.05)
(1) – (2) -2.70 (*p*=1.00)

* calculation based on variables after logarithmic transformation.

φ Bonferroni multiple comparisons are given for statistically significant F ratio.

A = original scores of WASO (mean & sd)

B = logarithmic scores of WASO (mean & sd)

Table 5.13 Comparison of 'Number of midsleep awakenings' (MSA)* (number) of the three groups before, during and after therapy (Using RANOVA).

		Before therapy mean (sd)	During therapy mean (sd)	After therapy mean (sd)	Within-subject effects F value (p value)	∂ Sphericity test (df)
Group A (Junci Medulla) (n=30)	A	19.40 (5.67)	20.70 (7.69)	21.80 (7.29)	1.15 (p=0.32)	Mauchly's W (df=2, 58)
	B	2.92 (0.29)	2.97 (0.36)	3.03 (0.35)		
Group B (Semen Vaccariae) (n=30)	A	18.23 (7.52)	19.07 (7.69)	19.27 (6.64)	1.19 (p=0.31)	Mauchly's W (df=2, 58)
	B	2.82 (0.40)	2.88 (0.38)	2.90 (0.35)		
Group C (Magnetic pearls) (n=60)	A	17.10 (6)	17.48 (5.54)	16.55 (4.74)	0.66 (p=0.51)	G-G (df=1.82, 107.28)
	B	2.77 (0.40)	2.81 (0.33)	2.76 (0.33)		

* calculation based on variables after logarithmic transformation.

A = original scores of MSA (mean & sd)

B = logarithmic scores of MSA (mean & sd)

∂ degree of freedom of F ratio is evaluated by Greenhouse-Geisser (G-G) as estimates of adjustment (epsilon), if Mauchly's test of sphericity is not assumed.

Table 5.14 Comparison of 'Sleep efficiency' (SE) (%) of the three groups before, during and after therapy (Using RANOVA).

	Before therapy (1) mean (sd)	During therapy (2) mean (sd)	After therapy (3) mean (sd)	Within-subject effects F value (p value)	☙ Sphericity test (df)
Group A (Junci Medulla) (n=30)	71.23 (14.50)	70.23 (15.75)	67.73 (15.04)	7.56 (p<0.01) φ	Mauchly's W (df=2, 58)
	Bonferroni multiple comparisons Mean difference: (3) – (1) -3.50 (p<0.01) (3) – (2) -2.50 (p<0.05) (1) – (2) -1.00 (p=0.78)				
Group B (Semen Vaccariae) (n=30)	74.40 (12.49)	70.87 (13.36)	71.63 (12.97)	5.32 (p<0.05) φ	G-G (df=1.60, 46.25)
	Bonferroni multiple comparisons Mean difference: (3) – (1) -2.77 (p<0.01) (3) – (2) 0.76 (p=1.000) (1) – (2) -3.53 (p<0.05)				
Group C (Magnetic pearls) (n=60)	74.33 (11.97)	76.85 (10.52)	79.28 (10.77)	27.50 (p<0.001) φ	Mauchly's W (df=2, 118)
	Bonferroni multiple comparisons Mean difference: (3) – (1) 4.95 (p<0.001) (3) – (2) 2.43 (p<0.01) (1) – (2) 2.52 (p<0.001)				

φ Bonferroni multiple comparisons are given for statistically significant F ratio.

☙ degree of freedom of F ratio is evaluated by Greenhouse-Geisser (G-G) as estimates of adjustment (epsilon), if Mauchly's test of sphericity is not assumed.

Table 5.15 Evaluation of therapeutic effects in terms of improvement in nocturnal sleep time (NST) (minutes) after therapy.

	Group A (Junci Medulla) (*n*=30)	Group B (Semen Vaccariae) (*n*=30)	Group C (Magnetic pearls) (*n*=60)	Total
Markedly effective (improved NST > 10%)	0 (0%)	0 (0%)	8 (13%)	8 (7%)
Moderately effective (improved NST 6%-10%)	0 (0%)	0 (0%)	15 (25%)	15 (13%)
Slightly effective (improved NST 1%-5%)	7 (23%)	7 (23%)	26 (43%)	40 (33%)
Ineffective (improved NST ≤ 0%)	23 (77%)	23 (77%)	11 (18%)	57 (48%)
Total (% within grouping)	30 (100%)	30 (100%)	60 (100%)	120 (100%)

Table 5.16 Evaluation of therapeutic effects in terms of improvement in sleep efficiency (SE) (%) after therapy.

	Group A (Junci Medulla) (*n*=30)	Group B (Semen Vaccariae) (*n*=30)	Group C (Magnetic pearls) (*n*=60)	Total
Markedly effective (improved SE > 10%)	0 (0%)	0 (0%)	10 (17%)	10 (8%)
Moderately effective (improved SE 6%-10%)	0 (0%)	0 (0%)	13 (22%)	13 (11%)
Slightly effective (improved SE 1%-5%)	7 (23%)	7 (23%)	26 (43%)	40 (33%)
Ineffective (improved SE ≤ 0%)	23 (77%)	23 (77%)	11 (18%)	57 (48%)
Total (% within grouping)	30 (100%)	30 (100%)	60 (100%)	120 (100%)

5.5 Effectiveness of therapy in clients with different traditional Chinese diagnosis on insomnia.

A similar number of cases with insomnia due to 'excessive syndrome' (n=59) and 'deficiency syndrome' (n=61) enrolled in this study (Table 5.17). Insomnia due to 'excessive syndrome' includes 'Liver *Qi*-stagnation turning into fire', 'Disturbance of stomach-*Qi*', or 'Internal disturbance of phlegm-heat'; while the reasons for insomnia due to 'deficiency syndrome' pertains to 'Cardiac and splenic deficiency', 'Disharmony between the heart and kidneys' or '*Qi*-deficiency of the heart and gallbladder'.

Participants (n=10) who demonstrated marked improvement in sleep efficiency all belong to Group C, with an equal number of participants having either 'excessive' or 'deficiency' syndrome (Table 5.18). The information illustrating the distribution of participants with different traditional Chinese diagnosis on insomnia and their therapeutic effects measured by sleep efficiency (SE) is displayed in Table 5.19.

When the therapeutic effect was evaluated in the experimental group, no significant difference in the effect of the therapy in terms of SE could be observed between clients with 'excessive' and 'deficiency' syndrome even when the treatment protocol was standardized (t_{58}=-0.41, p=0.69) (Table 5.20), and a detailed breakdown of the treatment effect in participants with different traditional Chinese diagnosis on insomnia is shown in Table 5.21.

The auricular therapy not only improved the sleep behaviours of the participants in this study, but also demonstrated its effectiveness in treating certain minor ailments in some cases. Several positive effects were reported especially by participants in the experimental group (Table 5.22). Alternate effects included improvement in appetite (n=21), alleviation of the condition of headache/dizziness (n=19), decrease in the frequency of nocturnal polyuria (n=4) and calming of mind (n=2). In some cases, improvement in more than one area mentioned above could be observed. Adverse effects arising from the therapy were unusual, about 36.7% (n=44) of participants reported having a certain degree of itchiness on their auricles induced by the plastic tapes that adhered on the acupoints.

Table 5.17 Traditional Chinese diagnosis on insomnia of three groups of participants.

	Group A (Junci Medulla) (*n*=30)	Group B (Semen Vaccariae) (*n*=30)	Group C (Magnetic pearls) (*n*=60)	Total
Insomnia due to 'Excessive syndrome'				
Liver *Qi*-stagnation turning into fire	4 (33%)	5 (33%)	10 (31%)	19 (32%)
Disturbance of stomach-*Qi*	5 (42%)	8 (53%)	17 (53%)	30 (51%)
Internal disturbance of phlegm-heat	3 (25%)	2 (14%)	5 (16%)	10 (17%)
Total (% within grouping)	12 (100%)	15 (100%)	32 (100%)	59 (100%)
Insomnia due to 'Deficiency syndrome'				
Cardiac and splenic deficiency	4 (22%)	4 (27%)	11 (39%)	19 (31%)
Disharmony between the heart and kidneys	8 (45%)	6 (40%)	11 (39%)	25 (41%)
Qi-deficiency of the heart and gallbladder	6 (33%)	5 (33%)	6 (22%)	17 (28%)
Total (% within grouping)	18 (100%)	15 (100%)	28 (100%)	61 (100%)

Table 5.18 Evaluation of therapeutic effects of sleep efficiency (SE) (%) of participants with insomnia due to excessive/deficiency syndrome.

		Group A (Junci Medulla) (*n*=30)	Group B (Semen Vaccariae) (*n*=30)	Group C (Magnetic pearls) (*n*=60)	Total (*n*=120)
Markedly effective (improved SE > 10%)	Excessive syndrome	0 (0%)	0 (0%)	5 (50%)	5 (50%)
	Deficiency syndrome	0 (0%)	0 (0%)	5 (50%)	5 (50%)
Total (% within grouping)		0 (0%)	0 (0%)	10 (100%)	10 (100%)
Moderately effective (improved SE 6%-10%)	Excessive syndrome	0 (0%)	0 (0%)	5 (38.5%)	5 (38.5%)
	Deficiency syndrome	0 (0%)	0 (0%)	8 (61.5%)	8 (61.5%)
Total (% within grouping)		0 (0%)	0 (0%)	13 (100%)	13 (100%)
Slightly effective (improved SE 1%-5%)	Excessive syndrome	6 (85.7%)	4 (57.1%)	16 (61.5%)	26 (65%)
	Deficiency syndrome	1 (14.3%)	3 (42.9%)	10 (38.5%)	14 (35%)
Total (% within grouping)		7 (100%)	7 (100%)	26 (100%)	40 (100%)
Ineffective (improved SE ≤ 0%)	Excessive syndrome	6 (26.1%)	11 (47.8%)	6 (54.5%)	23 (40.4%)
	Deficiency syndrome	17 (73.9%)	12 (53.2%)	5 (45.5%)	34 (59.6%)
Total (% within grouping)		23 (100%)	23 (100%)	11 (100%)	57 (100%)

Table 5.19 Evaluation of therapeutic effects of sleep efficiency (SE) (%) of participants with different traditional Chinese diagnosis on insomnia.

		Group A (Junci Medulla) (*n*=30)	Group B (Semen Vaccariae) (*n*=30)	Group C (Magnetic pearls) (*n*=60)	Total (*n*=120)
Markedly effective (improved SE > 10%)	Dx 1	0	0	1	10
	Dx 2	0	0	3	
	Dx 3	0	0	1	
	Dx 4	0	0	1	
	Dx 5	0	0	4	
	Dx 6	0	0	0	
Moderately effective (improved SE 6%-10%)	Dx 1	0	0	2	13
	Dx 2	0	0	2	
	Dx 3	0	0	1	
	Dx 4	0	0	4	
	Dx 5	0	0	2	
	Dx 6	0	0	2	
Slightly effective (improved SE 1%-5%)	Dx 1	2	1	5	40
	Dx 2	4	2	9	
	Dx 3	0	1	2	
	Dx 4	0	1	5	
	Dx 5	1	1	3	
	Dx 6	0	1	2	
Ineffective (improved SE ≤ 0%)	Dx 1	2	4	2	57
	Dx 2	1	6	3	
	Dx 3	3	1	1	
	Dx 4	4	3	1	
	Dx 5	7	5	2	
	Dx 6	6	4	2	

Dx 1 = Liver *Qi*-stagnation turning into fire

Dx 2 = Disturbance of stomach-*Qi*

Dx 3 = Internal disturbance of phlegm-heat

Dx 4 = Cardiac and splenic deficiency

Dx 5 = Disharmony between the heart and kidneys

Dx 6 = *Qi*-deficiency of the heart and gallbladder

Dx 1, Dx 2 and Dx 3 belong to insomnia due to 'Excessive syndrome'.

Dx 4, Dx 5 and Dx 6 belong to insomnia due to 'Deficiency syndrome'.

Table 5.20 Testing the difference between the means of sleep efficiency (SE) (%) of experimental group participants with insomnia due to excessive/deficiency syndrome.

Variable	*n*	SE Mean (sd)	Mean difference in SE	*t*-test (*df*) *p* value
TCM Dx				
Excessive syndrome	32	78.75 (9.83)	1.14	t_{58}=-0.41, *p*=0.69
Deficiency syndrome	28	79.89 (11.90)		

Table 5.21 Evaluation of therapeutic effects of sleep efficiency (SE) (%) of experimental group participants with different traditional Chinese diagnosis on insomnia.

	Dx 1	Dx 2	Dx 3	Dx 4	Dx 5	Dx 6	Total (*n*=60)
Markedly effective (improved SE > 10%)	1	3	1	1	4	0	10
Moderately effective (improved SE 6%-10%)	2	2	1	4	2	2	13
Slightly effective (improved SE 1%-5%)	5	9	2	5	3	2	26
Ineffective (improved SE ≤ 0%)	2	3	1	1	2	2	11
Total	10	17	5	11	11	6	60

Dx 1 = Liver *Qi*-stagnation turning into fire

Dx 2 = Disturbance of stomach-*Qi*

Dx 3 = Internal disturbance of phlegm-heat

Dx 4 = Cardiac and splenic deficiency

Dx 5 = Disharmony between the heart and kidneys

Dx 6 = *Qi*-deficiency of the heart and gallbladder

Dx 1, Dx 2 and Dx 3 belong to insomnia due to 'Excessive syndrome'.

Dx 4, Dx 5 and Dx 6 belong to insomnia due to 'Deficiency syndrome'.

Table 5.22 Other therapeutic effects arising from the auricular therapy.

	Group A (Junci Medulla) (*n*=30)	Group B (Semen Vaccariae) (*n*=30)	Group C (Magnetic pearls) (*n*=60)	Total
Improvement in appetite	0	0	14	14
Alleviate headache/dizziness	1	0	12	13
Decreased nocturnal polyuria	1	0	4	5
Calming of mind	0	0	2	2
Improvement in appetite & alleviate headache/dizziness	0	0	7	7

5.6 Conclusion

One hundred and twenty participants from 12 hostels for the elderly were recruited into the main study. After the auricular therapy had been administered for the three groups, participants in the experimental group demonstrated gradual improvement in their sleep during the period of therapy. Improvement in the sleep of the experimental group in comparison with the two control groups could also be seen when the therapy was completed. Further Bonferroni post-hoc analyses demonstrated that the experimental group had significant improvement in NST, SL, TWT, WASO, MSA and SE when compared with the controls. However no significant improvement on sleep could be observed in the two control groups, and no differences in the sleep parameters could be detected between the two groups as well.

The hypotheses whether the sleep parameters have significant differences before, during, and after the therapy of individual groups were further tested by RANOVA. Significant improvement in certain sleep parameters, including NST, SL, TWT, WASO and SE, could be found in the experimental group during and after the therapy.

The effectiveness of therapy in participants having different traditional Chinese diagnosis on insomnia was evaluated. No significant differences in the effects of the therapy in terms of SE could be observed between clients with 'excessive' and 'deficiency' syndrome even when the treatment

protocol was standardized among the experimental group participants. Auricular therapy using magnetic pearls not only improved the sleep behaviours of the participants in this study, but also demonstrated its effectiveness in treating certain minor ailments as self reported by the subjects in this study, including improvement in appetite, alleviation of headache/dizziness, decrease in the frequency of nocturnal polyuria, and calming of mind.

CHAPTER 6

RESULTS OF THE MAIN STUDY (PART II)

The second part of the results are reported in this chapter in which the relationship between the therapeutic effects in the experimental group and other variables such as age group, gender, number of years of having suffered from insomnia, or side of the ears where treatment commenced were explored. The long-term effect of auricular therapy using magnetic pearls was evaluated for 15 selected cases at 1-month, 3-month and 6-month intervals after the treatment course. Multiple regression analyses were also conducted to evaluate the effectiveness of the therapy among the female participants in this study.

6.1 Effectiveness of auricular therapy in the experimental group.

About 90% (n=54) of the participants in the experimental group (Group C) receiving magnetic pearls as auricular therapy expressed having slight to great improvement in their sleep after the therapy.

There was no significant difference in the NST or SE between participants in (a) different age groups (60-80, and 81-100) (t_{58}=1.43, p=0.16), (b)

having suffered from insomnia for a different number of years (0-10, 11 or above) (t_{58}=0.87, p=0.39), or (c) having treatment commencing on either side of the ears (t_{58}=-0.57, p=0.57) (Table 6.1 & Table 6.2). Though there were only three male participants enrolled into the experimental group, they all demonstrated marked improvement in both NST and SE after the therapy (Table 6.3 & 6.4).

The long-term effect of auricular therapy using magnetic pearls was evaluated when selected cases (n=15) who showed positive effects after the treatment and were willing to continue participating in the study were followed up at 1-month, 3-month and 6-month intervals after the therapy. Results of RANOVA have demonstrated that there were significant differences of NST among the six time intervals ($F_{2.66,\ 34.60}$=3.42, p<0.05). Therapeutic effects in terms of NST and SE in the majority of the cases could be sustained even at three months or six months after the therapy (Table 6.5 & Table 6.6). When the sleep parameters at the baseline (i.e. before the therapy) were compared to different intervals, the peak NST mean difference was noted at three months (t_{14} = -2.50, p<0.05) (Table 6.7); and the peak SE mean difference was observed immediately after the treatment period (t_{14} = -4.86, p<0.001) (Table 6.8).

When reviewing the plots of NST means and SE means at six time intervals, the NST means peaked at three months after the therapy; while the SE mean reached its peak immediately after the treatment period. Although a

gradual decrease of SE was observed at 3-month and 6-month intervals, the average sleep efficiencies at these periods were still higher than the mean SE at the baseline period (Figure 6.1 and Figure 6.2).

Table 6.1 Evaluation of therapeutic effects of nocturnal sleep time (NST) (minutes) in experimental group participants in different age groups, different number of years of insomnia, and different side of ear where treatment commenced.

Variables	*n*	NST Mean (sd)	Mean difference in NST	*t*-test (*df*) *p* value
Age group				
60-80	20	452.90 (66.84)	27.60	t_{58}=1.43, *p*=0.16
81-100	40	425.30 (72.02)		
Number of years of insomnia				
0-10	48	438.48 (73.79)	19.90	t_{58}=0.87, *p*=0.39
11 or above	12	418.58 (58.44)		
Side of ear				
Right	30	429.27 (74.39)	-10.47	t_{58}=-0.57, *p*=0.57
Left	30	439.73 (68.27)		

Table 6.2 Evaluation of therapeutic effects of sleep efficiency (SE) (%) in experimental group participants in different age groups, different number of years of insomnia, and different side of ear where treatment commenced.

Variables	*n*	SE Mean (sd)	Mean difference in SE	*t*-test (*df*) *p* value
Age group				
60-80	20	82.25 (10.60)	4.45	t_{58}=1.53, *p*=0.13
81-100	40	77.80 (10.67)		
Number of years of insomnia				
0-10	48	79.65 (11.58)	1.81	t_{58}=0.52, *p*=0.61
11 or above	12	77.83 (6.77)		
Side of ear				
Right	30	77.43 (13.21)	-3.70	t_{58}=-1.34, *p*=0.19
Left	30	81.13 (7.38)		

Table 6.3 Evaluation of therapeutic effects of nocturnal sleep time (NST) (minutes) in experimental group participants with gender differences.

	Male	Female	Total
Markedly effective (improved SE > 10%)	3 (100%)	5 (9%)	8 (14%)
Moderately effective (improved SE 6%-10%)	0 (0%)	15 (26%)	15 (25%)
Slightly effective (improved SE 1%-5%)	0 (0%)	26 (46%)	26 (43%)
Ineffective (improved SE ≤ 0%)	0 (0%)	11 (19%)	11 (18%)
Total	3 (100%)	57 (100%)	60 (100%)

Table 6.4 Evaluation of therapeutic effects of sleep efficiency (SE) (%) in experimental group participants with gender differences.

	Male	Female	Total
Markedly effective (improved SE > 10%)	3 (100%)	7 (12%)	10 (17%)
Moderately effective (improved SE 6%-10%)	0 (0%)	13 (23%)	13 (22%)
Slightly effective (improved SE 1%-5%)	0 (0%)	26 (46%)	26 (43%)
Ineffective (improved SE ≤ 0%)	0 (0%)	11 (19%)	11 (18%)
Total	3 (100%)	57 (100%)	60 (100%)

Table 6.5 Comparison of 'Nocturnal sleep time' (NST) (minutes) of the 15 cases in the experimental group before, during, immediately after therapy, at 1-month, 3-month, and 6-month intervals after therapy (Using RANOVA).

Cases	Before therapy	During therapy	Immediately after therapy	1month	3 months	6 months
	(1)	(2)	(3)	(4)	(5)	(6)
1	432	474	483	474	520	425
2	395	381	372	395	347	397
3	368	410	392	438	483	452
4	402	422	446	459	456	484
5	290	351	317	323	397	399
6	247	319	354	352	484	418
7	385	405	416	404	427	361
8	265	262	496	503	489	434
9	310	334	366	325	366	*
10	326	317	360	346	194	204
11	359	385	376	386	389	452
12	491	479	520	504	483	472
13	507	461	533	497	514	424
14	257	388	360	442	401	323
15	494	449	562	493	513	454
Means (SD)	368.53 (86.79)	389.13 (63.62)	423.53 (77.13)	422.73 (65.96)	430.87 (86.61)	407.07 (72.55)

∂ Sphericity test (df) G-G (df=2.66, 34.60)

Test of within-subjects effects F value (*p* value) F value = 3.42 ($p<0.05$) φ

Bonferroni multiple comparisons : Mean difference (*p*-value)

(1)– (2) : -20.36 (1.00) (2) – (3) : -34.57 (1.00) (3) – (4) : -2.07 (1.00) (4)– (5) : -5.79 (1.00) (5)– (6) : 28.43 (0.94)
(1) – (3) : -54.93 (0.07) (2) – (4) : -36.64 (0.72) (3)– (5) : -7.86 (1.00) (4)– (6) : 22.64 (1.00
(1) – (4) : -57.00 (0.18) (2)– (5) : -42.43 (1.00) (3)– (6) : 20.57 (1.00)
(1)– (5) : -62.79 (0.53) (2)– (6) : -14.00 (1.00)
(1)– (6) : -34.36 (1.00)

φ Bonferroni multiple comparisons given for statistically significant F ratio.

∂ degree of freedom of F ratio is evaluated by Greenhouse-Geisser (G-G) as estimates of adjustment (epsilon), if Mauchly's test of sphericity is not assumed.

* Client not taking actigraphic monitoring due to influenza.

Table 6.6 Comparison of 'Sleep efficiency' (SE) (%) of the 15 cases in the experimental group before, during, immediately after therapy, at 1-month, 3-month, and 6-month intervals after therapy (Using RANOVA).

Cases	Before therapy	During therapy	Immediately after therapy	1month	3 months	6 months
1	72	79	78	77	82	68
2	82	83	85	88	80	88
3	85	88	93	93	95	95
4	71	73	74	81	77	83
5	76	83	78	87	88	85
6	49	57	63	63	74	67
7	83	85	91	83	85	77
8	72	72	87	86	88	84
9	64	69	73	66	72	*
10	54	64	73	53	31	51
11	75	73	70	69	66	77
12	81	82	88	84	82	77
13	83	84	88	78	80	74
14	44	54	54	68	58	51
15	85	82	91	83	86	85
Means (SD)	71.73 (13.33)	75.20 (10.46)	79.07 (11.36)	77.27 (16.69)	76.27 (15.59)	75.86 (12.95)
◐ Sphericity test (df)	G-G (df=2.37, 30.83)					
Test of within-subjects effects F value (*p* value)	F value = 2.24 (*p*=0.12)					

◐ degree of freedom of F ratio is evaluated by Greenhouse-Geisser (G-G) as estimates of adjustment (epsilon), if Mauchly's test of sphericity is not assumed.

* Client not taking actigraphic monitoring due to influenza.

Table 6.7 The mean difference of 'Nocturnal sleep time' (NST) (minutes) of the 15 cases in the experimental group between baseline measurement and at different intervals after therapy.

	Intervals	Mean NST (SD)	Pair samples test	Mean difference	*t* value (df)	*p* value
(1)	Before therapy (Baseline)	368.53 (86.79)	---	---	---	---
(2)	During therapy	389.13 (63.62)	(1) – (2)	-20.60	-1.73 (df=14)	0.11
(3)	Immediately after therapy	423.53 (77.13)	(1) – (3)	-55.00	-3.63 (df=14)	<0.01
(4)	1 month	422.73 (65.96)	(1) – (4)	-54.20	-2.95 (df=14)	<0.05
(5)	3 months	430.87 (86.61)	(1) – (5)	-62.33	-2.50 (df=14)	<0.05
(6)	6 months	407.07 (72.55)	(1) – (6)	-38.54	-1.44 (df=13)	0.18

Table 6.8 The mean difference of 'Sleep Efficiency' (SE) (%) of the 15 cases in the experimental group between baseline measurement and at different intervals after therapy.

	Intervals	Mean SE (SD)	Pair samples test	Mean difference	*t* value (df)	*p* value
(1)	Before therapy (Baseline)	71.73 (13.33)	---	---	---	---
(2)	During therapy	75.20 (10.46)	(1) – (2)	-3.47	-3.25 (df=14)	<0.01
(3)	Immediately after therapy	79.07 (11.36)	(1) – (3)	-7.33	-4.86 (df=14)	<0.001
(4)	1 month	77.27 (11.13)	(1) – (4)	-5.53	-2.62 (df=14)	<0.05
(5)	3 months	76.27 (15.59)	(1) – (5)	-4.53	-1.53 (df=14)	0.15
(6)	6 months	75.86 (12.95)	(1) – (6)	-4.13	-1.64 (df=13)	0.13

Figure 6.1 Mean nocturnal sleep time (NST) (minutes) of the 15 cases in the experimental group at six time intervals.

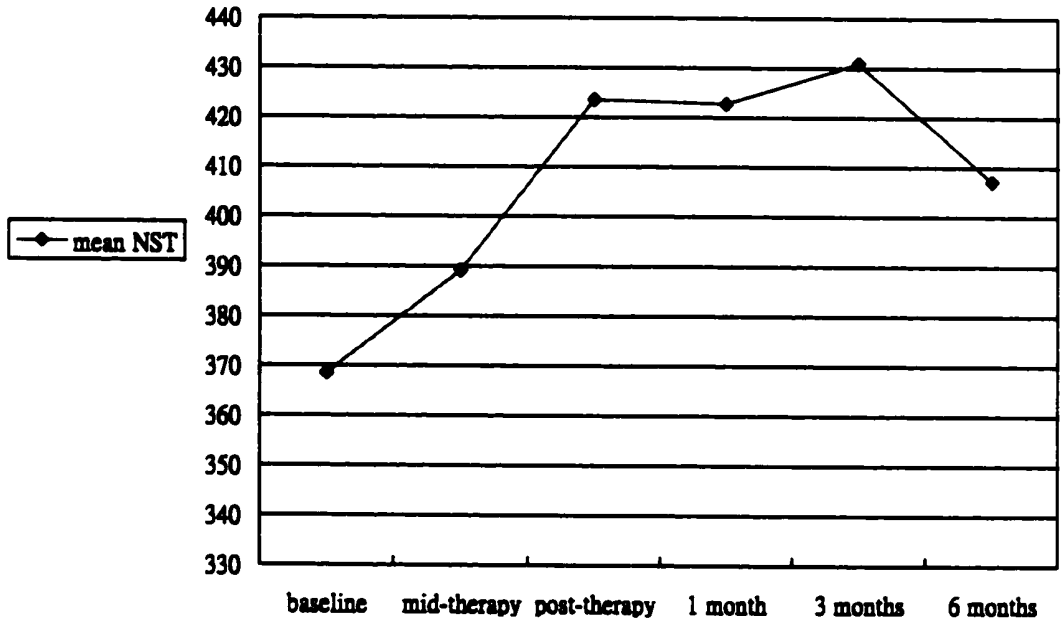
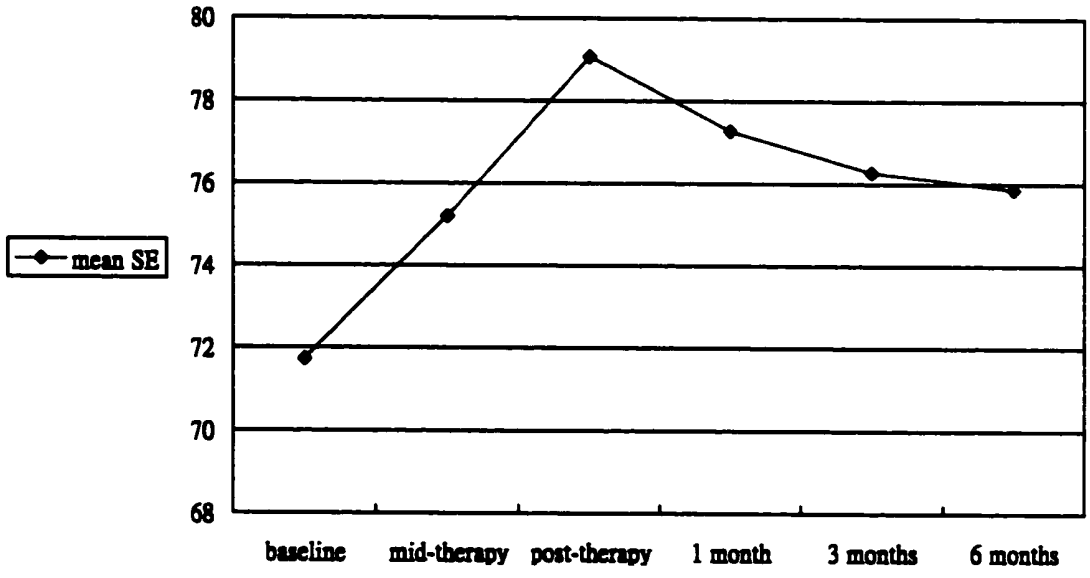


Figure 6.2 Mean sleep efficiency (SE) (minutes) of the 15 cases in the experimental group at six time intervals.



6.2 Evaluation of treatment effect using multiple regression analyses.

The objective of using multiple regression analyses was to examine whether sleep efficiency of 110 female participants was affected by the therapy after allowing for a myriad of possible predictors. The male participants were excluded from the regression analyses to avoid possible bias of the results due to the limited number of males in this study (n=10). In addition, it was unlikely that gender was a potential confounding variable in this study, as the distribution of the male participants was similar across the three groups (Table 5.1).

6.2.1 Method for selecting variables

Backward elimination was used to build multiple regression models. It started with a regression model that contains two interaction terms and ten explanatory variables. They are:

- two interaction terms - SNACK*DAIRY [X_1], AGE*INSOMNIA [X_2]
- side of ear where treatment commences [SIDE] (0=right, 1=left)
- years of insomnia [INSOMNIA] (0=1 to 10 years, 1=11 years or above)
- age [AGE]
- insomnia due to 'Excessive' or 'Deficiency' syndrome [SYNDROME] (0=excessive, 1=deficiency)
- nervous/anxiety in the last six months (0=no, 1=yes)
- regular caffeine intake [CAFFEINE] (0=no, 1=yes)
- regular dairy intake [DAIRY] (0=no, 1=yes)
- snack before bedtime [SNACK] (0=no, 1=yes)
- type of intervention - Group A [GROUP A] as the referent category, Group B [GROUP B] and Group C [GROUP C] as dummy variables.

The reasons for putting the above explanatory variables into the model are due to the possible effects they may have on sleep such as caffeine intake, dairy products consumption and anxiety level. Other potential confounding variables which are thought to have an influence on the dependent variable (sleep efficiency) were also considered in the models - including age, number of years suffered from insomnia, insomnia due to 'Excessive' or 'Deficiency' syndrome, habitual bedtime snack, and side of the ear where therapy was commenced. The interaction terms between SNACK and DAIRY, AGE and INSOMNIA were created. Interaction terms represent the combined effect of two variables over and above any additive combination of their separate effects (Polit, 1996, p.277). It is common for the participants to consume dairy products such as milk as a bedtime snack, and years of having insomnia may also increase with age.

At each step, the variable that changes R^2 least was removed from the model, using a preset significance level of 0.05 (Table 6.9). As the effects of the interventions (GROUP B, GROUP C) were the prime interest in this study, therefore these two variables had to be retained in every model.

No effect modification was detected between bedtime snacks and dairy intake, as well as between age and the length of time suffered from insomnia. Certain potential confounding variables which were found to have no significant influence on the sleep efficiency were excluded from the final model - including number of years having insomnia, insomnia due to

'Excessive' or 'Deficiency' syndrome, worry/anxiety over the past six months, regular caffeine intake, dairy consumption, habitual bedtime snack, and side of the ear where therapy commences.

6.2.2 Tolerance and multicollinearity

The strength of the linear relationships among the independent variables is represented by a statistic called the tolerance (Norusis, 1998, p.467). It has been checked that no tolerances are smaller than 0.1. Besides, the variance inflation factor (VIF) is checked for all explanatory variables and all are below 10, therefore no multicollinearity exists.

6.2.3 Final model

Model 10 is a final model which contains three explanatory variables, namely AGE, and two dummy variables (GROUP B, GROUP C). The explanatory variables in the final model account for 20% (R^2 = 0.20) of the variability in sleep efficiency. The partial regression coefficient of age -0.42 estimates an average of 0.42% decrease in sleep efficiency per year of age-increase when therapy remain constant in female participants. The effect of the therapy is highly statistically significant after adjusting for AGE in female participants ($F_{3,106}$ = 9.04, p<0.001).

The regression coefficients of the dummy variables for GROUP B and GROUP C have the following meanings:

- The mean sleep efficiency in GROUP B (Semen Vaccariae) is 5.28%

higher than GROUP A (Junci Medulla) – the referent group, after allowing for AGE.

- The mean sleep efficiency in GROUP C (Magnetic pearls) is 11.84% higher than GROUP A (Junci Medulla), after allowing for AGE.
- GROUP C (Magnetic pearls) also has a sleep efficiency of 6.56% higher than GROUP B (Semen Vaccariae), after allowing for AGE.

Having decided on the appropriate model for the data, the adjusted mean SE for each group could be calculated, after allowing for differences in the covariates. For all the female participants (n=110), the mean age is 82.01. The fitted values are:

Group A

SE = 102.83 – 0.42 × mean age (82.01)

= 68.39%

Group B

SE = 102.83 – 0.42 × mean age (82.01) + 5.28

= 73.67%

Group C

SE = 102.83 – 0.42 × mean age (82.01) + 11.84

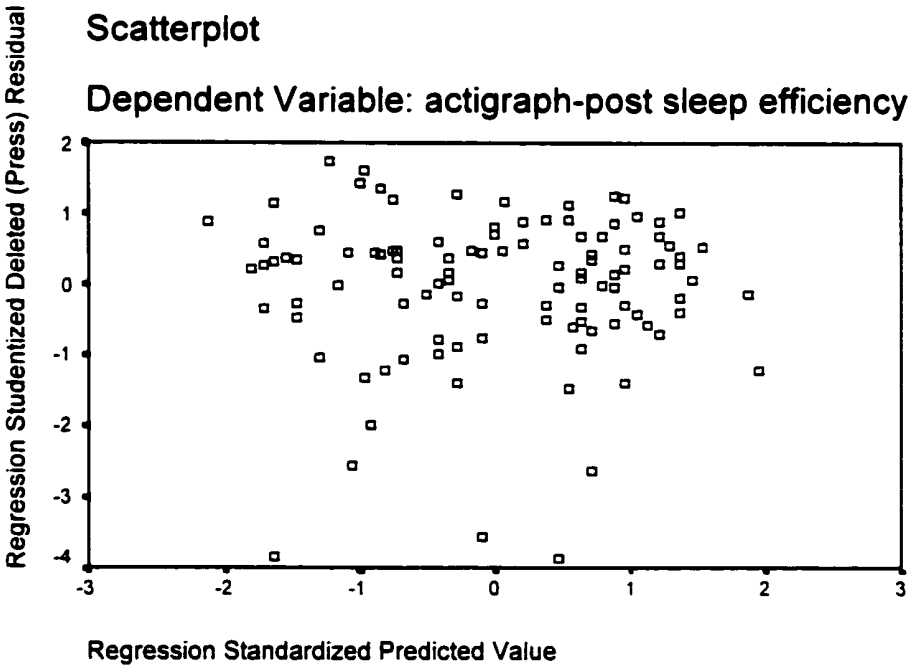
= 80.23%

6.2.4 Check for assumptions of the residuals in the final model

Several ways are used to check for the following assumptions of the residual in the final model:

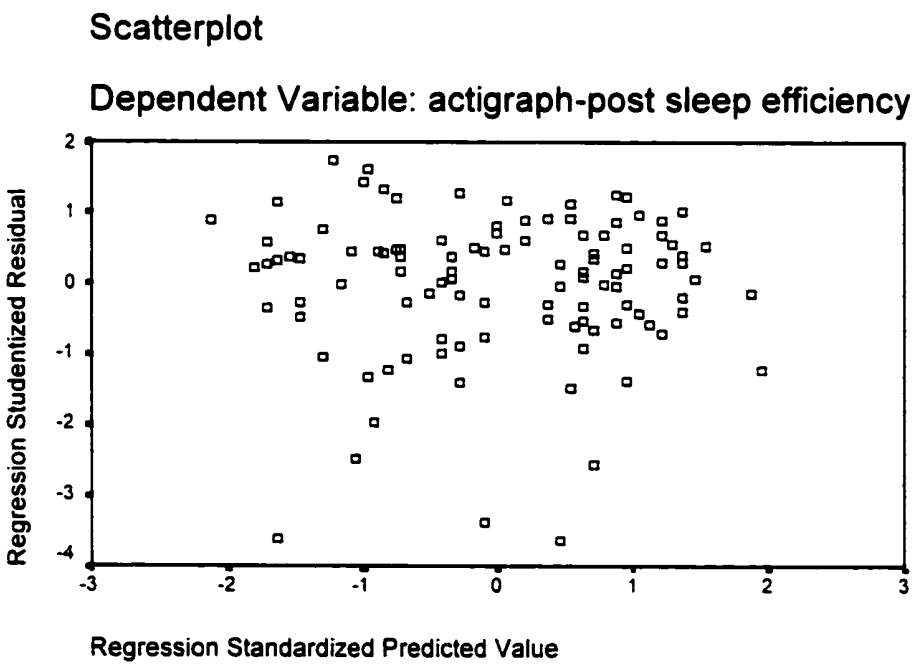
(1) Checking for constant variance (Homoscedasticity)

Plot Studentized deleted residuals (Jackknifed residuals) against Standardized predicted values of the final model to check for constant variance (Norusis, 1998, pp.447-448). Since there is no obvious pattern and the residuals appear to be randomly scattered around a horizontal line through zero, therefore the residuals of the final model have a constant variance σ^2.

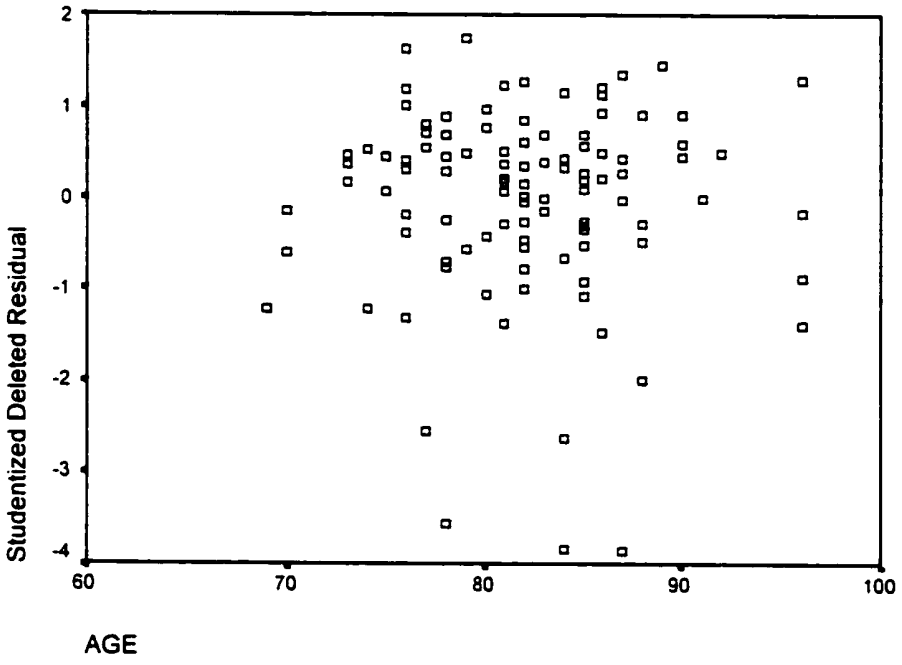


(2) Checking linearity:

a) To evaluate the linearity assumption by plotting the Studentized residuals against the predicted value (Norusis, 1998, p.440). The assumption of linearity is established since no curve in the plot can be seen.



b) Plot Studentized deleted residuals (jackknifed residuals) against the continuous variable (AGE) to check linearity (Norusis, 1998, p.498). The plot looks like a horizontal band and no obvious pattern can be seen. Therefore the errors have mean 0 and the relationship between the dependent variable (sleep efficiency after therapy) and AGE is linear.



(3) Checking for normality:

Use Studentized deleted residuals to look for violations of the regression assumption on normality. The residuals in the stem-and-leaf plot look symmetrical and have a single peak.

```
   Studentized Deleted Residual Stem-and-Leaf Plot

 Frequency    Stem &  Leaf

     6.00 Extremes    (=<-2.0)
     1.00       -1 .  4
     5.00       -1 .  22333
     2.00       -1 .  00
     3.00       -0 .  899
     5.00       -0 .  66777
     6.00       -0 .  444555
     8.00       -0 .  22222333
     7.00       -0 .  0001111
    10.00        0 .  0000001111
    16.00        0 .  2222222333333333
    15.00        0 .  444444444455555
     6.00        0 .  666677
     8.00        0 .  88888999
     5.00        1 .  01111
     4.00        1 .  2223
     1.00        1 .  4
     2.00        1 .  67

 Stem width:   1.00000
 Each leaf:       1 case(s)
```

(4) Check for leverage

By examining Cook's distance of the residuals, D_i, which measures how much the regression coefficients change if the *i*-th observation is omitted. Cook's distance for a case depends on both the Studentized residual and the leverage values (Norusis, 1998, p.497). All the observations (n=110) have $D_i < 1$ (minimum 0.000, maximum 0.148, mean 0.01, sd 0.02), therefore no influential point is noted.

Table 6.9 Summary of the regression models.

Model	Variables entered	Unstandardized coefficients		t	Sig.	Variables removed	R	R^2	Adjusted R^2	F value (df) (Sig.)
		Beta	Std error							
1.	(Constant)	118.49	17.83	6.65	.000	—	.56	.31	.22	F=3.63, df=12, 97 (p<.001)
	X_1	-7.67	4.30	-1.78	.078					
	X_2	-.29	.40	.74	.459					
	SIDE	3.37	1.96	1.72	.089					
	INSOMNIA	-27.08	32.43	-.84	.046					
	ANXIETY	3.20	2.26	-1.41	.161					
	AGE	-6.10	.21	-2.93	.004					
	SYNDROME	-3.51	2.09	-1.68	.096					
	CAFFEINE	-1.61	1.95	-.82	.412					
	DAIRY	5.46	2.73	2.00	.048					
	SNACK	4.18	3.61	1.16	.249					
	GROUP B	4.75	2.78	1.71	.091					
	GROUP C	11.50	2.40	4.79	.000					
2.	(Constant)	111.65	15.24	7.33	.000	X_2	.55	.31	.23	F=3.92, df=11, 98 (p<.001)
	X_1	-7.55	4.29	-1.76	.081					
	SIDE	3.35	1.96	1.71	.090					
	INSOMNIA	-3.04	2.53	-1.20	.232					
	ANXIETY	-3.07	2.25	-1.37	.176					
	AGE	-.53	.18	-2.97	004					
	SYNDROME	-3.26	2.05	-1.59	.115					
	CAFFEINE	-1.52	1.95	-.78	.437					
	DAIRY	5.49	2.72	2.02	.046					
	SNACK	4.24	3.60	1.18	.242					
	GROUP B	4.92	2.77	1.78	.079					
	GROUP C	11.51	2.39	4.81	.000					
3.	(Constant)	114.03	15.34	7.44	.000	X_1	.53	.28	.21	F=3.92 df=10, 99 (p<.001)
	SIDE	-3.21	1.98	-1.62	.11					
	INSOMNIA	-3.75	2.53	-1.48	.14					
	ANXIETY	-2.48	2.25	-1.10	.27					
	AGE	-.54	2.79	-2.97	.004					
	SYNDROME	-3.98	2.03	-1.96	053					
	CAFFEINE	-1.28	1.96	-.65	.516					
	DAIRY	2.65	2.21	1.20	.234					
	SNACK	-1.02	2.02	-.51	.615					
	GROUP B	5.33	2.79	1.91	.059					
	GROUP C	11.39	2.42	4.71	.000					
4.	(Constant)	112.97	15.14	7.46	.000	SNACK	.53	.28	.22	F=4.36 df=9, 100 (p<.001)
	SIDE	3.07	1.95	1.57	.119					
	INSOMNIA	-3.85	2.51	-1.53	.128					
	ANXIETY	-2.54	2.24	-1.14	.259					
	AGE	-.53	.18	-2.95	.004					
	SYNDROME	-3.70	1.95	-1.90	.060					
	CAFFEINE	-1.15	1.94	-.59	.555					
	DAIRY	2.47	2.18	1.14	.258					
	GROUP B	5.38	2.78	1.94	.055					
	GROUP C	11.44	2.41	4.75	.000					

(To be continued)

(Con't Table 6.9)

Model	Variables entered	Unstandardized coefficients		t	Sig.	Variables removed	R	R^2	Adjusted R^2	F value (df) (Sig.)
5.	(Constant)	111.08	14.75	7.53	.000	CAFFEINE	.53	.28	.22	F=4.90 df=8, 101 (p<.001)
	SIDE	2.94	1.93	1.52	.131					
	INSOMNIA	-3.84	2.50	-1.53	.128					
	ANXIETY	-2.61	2.23	-1.17	.245					
	AGE	-.51	.18	-2.91	005					
	SYNDROME	-3.61	1.94	-1.86	.065					
	DAIRY	2.56	2.16	1.18	.240					
	THERAPY B	5.48	2.76	1.98	.050					
	THERAPY C	11.48	2.40	4.79	.000					
6.	(Constant)	106.27	14.19	7.49	.000	ANXIETY	.52	.27	.22	F=5.38 df=7, 102 (p<.001)
	SIDE	2.57	1.91	1.35	.181					
	INSOMNIA	-4.07	2.50	-1.63	.107					
	AGE	-.47	.174	-2.72	.008					
	SYNDROME	-3.34	1.93	-1.73	086					
	DAIRY	3.45	2.03	1.70	.092					
	GROUP B	5.61	2.76	2.03	.045					
	GROUP C	11.51	2.40	4.79	.000					
7.	(Constant)	105.41	14.23	7.41	.000	SIDE	.51	.26	.21	F=5.93 df=6, 103 (p<.001)
	INSOMNIA	-4.09	2.51	-1.63	.106					
	AGE	-.45	.17	-2.59	.011					
	SYNDROME	-2.97	1.91	-1.55	.124					
	DAIRY	3.41	2.04	1.67	.097					
	GROUP B	5.64	2.78	2.03	.045					
	GROUP C	11.58	2.41	4.80	.000					
8.	(Constant)	101.74	14.13	7.20	.000	SYNDROME	.49	.24	.20	F=6.54 df=5, 104 (p<.001)
	INSOMNIA	-4.11	2.53	-1.63	.107					
	AGE	-.42	.17	-2.44	.016					
	DAIRY	3.26	2.05	1.59	.115					
	GROUP B	5.84	2.79	2.09	.039					
	GROUP C	11.93	2.42	4.94	.000					
9.	(Constant)	104.08	14.16	7.35	.000	DAIRY	.47	.22	.19	F=7.44 df=4, 105 (p<.001)
	INSOMNIA	-3.85	2.54	-1.52	.132					
	AGE	-.43	.18	-2.43	.017					
	GROUP B	5.28	2.79	1.89	.061					
	GROUP C	12.02	2.43	4.94	.000					
10.	(Constant)	102.83	14.22	7.23	.000	INSOMNIA	.45	.20	.18	F=9.04 df=3, 106 (p<.001)
	AGE	-.42	.18	-2.37	.019					
	GROUP B	5.28	2.81	1.88	.062					
	GROUP C	11.84	2.45	4.84	.000					

Dependent variable: Sleep efficiency (after therapy)

6.3 Conclusion

When the therapeutic effect of auricular therapy is evaluated in the experimental group, no significant differences in the NST and SE could be observed in participants (a) in different age group, (b) having suffered from insomnia for a different number of years, or (c) commencing treatment on different sides of the ear. It was also found that the treatment effect in the experimental group could be sustained even at six months after therapy.

In multiple regression analyses using backward elimination, the effect of auricular therapy on sleep efficiency is highly statistically significant after allowing for age in female participants ($F_{3, 106} = 9.04$, $p<0.001$). The R^2 value of the final model (0.20) shows that 20% variability in the measurements of the sleep efficiency of 110 female elderly is accounted for by their differences in age, and the type of auricular therapy they received. According to the results of regression analyses, a higher sleep efficiency is attained if the participant is relatively young, or receiving magnetic pearls as auricular therapy.

The residuals of the final model also correspond to the assumptions that the errors have a mean of 0 (linearity), all have variance σ^2 (homoscedasticity), and are normally distributed (normality). Furthermore, no influential point among the residuals is noted.

CHAPTER 7

DISCUSSION

7.1 Summary of findings

The results of this randomized controlled study support the hypothesis that auricular therapy using magnetic pearls can improve sleep behaviours among the elderly. Participants in the experimental group made significant improvement in certain sleep parameters, such as increased nocturnal sleep time and sleep efficiency, as well as decreased sleep latency and awakening time during sleep when compared with the controls. A gradual improvement of the sleep behaviours could also be observed when significant improvements in certain sleep parameters were found in the experimental group during and after the therapy. No significant improvement of sleep could be observed in the two control groups which used either Junci Medulla or Semen Vaccariae. No significant differences in the sleep parameters between the two control groups after the therapy were recorded, and this seems to indicate that Semen Vaccariae works no better than Junci Medulla on sleep improvement if pressing is not applied to the semens.

When the therapeutic effect of auricular therapy in the experimental group was evaluated, no significant differences in the parameters that indicated

sleep improvement were observed in participants (a) in different age groups, (b) having suffered from insomnia for a different number of years, or (c) commencing treatment on different sides of the ear. The long-term effects of the therapy using magnetic pearls were found to continue in the majority of the participants who were selected for an additional six months monitoring after therapy. The findings of this study also suggest that there are no significant differences in the effects of auricular therapy on sleep in the experimental group participants with diverse traditional Chinese diagnosis on insomnia even if the treatment protocol is standardized. The result of regression analyses shows that the effect of auricular therapy on sleep efficiency is highly statistically significant after allowing for age in female participants. This offers an alternative illustration that the relationship between auricular therapy using magnetic pearls and sleep improvement does exist.

The following sections move on to discuss the results summarized above. This includes the extent of causal relationships between auricular therapy using magnetic pearls and sleep improvement, the internal validity of the study, the mechanisms of magnets that work on the acupoints, and the validity of using actigraphic monitoring as objective measurements. Using standardized protocols for clients with diverse traditional Chinese diagnosis on insomnia is then justified and discussed. Finally, the implications of the findings for the clinical, community and nursing professionals are delineated.

7.2 Causal relationships between auricular therapy using magnetic pearls and sleep improvement

Causal relationships between the effects of auricular therapy when using magnetic pearls and sleep improvement were supported mainly because an experimental design using randomization was chosen to test the hypotheses in the current study. Participants were comparable across the three groups on all major variables of interest at baseline, supporting the success of the randomization procedure. Because elements of manipulation, control and randomization were adhered, it was considered that an experimental design would offer the most convincing evidence concerning the effect of the independent variable on the dependent variable (Kerr, Jowett & Smith, 1996).

Several attempts were used to increase the internal validity of the findings, for example, (a) conducting interrater reliability checks to ensure the accuracy of identification of acupoints by the researcher, (b) administration of therapy consistently by the same researcher, (c) using actigrahic monitoring as an objective measurement to avoid bias on estimation of therapeutic effects, and (d) inviting staff in the nursing homes to fill in the sleep diaries to minimize possible bias when a single-blind study was conducted.

The absence of significant differences between the two control groups has several implications: (a) Semen Vaccariae works no better than Junci Medulla on sleep improvement if no pressing is applied to the semens, (b) Since the effect of Semen Vaccariae when taken orally can activate blood circulation (Yuan et al., 1996), the absence of therapeutic effect of Semen Vaccariae leads to the rejection of the hypothesis that sleep improvement, if any, is due to properties of the semens absorbed by skin, (c) a standardized protocol for pressing should be considered if seed pressing is adopted in future studies so that a stronger causal relationship than those reported in previous studies can be concluded, (d) since the physical appearance (diameter of ~ 0.13cm) of seed-like objects like Semen Vaccariae did not induce any effect on the acupoints, Semen Vaccariae can serve as a referent group for the experimental group when magnetic pearls which also have a diameter of ~ 0.13cm are used. The therapeutic effects that were observed in the experimental group were concluded to be solely due to magnetic effects rather than physical pressure induced by the pearls on the acupoints.

It was also found that the treatment effect in terms of NST and SE could be sustained at specific intervals after stopping all treatments in 15 selected cases of the experimental group, and a partial relapse of symptoms was found in only a few cases (See Chapter 6, Table 6.5 & 6.6). The long-term effects of auricular therapy on sleep improvement could also be observed in various studies using seed pressing techniques when the participants were

visited after six months (Shang, 1996[27]; Zhu, 1998[46]), one year (Hu, 1997[12]; Shang, 1997[28]), and even two years (Dang, 1995[2]) after the therapies ceased. Although no further data were obtained after six months in the current study, it is possible that the therapeutic effects might continue to be maintained for longer periods in some cases. However it was also noted that when the baseline sleep parameters (i.e. before the therapy) were subsequently compared with those obtained at different intervals, the peak NST mean difference and peak SE mean difference was noted at three months and immediately after the therapy respectively (Table 6.7 & Table 6.8), and a gradual decrease in the sleep parameters after the peak was reached. This might indicate that an additional treatment protocol may be required to "top-up" the effect at around three months after the therapy.

It was found that a Hawthorne effect occurred during treatment in around 10% (n=13) of all participants, in that they stated that their sleep had improved although no evidence of improvement was shown in their SE or NST after the therapy. A placebo effect has never been found to be persistent, consistent and dramatical (Lee, 1977). As the Hawthorne effect is a kind of placebo effect (Polit & Hungler, 1997, p.161), this point is noted to show that the question of a Hawthorne effect in this study was minimal - the therapeutic effects of magnetic pearls were obvious, long-term effects were seen in a majority of cases that were being monitored at different intervals after the therapy, and objective measurement using actigraphic monitoring was adopted.

It seems unlikely that the therapeutic effects of auricular therapy on sleep improvement were confounded by sleep hygiene measures or other confounding variables such as number of years having insomnia, insomnia due to either 'Excessive' or 'Deficiency' syndrome, anxiety levels, regular caffeine intake, dairy consumption, habitual bedtime snacks, and side of the ear where therapy was commenced. However, according to the results of regression analyses, a higher sleep efficiency is estimated if the participant is relatively young, or receiving magnetic pearls as auricular therapy.

7.3 Mechanisms of magnetotherapy

According to the results of the study, the effects of using auricular therapy using magnetic pearls were evidenced. With the exception of skin allergy caused by the plaster adhering to the ears, none of the participants reported serious side effects resulting from the use of magnetic pearls. The mechanisms for the interaction of magnetic fields with biological tissues resulting in functional changes may be due to some underlying principles of physics mentioned before – the Faraday's law and the Hall effect (See Chapter 1, section 1.3, p.12). According to these principles, auricular therapy using magnetic pearls might promote the circulation of *Qi* and blood in the meridians, regulate functions of the *Zang Fu* organs, thus obviously improving the physiological functions of the body. This idea also

accords with the findings in previous studies that have used magnetic pearls as auricular therapy was successful in treating various diseases of the body (Chen et al. 1998[1]; Mao & Gong, 1994[21]; Zhao, 1996[44]). However, further studies from a biomedical perspective need to be carried out to help us understand clearly the biological effects of magnets on the *Qi*, meridians and *Zang Fu* organs of the body.

7.4 Validity of findings using actigraphic monitoring

As mentioned earlier, the actigraph is a motion sensor and therefore it is not capable of distinguishing between immobile sleep and immobile waking. It is possible that some participants lie in bed awake without moving their bodies. Although estimates of total sleep time derived from an actigraph recording may not be as accurate a measure of sleep as the polysomnogram (PSG), several factors make the actigraph a desirable method for many clinical sleep-related studies. The actigraphic device produces less skin irritation, is more comfortable and convenient for the participant, who can sleep in his/her natural sleeping environment if desired, free from electrodes (Hauri & Wisbey, 1992; Mullaney, Kripke & Messin, 1980). In comparison, PSG is more labor-intensive and expensive, and such a burdensome measure can significantly constrain the generalizability of the subject sample being recruited (King, Oman, Brassington, Bliwise & Haskell, 1997).

The factors that cause the actigraph to overestimate or underestimate sleep time for a given patient are relatively consistent from one night to the next. Actigraphy has been found to be useful in the assessment of internight variability as a within-subject coefficient of 0.81 was noted (Jean-Louis, Zizi, Gizycki & Hauri, 1999). Many authors also support the view that actigraphic monitoring is a desirable measure in research when night-to-night variability of a change in the sleeping pattern of subjects due to longitudinal changes within a treatment program or experimental protocol is monitored (Chambers, 1994; Hauri & Wisbey, 1992; Sadeh, Hauri, Kripke & Lavie, 1995). For these reasons, it is considered that the actigraph is sensitive enough to detect treatment effects in this present study.

Although limitations in the use of using actigraphs have been documented, actigraphs are still claimed to be a reliable measure to estimate sleep duration (i.e. TST) (Kripke, Mullaney, Messin & Wyborney, 1978; Zomer et al., 1987). Many validation studies comparing the total sleep time data (TST) derived from PSG to actigraphic data have reported that the agreement for sleep/wake time is 90% in normal adults (Alster & Sadeh, 1990), and 78.2% for insomniacs patients (Sadeh, Alster, Urbach & Lavie, 1989). Some previous research results show that automatic sleep/wake scoring from wrist activity agrees reasonably well with polysomnographic sleep/wake scoring even in subjects suffering from conditions that disturb sleep (Brooks III, Friedman, Bliwise & Yesavage, 1993; Cole, & Kripke, 1988; Hauri &

Wisbey, 1992; Sadeh, Alster, Urbach & Lavie, 1989).

On the other hand, a discrepancy in certain sleep parameters exists between actigraphic monitoring and those subjectively reported by participants in this study (See Chapter 5, Table 5.3). For example, the mean NST of all participants monitored by actigraphs was 210.78 minutes higher than those recorded in the sleep diaries; the sleep latency in the diaries was ~ 2 hours longer than those recorded by the actigraphs; and the number of midsleep awakenings detected by the actigraphs was more frequent than those perceived by the participants. Similar discrepancy was found in a previous study that showed actigraphs recorded a shorter sleep latency, advanced onset time, increased number and duration of night awakenings, delayed offset, increased night sleep duration when compared with the subjective data derived from sleep diaries (Lockley, Skene & Arendt, 1999).

The discrepancy between actigraphic monitoring and sleep diaries might be explained by the presence of the Sleep State Misperception (SSM) in some participants. Patients with SSM often describe severe chronic insomnia with as little as 2 hours of sleep at night, or the frequent occurrence of two or more consecutive nights with no sleep. However this severity is often exaggerated. Although the patient perceives the night of sleep as markedly abnormal, polysomnograhic investigation usually reveals normal sleep or only a mild sleep disturbance (Merlotti, Roehrs, Roth, Salin-

Pascual & Zorick, 1992). A short period of wakefulness may *seem* longer to the people with insomnia, if this assumption is correct, it may provide an explanation of why the measures on NST or SL in the sleep diaries were greater than those derived from the actigraphs. Another study conducted by Carskadon et al. (1976) on 122 subjects with chronic insomnia, the authors also noticed that most subjects consistently underestimated their total sleeping time and overestimated the amount of time it took them to get to sleep in comparison with electroencephalogram (EEG). Due to the presence of SSM or other psychophysiologic factors in some people with sleep disturbances, the actigraph comes considerably closer to the data obtained from the PSG than does the sleep diary (Hauri & Wisbey, 1992). Usui et al. (1999) also identified a few problems of sleep diaries, and has observed that the ratio of agreement between subjective and actigraphic sleep-wake state dropped during the sleep-wake transition periods, and that the sensitivity and specificity tend to be lower in elderly subjects and in cases of sleep disorders than in young healthy subjects.

The fact that more frequent number of midsleep awakenings was detected by the actigraphs than those reported by clients might be due to the motion sensor of the instruments that leads to overestimation. On the other hand, an increase in the number of awakenings at night for physiologic reasons after age 85 is usual (Hayter, 1983), and it was reported that insomnia in elderly persons is more active during periods of bedrest (Pollak, Perlick & Linsner, 1992).

Although a sleep diary does not provide an accurate measure of sleep in general, it could be useful in assessing subjects' perceptions of sleep (Brooks III et al., 1993), and is believed to be a useful tool for interpreting the actigraphic measures in sleep studies.

7.5 Standardized protocol for clients with diverse traditional Chinese diagnosis on insomnia

In addition to the correct choice of the modality of stimulation and the use of an objective measurement for the evaluation of treatment effect, another reason for the successful outcome of study may be due to the appropriate selection of auricular points by combining knowledge of modern medicine and TCM principles. Seven auricular points which were thought to have an effect on sleep promotion were selected. They were: 'Shenmen', 'Heart', 'Kidney', 'Liver', 'Spleen', 'Occiput' and 'Subcortex'. The selection of the above points is based on traditional Chinese medical theory as well as modern medicine.

Taking 'Occiput' and 'Subcortex' as acupoints for sleep improvement could easily be understood as both organs belong to the neurological system that may have an effect on improving one's sleep. As a consequence of age-related diminished renal concentrating capacity, decreased sodium

conserving ability, loss of the circadian rhythm of antidiuretic hormone secretion, reduction in the secretion of renin-angiotensin-aldosterone, and increased secretion of atrial natriuretic hormone, there is an age-related alteration in the circadian rhythm of water excretion leading to increased nighttime urine production in older people (Miller, 2000). Therefore the 'Kidney' was selected as a means to decrease the frequency of nocturnal polyuria.

Using a modern medical approach alone, one probably would not have selected points such as 'Shenmen', 'Heart', 'Liver' and 'Spleen'. The cardiovascular system has never been implicated in the production of insomnia from the modern medical point of view. From the perspective of Chinese medicine, sleep is controlled by the 'Kidney' system, a weakened kidney system will tend to result in overactivity of the 'Heart' system which induces wakefulness and palpitations, a syndrome known as 'disharmony between the heart and kidneys' in traditional Chinese medical terms (Lee, 1977). The 'Shenmen' point (Gate of Spirit), like 'Occiput', is known to produce a tranquilizing and sedating effect on the mind (Feng et al., 1994, p.103; Yang, 1988).

Although six distinct types of insomnia are differentiated by traditional Chinese diagnosis, all are closely related to the major viscera, the heart in particular playing a major role. The 'Heart', 'Liver', 'Spleen', and 'Kidney' points of the auricle are the reflective points of the corresponding 'viscera'.

These were selected according to different syndrome types as chief points to regulate the function of *Zang Fu* organs in treating the root cause of insomnia which was either 'deficient' or 'excessive' in nature.

Many people believe the saying that 'older people need less sleep' to be a true representation of the normal ageing process. However sleep disturbance may be one of the symptoms indicating poor health or functional deficits, and be a risk factor for survival (Manabe et al., 2000). According to the principles of Chinese medicine, most illnesses of the elderly have been attributed to the decline of Kidney-*Qi* or a combination of Spleen and Kidney vacuity. Kidney-*Qi*, which is responsible for growth, maturation, and development, inevitably declines over time. Blood stagnation is problematic because it affects the flow of *Qi* in the body. This physiological occurrence seems to be an integral part of the pathologies of ageing, and treatments should focus on strengthening the *Qi*, activating the blood, and transforming stasis (Gardner-Abbate, 2000). Moreover, alternative practitioners emphasize a 'holistic approach' that the patient should not be regarded as a set of symptoms to be resolved, but as a whole organism (Hillman, 1986). The traditional Chinese medical theory, therefore, does seem to have a valid physiological basis on acupoints selection in this study.

The philosophy of Rogers's Science of Unitary Human Beings shares similar views on the health status of a person as from a TCM perspective.

It is believed that a healthy person has a balance between inward and outward energy flow, with illness being the result of an imbalance or disruption in this energy field or flow (Mackey, 1995). If a patient and their illness are to be effectively treated, they must be considered and understood from a holistic perspective in which the energetic field disturbance must be rebalanced (Daley, 1997). An alternate form of energy healing using auricular therapy might promote the circulation of *Qi* and blood in the meridians, regulate functions of the *Zang Fu* organs, thus obviously improving the physiological functions of the body. The acupoints selected in this study are to regulate the function of *Zang Fu* organs of the elderly in treating the root cause of insomnia which was either 'deficient' or 'excessive' in nature. In this study, the theory of energy exchange is viewed as part of the broader conceptual system proposed by Rogers. Therefore using auricular therapy on people with insomnia could help to achieve a state of unity of balance and coordination of the *Zang Fu* organs, and reflects the principles of homeodynamics. Auricular therapy based on the philosophy of TCM have greater potential for usefulness with Rogers's framework because this therapy tends to reflect a more unitary view of the individual through the provision of holistic care which includes attending to a person's body, mind and spirit.

The bi-directional regulatory mechanism of auricular therapy was also demonstrated when Wu (1998a[34]) achieved similar therapeutic effects by using the same acupoints for cases with either insomnia or somnolence.

This indicates that auricular therapy can help a person to achieve a balance by regulating the functions of the body in a preferred direction. Such a direction essentially assumes that the standardized protocol in this study thus induced no harm to the participants having insomnia of any kind. When the therapeutic effect was evaluated in the experimental group, no significant differences in the effects of the therapy could be observed between clients with 'excessive' and 'deficiency' syndrome even when the treatment protocol was standardized. The therapeutic effects on sleep and other physiological functions such as improvement of appetite and calming of mind were reported. Some of the systemic symptoms like headache/dizziness and nocturnal polyuria also tend to be mitigated with the progress of the treatments. This further indicates that a standardized protocol of acupoint selection might be appropriate for the ageing population who are homogenous in terms of age and general health status in current study. Another reason for standardization of the acupoints is to increase the level of applicability of this therapy into nursing, so that nurses with or without adequate knowledge on conducting traditional Chinese diagnosis on insomnia could also adopt these acupoints when they administer auricular therapy for treating insomnia for the elderly patients.

7.6 Implications of findings

7.6.1 Clinical implications

The problem of insomnia is very common in the elderly population and constitutes one of the most difficult problems facing middle-aged and older adults (King et al., 1997). It was noticed that sleep disturbances were quite common in elderly who are residing in community institutions (Ancoli, Parker, Sinaee, Fell & Kripke, 1989; Clapin, 1986; Pollak, Perlick, Linsner, Wenston & Heieh, 1990; Pollak et al., 1992). If sleep medications are used, the elderly are more susceptible to the adverse effects of hypnotic drugs. Adverse effects include confusion, falls (King et al. 1997; Orr et al. 1982); impaired psychomotor performance, drug dependence, and rebound insomnia due to drug withdrawal (Blake, 1992; Borbey et al., 1983; Castor et al.,1991; Morin, 1993).

Auricular therapy using magnetic pearls is found to be cost-effective, hygienic, with fewer side effects and is more easily accepted by the clients than many other complementary therapies for insomnia. It becomes quite clear that this procedure is superior to the other forms of acupuncture therapeutics in dealing with insomnia. Several studies (Du, 1996[3]; Gao, 1995[9]; Liu, 1998[20]) have demonstrated that acupuncture is usually less effective than auricular pressing therapy for patients with insomnia, and the effective rate when using acupuncture for treating insomnia ranged from 59% to 83%. Whereas using auricular therapy alone for treating insomnia

is less traumatic and hygienic, and an effective rate of over 96% to 100% was frequently reported (Guo, 1996[10]; Huang et al., 1996[13]; Qin, 1998[24]; Shang, 1996[27]). Side effects of acupuncture, such as pneumothorax, cardiac tamponade, haemothorax, spinal epidural haematoma and subarachnoid haemorrhage due to unskilled hands are reported (Keane, Ahmadi & Gruen, 1993). Using fewer needles during therapy could also minimize a number of blood-borne diseases and avoid needle phobia experienced by the clients.

In an epidemiological survey conducted on 200 elderly people in the surrounding suburbs of Reykjavik in Iceland, it was noted that 'Difficulty maintaining sleep' (DMS) was the most commonly reported insomnia complaint among the elderly, followed by difficulty initiating sleep (DIS) and early morning awakening (EMA) (Gislason, Reynisdottir, Kristbjarnarson & Benediktsdottir, 1993). The positive findings of this study are of great significance to the well-being of the elderly when the study describes a therapy that could improve the quality as well as the quantity of sleep among the elderly. The therapeutic effects that are demonstrated by an increase in nocturnal sleep time and sleep efficiency in this study indicate that both the sleep quality and sleep quantity of the elderly in the experimental group were improved.

7.6.2 Community implications

Many Chinese people may receive Chinese medicine concurrently with Western medicine. Their openness and willingness to accept different forms of therapy allow Chinese people to draw the best from both systems (Mukai, 1999). Approximately 50% to 60% of the Hong Kong population have the experience of consulting TCM practitioners (Tang & Wong, 1998). The results of a recent survey conducted in Hong Kong showed that 78.40% of respondents support the view that government clinics should also include consultation services offered by TCM practitioners ("Survey conducted by", 2000). The impending legislation on Chinese medicine in Hong Kong indicates that the community has high expectations for the integration of Western and Chinese medicine (Lau & Yu, 2000).

The evaluation of TCM should be based on the best available empirical evidence that is being tested by scientific methods, so that the integration of Chinese and Western medicine into the existing health care system will be successful. The current study which adopted an experimental approach to the examination of the therapeutic effects of auricular therapy serves as a forerunner for future studies in this area. Community efforts should be made to register all randomized trials in TCM and to regularly review and disseminate the evidence from organized research (Tang & Wong, 1998).

Testing and using alternative therapies is not only a local concern, but also reflects worldwide interest. The WHO has set up an 'Office for the

Evaluation of Traditional Medicines' and has developed guidelines for the evaluation of these medicines (World Health Organisation, 1991). The results of this study may help to further stimulate global interest in examining the therapeutic and diagnostic value of this therapy so that more scientific evidence can be gathered to justify its clinical applications.

7.6.3 Professional implications

It is emphasized that nurses have a moral duty to adopt or facilitate complementary therapies within their practice particularly if patients request such care (Norton, 1995). Nurses are already embracing complementary and alternative therapies (CAM) techniques, which may fit well within their philosophy of care for their patients (Stone, 1999). With appropriate training, nurses could easily become competent in almost any branch of the complementary therapies (Lewith 1996). As Bryar (1994) emphasizes, nursing professionals should be lead to work more autonomously, and they are already able to use the full range of their skills to meet individual and community needs.

The Medical Service Development Committee of the Hospital Authority (HA) in Hong Kong has recently passed a proposal submitted by the Nursing Division to reorganize the development of nursing practice. Nurses are given the opportunity to take on expanded or extended roles such as nurse practitioner, nurse consultant and case manager to provide more cost-

effective care for patients. The direction has already been set for further development of nurse clinics focused on the improvement in the quality and cost-effectiveness of patient care (Hospital Authority, 2001, p.6). To keep pace with the rapid expansion of complementary therapies and holistic health care, the nurse practitioner should be an advocate for his/her clients encouraging them acquire optimal health care. At the same time, nurse practitioners themselves should pursue ongoing education and research in this dynamic health care system (Slagle, 1996).

Adopting auricular therapy as a nursing therapeutic is one of the alternatives for expanding the repertoire of interventions to enhance the quality of patient care. Nursing care which utilizes auricular therapy as a complementary therapy for treating insomnia among the elderly is based on the Rogerian conceptual model of Integrality which views the person and environment as complementary multi-dimensional energy fields engaged in interactions and repatterning to promote health and improve sleep conditions.

Nurses in the United States and Great Britain are also in the process of extending nursing practice to include the use of therapies which in recent years have not been considered within the sphere of normal practice (MaCabe, 1996). Therefore, after proper training, nurses should be proactive in seeking to improve and develop the holistic care of their patients by incorporating the principles of TCM into nursing after proper

training.

CHAPTER 8

CONCLUSION

8.1 Conclusion

To conclude, this randomized clinical trial has demonstrated significant results related to sleep improvement in the elderly through the use of auricular therapy with magnetic pearls. Participants in the experimental group demonstrated significant sleep improvement as was reflected by increased nocturnal sleep time and sleep efficiency when compared with participants in the control groups. Since there were no significant differences in the sleep parameters between the two control groups after the therapy, one would thus question whether there is evidence to show that physical presence of seed-like objects like Semen Vaccariae could induce any effect on the acupoints if no pressing was applied. It could be argued that the therapeutic effects that were observed in the experimental group were solely due to magnetic effects rather than the physical pressure induced by the pearls on the acupoints.

When the therapeutic effects of auricular therapy were evaluated in the experimental group, there were no significant differences in the therapeutic effects on participants (a) in different age groups, (b) having suffered from

insomnia for a different number of years, or (c) commencing treatment on different sides of the ear. The long-term effects of the auricular therapy using magnetic pearls were present in selected cases followed up at specific intervals after all treatments ceased. The findings of this study indicate that there are no significant differences in the therapeutic effects on the experimental group participants with diverse traditional Chinese diagnosis of insomnia even if the treatment protocol was standardized. This further suggests that a standardized protocol of acupoints selection might be appropriate for the ageing population who are homogeneous in terms of age and general health status.

In general, auricular therapy using magnetic pearls is cost-effective, hygienic, with fewer side effects, and more easily accepted by the clients than many other complementary therapies for insomnia. The results of this study could stimulate global interest in examining the therapeutic and diagnostic value of this therapy so that more scientific evidence could be gathered to justify its clinical applications. Auricular therapy based on the philosophy of TCM have greater potential for usefulness with the theory of Rogers's Science of Unitary Human Beings because they tend to reflect a more unitary view of the individual through the provision of holistic care which includes attending to a person's body, mind and spirit.

Further research is needed to confirm and extend these findings in the geriatric population before evidence of a strong causal relationship can be

established. Clarification of its mechanism of action would be assisted by future randomized controlled trials, as well as by employing both objective and subjective measures to evaluate therapeutic effectiveness.

8.2 Limitations of the study

As in most studies, some threats to the internal and external validity of this research were evident and so a degree of caution is required when considering the results.

Although actigraphic monitoring is claimed to be a reliable measure for estimating the treatment effects in this study, it may not be as accurate a measure of sleep as the polysomnogram (PSG). Changes in different sleep stages due to the therapy cannot be estimated. Night-to-night variability of a change in the sleeping pattern of subjects may also be affected by emotional or environmental factors other than the treatment itself. However due to the cost and time involved, and in order to maintain the compliance rate of the participants, daily actigraphic monitoring throughout the treatment protocol was not considered.

The single blind approach in this experimental study was inevitable, as the therapies were administered by the researcher who is aware of the type of therapy the participants received. Attempts were made to minimize personal bias in the interpretation of results, such as using objective

measurements to evaluate program effectiveness, and inviting the staff in the hostels who did not have prior knowledge about the type of intervention that the participants were receiving to assist with filling in the sleep diaries.

The males in the experimental group all demonstrated marked improvement after the therapy. However due to the small number of male participants enrolled in this study, gender differences on the therapeutic effects could not be concluded. It was also found that the male:female ratio (1:10) in this study was similar to the ratio of residents in the majority of the hostels participating in this study. Additionally, the final sample was shaped by subject self-selection and therefore may not be representative of all community elderly with insomnia. Generalizability of results is therefore limited to those who have insomnia but have relatively stable health conditions similar to those residing in the hostels for the elderly.

Since the advantages of auricular therapy were highlighted in the health talk during recruitment of participants, a general expectancy effect related to the therapy occurred. The Hawthorne effect might also be present and create bias in the evaluation of positive improvements in the sleep parameters subjectively reported by the participants. This phenomenon is not unusual in many intervention studies when one expects positive changes to arise from the treatment received. However the problem of Hawthorne effect in this study was likely to be minimal, and attempts were made to validate subjective data using objective measurements.

8.3 Recommendations for future studies

The scientific approach used to evaluate the effectiveness of auricular therapy in this study was new and has not been adopted in previous studies with a similar focus, therefore the positive findings in this study need to be corroborated by other studies before evidence of a strong causal relationship can be established. It is recommended that further evaluative work and replication studies adopting a similar approach should be undertaken in various institutional settings for the elderly, e.g. private nursing homes, geriatric units of the hospitals, Care and Attention Homes for the elderly, Estates with housing for senior citizens, and elderly centers. Only after a strong causal relationship between the auricular therapy using magnetic pearls and sleep improvement has been established, can a wider adoption of this therapy be made in clinical settings. The more we work with the elderly, the more likely we are to understand their unique needs and adjust our treatment modalities accordingly.

There are strong objective and subjective data demonstrating that sleep disturbances in depressed elderly is common (Knowles & MacLean, 1990; Livingstone et al., 1993; Waxman et al., 1985), therefore similar studies can be conducted in the elderly with emotional problems. Adjustment in the selection of acupoints may be required to meet the needs of individual groups of participants who are homogenous in certain attributes. More

male subjects, if available, could be recruited in future studies so that gender differences on the therapeutic effects can be evaluated. The results of a survey in Hong Kong indicate that about 12% of people with age ranges from 18-65 expressed having an average of three nights per week of sleep disturbances for various reasons ("Twelve percent of Hong Kong people" 2001). Comparison studies using a similar approach could be considered in younger subjects as well.

Adoption of other well established sleep instruments could be considered to validate findings using existing measures. The Pittsburgh Subjective Sleep Quality Index (PSQI) is one of the examples that is widely adopted in many sleep studies (Buysse et al., 1992; Singh, Clements & Fiatarone, 1997); and PSG in random cases can provide a more comprehensive picture of the treatment effects on different sleep stages. Sleep latency is a nighttime sleep behaviour that could be influenced by napping (Floyd, 1995), therefore including daytime sleep monitoring can provide a better picture of the therapeutic effects on the 24-hour sleep/wake patterns of the participants.

The possibility of Hawthorne effect in future studies can be avoided if studies can be advertised as 'healthy lifestyle' rather than 'sleep' studies, with measurement of a range of variables in addition to sleep outcomes. An alternative approach can be considered using a cross-over design so that participants could serve as their own controls when comparisons of the

therapeutic effects are made. A longer follow up period after the therapy would not only help to avoid bias in the interpretation of results when a Hawthorne effect is present, but also evaluate whether an additional treatment protocol is required to "top-up" the effect at around three months after the therapy. Moreover, though significant improvement in the sleep conditions was seen in many experimental group participants after the therapy, the mean sleep efficiency index was below 85%. This indicates that a longer period of treatment using auricular therapy may be required to improve the status of clients' sleep from clinically impaired to normal. Due to the presence of allergic reactions induced by the tapes that adhere to the acupoints, better methods for fixing the magnetic pearls to the ears to decrease the problems of skin sensitivity can also be explored.

The exact mechanisms for the interaction of magnetic fields with biological tissues resulting in functional changes are still unknown. The controversial beliefs about the mechanism of magnetotherapy were raised when both positive claims (Bassett, 1982; Coghill, 2000; Nakagawa, 1976; Null, 1998) and negative claims (Finegold, 1999; Orpin, 1982) for the magnetic effects prevailed. Although the therapeutic effects of auricular therapy using magnetic pearls was demonstrated in this study, no attempt has been made to understand clearly how the magnetic pathway works, as that was beyond the scope of this study. Further studies from a biomedical perspective could be conducted to help us understand more deeply what the biological effects magnets have on the *Qi*, meridians and *Zang Fu* organs of the body.

Auricular therapy has a wide application in treating various disorders of the body and successful examples have been reported in previous studies, such as hypertension (Zhou et al. 1991), cocaine addiction (Margolin et al. 1993), olfactory acuity (Tanaka & Mukaino, 1999), pain management (Kitade & Hyodo, 1979; Li et al., 1994), and obesity (Alkaysi et al., 1991; Dung 1986; Xu & Fei, 1985). However most of these studies adopted either auricular acupuncture or seed pressing to achieve therapeutic effects. The side effects of these stimulation modalities thus limit the application of this therapy in clinical settings. Moreover, strong causal relationships between intervention and effects on a scientific basis cannot be confirmed because of the limitations of the design in most studies. Therefore more carefully designed clinical trials using magnetic pearls can be conducted to accumulate clinical experience using this form of treatment. In addition, the use of auricular points in the diagnosis of diseases as an objective and painless method for early diagnosis is also of great practical and theoretical significance (Chen, 1993; Ishchenko, Kozlova & Shevyev, 1991; Ming & Yang, 1997), and more studies in this area are justified.

REFERENCES (ENGLISH)

Academics studying tai chi. (1999, July 28). *Hong Kong Standard*, A03.

Ace, D. & Okubadejo, T. (1996). Teaching alternative therapies to diploma nursing students. *Nursing Times*, **92:40,** 40-41.

[ACT 2000] (Beta version 1.43.01). Ardsley, New York: Ambulatory Monitoring, Inc.

[ACTION Programme] (version 1.32). Ardsley, New York: Ambulatory Monitoring, Inc.

Alkaysi, G.K., Leindler, L., Bajusz, H., Szarvas, F. & Karacsonyi, S. (1991). The treatment of pathological obesity by a new auricular acupuncture method: a five-year clinical experience. *American Journal of Acupuncture*, **19:4,** 323-328.

Alster. K. & Sadeh, A. (1990). Artifact and pattern recognition in wrist actigraphy. *Journal of Polysomnographic Technology,* **Spring/Summer,** 27-30.

Ancoli, I.S., Parker, L., Sinaee, R., Fell, R.L. & Kripke, D.F. (1989). Sleep fragmentation in patients from a nursing home. *Journal of Gerontology,* **44:1**, M18-21.

Bassett, C.A.L. (1982). Claims for magnetotherapy. *Canadian Medical Association Journal,* **127:11**, 1079-1080.

Benitez, M.A. (1999, October 18). Traditional Chinese medicine practitioners prepare the herbs in Baptist University. *Hong Kong Standard*, I03.

Blake, J.A. (1992). Sleep and pharmacology. In R. McMahon (Ed.), *Nursing at night: A professional approach.* London: Scutari Press.

Borbely, A.A., Mattmann, P., Loepfe, M., Fellmann, I., Gerne, M., Strauch, I. & Lehmann, D. (1983). A single dose of benzodiazepine hypnotics alters the sleep EEG in the subsequent drug-free night. *European Journal of Pharmacology,* **89:1983**, 157-161.

Bronstein, J. (1996). Healing hands. *The Canadian Nurse,* **92:1**, 32-36.

Brooks III, J.O., Friedman, L., Bliwise, D.L. & Yesavage, J.A. (1993). Use of the wrist actigraph to study insomnia in older adults. *American Sleep Disorders Association and Sleep Research Society,* **16:2**, 151-155.

Bryar, R. (1994). An examination of the need of new nursing roles in primary health care. *Journal of Interprofessional Care,* **8:1**, 73-84.

Buysse, D.J., Reynolds, C.F., Monk, T.H., Hoch, C.C., Yeager, A.L. & Kupfer, D.F. (1992). *Sleep,* **14:4,** 331-338.

Candlin, S. (1997). Primary health care: directions for nursing practice and teaching. *Asian Journal of Nursing Studies,* **3:1,** 15-22.

Carskadon, M.A., Dement, W.C., Mitler, M.M., Guilleminalult, C., Zarcone, V.P. & Spiegel, R. (1976). Self-reports versus sleep laboratory findings in 122 drug-free subjects with complaints of chronic insomnia. *American Journal of Psychiatry,* **133:12,** 1382-1387.

Castor, D., Woods, D., Pigott, K. & Hemmes, R. (1991). Effect of sunlight on sleep patterns of the elderly. *Journal of the American Academy of Physician Assistants,* **4,** 321-326.

Chambers, M.J. (1994). Actigraphy and insomnia: A closer look (Part 1). *Sleep,* **17:5,** 405-408.

Chan, P. (1981). *Ear acupressure: Healing and treating pain by the therapeutic stimulation of acupuncture points in the ear by use of finger pressure.* Wellingborough: Thorsons Publishers Ltd.

Chen, G. (1991). Advances in researches on auriculo-acupoints. *Journal of Traditional Chinese Medicine*, **11:3,** 216-223.

Chen, H.P. (1993). Recent studies on auriculoacupuncture and its mechanism. *Journal of Traditional Chinese Medicine*, **13:2,** 129-143.

Chen, Z., Zhou, W.S., Hu, M.C. (1998). *Magnetotherapy*. Beijing: Public Health Press. *(in Chinese)*[1]

Clapin, F.E. (1986). Sleep patterns of aged persons in long-term care facilities. *Journal of Advanced Nursing*, **11:1,** 57-66.

Coghill, R. (2000). *The book of magnet healing: A holistic approach to pain relief.* New York: Fireside, Simon & Schuster.

Cole, R.J. & Kripke, D.F. (1988). Progress in automatic sleep/wake scoring by wrist actigraph (Abstract). *Sleep Research*, **17,** 331.

Cox, B.G. (1975). Patient motivation: A factor in weight reduction with auricular acupuncture. *American Journal of Acupuncture*, **3:4,** 339-341.

Curless, R., French, J.M., James, O.F.W. & Wynne, H.A. (1993). Is caffeine a factor in subjective insomnia of elderly people? *Age and Ageing*, **22,** 41-45.

Daley, B. (1997). Therapeutic touch, nursing practice and contemporary cuntaneous wound healing research. *Journal of Advanced Nursing*, **25:6,** 1123-1132.

Dang, F.M. (1995). Using auricular pressing therapy on 58 cases with insomnia. *Shanghai Journal of Acupuncture and Moxibustion*, **14:4,** 162. *(in Chinese)*[2]

Dorociak, Y. (1990). Aspects of Sleep. *Nursing Times*, **86:51,** 38-40.

Du, H. (1996). Auricular seed pressing therapy using Fright-Wind Pills 68 cases of insomnia. *Sichuan Journal of Traditional Chinese Medicine*, **14:5,** 54. (*in Chinese*)[3]

Dung, H.C. (1986). Attempts to reduce body weight through auricular acupuncture. *American Journal of Acupuncture*, **14:2,** 117-122.

Duxbury, J. (1994). Understanding the nature of sleep. *Nursing Standard*, **23:9,** 25-28.

Falco, S.M. & Lobo, M.L. (1995). Martha E. Rogers. In J.B. George (Ed.). *Nursing theories: The base for professional nursing practice* (4th ed). (pp.229-248). USA: Appleton & Lange.

Fan, W.H. & Wang, J.J. (1996). Acupuncture combined with auricular magnet on treating 83 cases with facial palsy. *Journal of Clinical Acupuncture and Moxibustion*, **12:12,** 11. (*in Chinese*)[4]

Fei, L.C. (1996). Auricular tapping and auricular magnet on 150 cases having mumps. *Journal of Clinical Acupuncture and Moxibustion*, **12:7-8,** 60. (*in Chinese*)[5]

Feng, C.X., Bai, X.H. & Du, Y. (1994). *Chinese auricular therapy* [中國耳穴療法]. Beijing: Scientific and Technical Documents Publishing House. (*Chinese-English edition*)

Feng, S.H. (1998). Clinical observation on combined therapies using acupuncture and auricular pressing therapy on cases with insomnia. *The Practical Journal of Integrating Chinese with Modern Medicine*, **11:7,** 646. (*in Chinese*)[6]

Ferrer, C.F., Bisson, R.U. & French, J. (1995). Circadian rhythm desynchronosis in military deployments: a review of current strategies. *Aviation, Space and Environmental Medicine*, **66:6**, 571-578.

Finegold, L. (1999). The physics of alternative medicine : Magnet therapy. *The Scientific Review of Alternative Medicine,* **3:1,** 26-33.

Floyd, J.A. (1995). Another look at napping in older adults. *Geriatric Nursing,* **16:13,** 136-138.

Fordham, M. (1991). Sleep disturbance. In J. Wilson-Barnett & L. Batehup (Ed), *Patient problems – A research base for nursing care.* London: Scutari Press.

Forty percent of the elderly have the problem of insomnia (1999). *Hong Kong Health Journal* (香港健康報), **6:4,** 1.

Gao, J.W, & Sun Y.X. (1996). Using auricular pill pressing therapy on cases with severe insomnia. *Journal of Shaanxi College of Traditional Chinese Medicine,* **19:4,** 27. (*in Chinese*)[8]

Gao, Y. (1995). Using auricular pressing therapy on 128 cases with insomnia. *Shanghai Journal of Acupuncture and Moxibustion,* **14:4,** 161-162. (*in Chinese*)[9]

Gardner-Abbate, S. (2000). Clinical considerations in treating the elderly. *Journal of Chinese Medicine,* **64,** 6-12.

Gislason, T., Reynisdottir, H., Kristbjarnarson, H. & Benediktsdottir, B. (1993). Sleep habits and sleep disturbances among the elderly – an epidemiological survey. *Journal of Internal Medicine,* **234:1**, 31-39.

Guan, Z.X., Li, H.F., Guan, Z.J. & Guan, Z.J. (1994). *Common disorders and auricular acupuncture.* Beijing: Jin Dun Press. (*in Chinese*)[7]

Guo, Y.H. (1996). Using auricular pressing therapy on treating insomnia. *Jiangsu Journal of Traditional Chinese Medicine,* **17:7,** 35-36. (*in Chinese*)[10]

Guo, Y.H. (1997). Using magnetic treatment on inflammation of cartilage of pinna. *Practical Journal of Medical Technology*, **4:11,** 883. (*in Chinese*)[11]

Hartmann, E. (1973). *The functions of sleep.* London: Yale University Press.

Hauri, P.J. & Wisbey, J. (1992). Wrist actigraphy in insomnia. *Sleep*, **15:4,** 293-301.

Hayter, J. (1983). Sleep behaviours of older people. *Nursing Research*, **32:4,** 242-246.

Heidt, P. (1981). Effect of therapeutic touch on anxiety level of hospitalized patients. *Nursing Research*, **30,** 32-37.

Hillman, A. (1986). *Alternative medicine – an introduction.* Bailliere Tindall.

Hong, C.Z., Lin, J.C., Bender, L.F., Schaeffer, J.N., Meltzer, R.J. & Causin, P. (1982). Magnetic necklace : Its therapeutic effectiveness on neck and shoulder pain. *Archives of Physical Medicine & Rehabilitation*, **63(10),** 462-466.

Hooyman, N.R. & Kiyak, H.A. (1993). *Social gerontology* (3rd edn). USA: The Annenberg/CPB Collection.

Hospital Authority (2001). *Executive summary on Medical Services Development Committee* (HA paper No.122, 7 March 2001). Hong Kong: Hospital Authority.

Hu, S.P. (1997). Clinical observation using auricular pressing therapy on 166 cases with insomnia. *Hunan Journal of Traditional Chinese Medicine*, **13:3,** 36. (*in Chinese*)[12]

Huang, D., Yuan, P., Yuan L. & Li, B.H. (1996). Using auricular pill pressing therapy on 30 cases with severe insomnia. *China Journal of Traditional Medical Science and Technology,* **4:5,** 302. (*in Chinese*)[13]

Huang, L.C. (1995). *Auricular diagnosis.* Beijing: Science & Technology Press. (*in Chinese*)[14]

Irwin, P. (1992). The physiology of sleep. In R. McMahon (Ed.) *Nursing at night: A professional approach* (pp. 30-42). London: Scutari Press.

Ishchenko, A.N., Kozlova, V.P. & Shevyev, P.P. (1991). Auricular diagnostics used in the system of screening surveys. *Medical Progress through Technology,* **17,** 29-32.

Jean-Louis, G., Zizi, F., Spielman, A., Hauri, P. & Taub, H. (1997a). The actigraph data analysis software: I. A novel approach to scoring and interpreting sleep-wake activity. *Perceptual and Motor Skills,* **85,** 207-216.

Jean-Louis, G., Zizi, F., Spielman, A., Hauri, P. & Taub, H. (1997b). The actigraph data analysis software: II. A novel approach to scoring and interpreting sleep-wake activity. *Perceptual and Motor Skills,* **85,** 219-226.

Jean-Louis, G., Zizi, F., Gizycki, H.V. & Hauri, P. (1999). Actigraphic assessment of sleep in insomnia: application of the actigraph data analysis software (ADAS). *Physiology and Behavior,* **65:4/5,** 659-663.

Jiang, J.P., Deng, D.H., Li, C.S., Xie, B.F., Yang, Q.F., Wu, J.Z. & Wu, Q.P. (1995). Clinical study and application of auricular magnet anesthesia for the operation of the thyroid. *Acupuncture Research,* **20:3,** 4-8. (*in Chinese*)[15]

Johnston, J.E. (1994). Sleep problems in the elderly. *Journal of American Academy of Nurse Practitioners,* **6:4,** 161-166.

Ju, L.S. (1997). Cases of sleepless treated by auricura-seed-pressing. *Shanghai Journal of Acupuncture and Moxibustion,* **16:3,** 15. (*in Chinese*)[16]

Keane, J., Ahmadi, J. & Gruen, P. (1993). Spinal epidural haematoma with subarachnoid haemorrhage caused by acupuncture. *American Journal of Neuroradiology*, **14:2,** 365-366.

Kenosian, C.V. (1995). Wound healing with noncontact therapeutic touch used as an adjunct therapy. *Journal of Wound, Ostomy, and Continence Nursing*, **22:2**, 95-99.

Kerr, S.M., Jowett, S.A. & Smith, L.N. (1996). Preventing sleep problems in infants: a randomized controlled trial. *Journal of Advanced Nursing*, **24,** 938-942.

King, A.C., Oman, R.F., Brassington, G.S., Bliwise, D.L. & Haskell, W.L. (1997). Moderate-intensity exercise and self-rated quality of sleep in older adults: a randomized controlled trial, *JAMA*, **277:1**, 32-37.

Kitade, T. & Hyodo, M. (1979). The effects of stimulation of ear acupuncture points on the body's pain threshold. *American Journal of Chinese Medicine*, **7:3,** 241-252.

Knowles, J.B. & MacLean, A.W. (1990). Age-related changes in sleep in depressed and healthy subjects: a meta-analysis. *Neuropsychopharmacology*, **3**, 251-259.

Krebs, D. (1983). Nursing in primary health care. *International Nursing Review*, **30:5,** 141-145.

Krieger, D. (1990). Therapeutic touch: Two decades of research, teaching, and clinical practice. *Imprint*, **37,** 83-88.

Kripke, D.F., Mullaney, D.J., Messin, S. & Wyborney, V.G. (1978). Wrist actigraphic measures of sleep and rhythms. *Electroencephalography and Clinical Neurophysiology*, **44,** 674-676.

Lam, S. (1999, September 13). Mainland still leads in Chinese Medicine. *Hong Kong Standard*, E07.

Lau, J.T.F. & Yu, A. (2000). The choice between Chinese medicine and western medicine practitioners by Hong Kong Adolescents. *American Journal of Chinese Medicine*, **28:1**, 131-139.

Lee, M. (1999, November 4). Science park to host herbal research centre. *Hong Kong Standard*, A04.

Lee, T.N. (1977). Lidocaine injection of auricular points in the treatment of insomnia. *American Journal of Chinese Medicine*, **5:1**, 71-77.

Levine, M.E. (1971). Holistic Nursing. *Nursing Clinics of North America*, **6**, 253.

Lewith, G.T. (1996). An account of nurses' role using complementary therapies. *Complementary Therapies in Nursing & Midwifery*, **2**, 130-133.

Li. J.Y., Song, G.Y., Li, M.Z., Sun, Q.H., Zhang, J.B. & Wang, C.P. (1995). Combined treatment using low voltage electrotherapy and auricular magnets on patients with gallstones. *Chinese Journal of Physical Therapy*, **18:3**, 159. (*in Chinese*)[17]

Li, Q.S., Cao, S.H., Xie, G.M., Gan, Y.H., Ma, H.J., Lu, J.Z. & Zhang, Z.H. (1994). Combined traditional Chinese medicine and Western medicine: relieving effects of Chinese herbs, ear-acupuncture and epidural morphine on postoperative pain in liver cancer. *Chinese Medical Journal*, **107:4**, 289-294.

Li, S.Z. & Tan, X.H. (1998). *Chinese therapeutic methods of acupoints* [中國穴位療法]. Hunan: Hunan Science & Technology Press. (*Chinese-English edition*)

Li, X.Y. (1997). Nursing care on cases with insomnia receiving auricular pressing therapy. *Tianjin Journal of Nursing Care*, **5:4,** 178. (*in Chinese*)[18]

Lian, N. & Yan, Q.M. (1990). Insomnia treated by auricular pressing therapy. *Journal of Traditional Chinese Medicine*, **10:3,** 174-175.

Liu, F. & Liu, Y.M. (1989). *Chinese medical terminology* [中國名詞彙編]. Hong Kong: The Commercial Press (Hong Kong) Ltd. (*Chinese-English edition*)

Liu, F.G. & Ni, X.H. (1997). Using herbal medicine with magnetic plaster on treating 42 cases with allergic rhinitis. *Journal of Chinese and Western Perspectives in Ear, Throat and Throat*, **5:3,** 135. (*in Chinese*)[19]

Liu, G.W. & Akira, H. (1998). *Fundamentals of acupuncture & moxibustion* [針灸學(基礎篇)]. Tianjin: Tianjin Science & Technology Translation & Publishing Corporation.

Liu, Y.C. (1995). *The essential book of traditional Chinese medicine (Vol. 2: Clinical Practice).* New York: Columbia University Press.

Liu, Y.M. (1998). Comparing the effects between using auricular pressing and acupuncture on 60 cases with insomnia. *Correspondence Journal of Traditional Chinese Medicine*, **17:3,** 33-34. (*in Chinese*)[20]

Livingstone, G., Blizard, B. & Mann, A. (1993). Does sleep disturbance predict depression in elderly people? A study in inner London. British *Journal of General Practice*, **43:376,** 445-448.

Lockley, S.W., Skene, D.J. & Arendt, J. (1999). Comparison between subjective and actigraphic measurement of sleep and sleep rhythms. *Journal of Sleep Research*, **8,** 175-183.

Low, J. & Reed, A. (1992). *Electrotherapy explained: Principles & practice.* London: Butterworth-Heinemann Ltd.

Mackey, R.B. (1995). Discover the healing power of therapeutic touch. *American Journal of Nursing,* **5:1**, 26-33.

Magnetech (No date). Tsubo-Mag magnetic pellets [Outline]. Available HTTP: http://www.healthtechnologies.com/magnets/tsubo.html [2000, February 1].

Manabe, K., Matsui, T., Yamaya, M., Sato-Nakagawa, T., Okamura, N., Arai, H. & Sasaki, H. (2000). Sleep patterns and mortality among elderly patients in a geriatric hospital. *Gerontology,* **46,** 318-322.

Mantle, F. (1996). Safe practices. *Nursing Times,* **92:6,** 36-38.

Margolin, A., Chang, P., Avants, S.K. & Kosten, T.R. (1993). Effects of sham and real auricular needling: implications for trials of acupuncture for cocaine addiction. *American Journal of Chinese Medicine,* **21:2,** 103-111.

Mao, L.Z. & Gong, X.Y. (1994). Prevention of drug reaction of the gastrointestinal tract by massage of otopoint with magnetic pearls. *Shanxi Journal of Nursing,* **9:1,** 35. (*in Chinese*)[21]

McCabe, P. (1996). Complementary therapy in nursing practice. *The Australian Journal of Holistic Nursing,* **3:1,** 4-11.

McIntosh, A. (1989). Sleep deprivation in critically ill patients. *Nursing,* **3:35,** 44-45.

Meehan, T.C. (1993). Therapeutic touch and postoperative pain: A Rogerian research study. *Nursing Science Quarterly,* **6:2,** 69-78.

Merlotti, L.A., Roehrs, .T.A., Roth, T., Salin-Pascual, R.J. & Zorick, F. (1992). Long-term study of the sleep of insomnia patients with sleep state misperception and other insomnia patients. *American Journal of Psychiatry,* **149:7,** 904-908.

Miller, M. (2000). Nocturnal polyuria in older people: pathophysiology and clinical implications. *Journal of the American Geriatric Society,* **48,** 1321-1329.

Ming, S.P. & Yang, S.Y. (1997). *Advanced textbook on traditional Chinese medicine and pharmacology (Vol. IV: Acupuncture and Moxibustion).* Beijing: New World Press.

Morin, C.M. (1993). *Insomnia: Psychological assessment and management.* New York: The Guilford Press.

Morin, C.M., Colecchi, C., Stone, J., Sood, R. & Brink, D.P. (1999). Behavioural and pharmcological therapies for late-life insomnia: A randomized controlled trial. *JAMA*, **281: 11**, 991-999.

Mukai, C.P.S.W. (1999). Chinese perspectives. *Geriatric Nursing,* **20:1**, 18-22.

Mullaney, D.J., Kripke, D.F. & Messin, S. (1980). Wrist-actigraphic estimation of sleep time. *Sleep,* **31:1,** 83-92.

Mulloney, S.S. & Wells-Federman, C. (1996). Therapeutic touch: A healing modaility. *Journal of Cardiovascular Nursing*, **10:3,** 27-49.

Nakagawa, K. (1976). Magnetic field-deficient syndrome and magnetic treatment. *Japanese Medical Journal*, **2745**, 24-32.

Nakra, B.R.S., Grossberg, G.T. & Peck, B. (1991). Insomnia in the elderly. American Family Physician, **43:2,** 477-483.

Neuman, B. (1989). *The Neuman Systems Model* (2nd edn). Norwalk : Appleton-Lange.

Null, G. (1998). Healing with magnets. London: Robinson Publishing Ltd.

Norton, L. (1995). Complementary therapies in practice: the ethical issues. *Journal of Clinical Nursing*, **4**, 343-348.

Norusis, M.J. (1998). *SPSS 8.0 guide to data analysis*. Chicago: Prentice-Hall.

Orpin, J.A. (1982). False claims for magnetotherapy. *Canadian Medical Association Journal*, **126**, 1375.

Orr, W.C., Altshuler, K.Z. & Stahl, M.L. (1982). *Managing sleep complaints*. Chicago: Year Book Medical Publishers.

Penson & Holloway (1989). Fringe benefits: alternative medicine in patient care. *Senior Nurse*, **8:9**, 9-10.

Perkin, M.R. (1994). A comparison of the attitudes shown by general practitioners, hospital doctors and medical students towards alternative medicine. *Journal of the Royal Society of Medicine*, **87:9**, 523-525.

Polit, D.F. (1996). *Data analysis and statistics for nursing research*. Stamford: Appleton & Lange.

Polit, D.F. & Hungler, B.P. (1997). *Essentials of nursing research: Methods, appraisal, and utlilization* (4th edn). Philadelphia: Lippincott.

Pollak, C.P., Perlick, D., Linsner, J.P., Wenston, J. & Hsieh, F. (1990). Sleep problems in the community elderly as predictors of death and nursing home placement. *Journal of Community Health*, **15:2**, 123-135.

Pollak, C.P., Prelick, D. & Linsner, J.P. (1992). Daily sleep reports and circadian rest-activity cycles of elderly community residents with insomnia. *Biological Psychiatry*, **32**, 1019-1027.

Portney, L.G. & Watkins, M.P. (1993). *Foundation of clinical research: Applications to practice*. London: Appleton & Lange.

Qi, F.J. (1999). *Diagnosis and treatment using Homuncular Reflex Theory.* Beijing: Chinese Medicine, Science & Technology Press. (*in Chinese*)[22]

Qiu, H.Y. (1996). Using auricular pressing therapy on 65 cases with insomnia. *Shaanxi Journal of Traditional Chinese Medicine,* **17:3,** 126. (*in Chinese*)[23]

Qin, R.H. (1998). Using auricular pressing therapy on 126 cases with insomnia. *Shanxi Journal of Traditional Chinese Medicine,* **14:6,** 31. (*in Chinese*)[24]

Quinn, J.F. & Strelkauskas, A.J. (1993). Psychoimmunologic effects of therapeutic touch on practitioners and recently bereaved recipients: A pilot study. *Advances in Nursing Science,* **15:4,** 13-26.

Ramey, D.W. (1998). Magnetic and electromagnetic therapy. *The Scientific Review of Alternative Medicine,* **2:1,** 13-19.

Rankin-Box, D. (Ed.) (1988). *Complementary health therapies: A guide for nurses and the caring professions.* London: Croom Helm.

Reynolds, C.F., Kupfer, D.J., Hoch, C.C. & Sewitch, D.E. (1985). Sleeping pills for the elderly: are they ever justified? *Journal of Clinical Psychiatry,* **46:2 Pt 2),** 9-12.

Rogers, M.E. (1970). *The theoretical basis of nursing.* Philadelphia: Davis.

Roy (1984). *Introduction to nursing: An Adaptation Model* (2nd edn). Prentice Hall: Englewood Cliffs NJ.

Sadeh, A., Alster, J., Urbach, D. & Lavie, P. (1989). Actigraphically based autonomic bedtime sleep-wake scoring: validity and clinical applications. *Journal of Ambulatory Monitoring,* **2,** 209-216.

Sadeh, A., Hauri, P.J., Kripke, D.F. & Lavie, P. (1995). The role of actigraphy in the evaluation of sleep disorders. *Sleep,* **18:4**, 288-302.

Shang, L. (1995). Using auricular pill pressing therapy on 35 cases with insomnia. *Yunnan Journal of Traditional Chinese Medicine and Materia Medica,* **16:4,** 23. (*in Chinese*)[25]

Shang, L.C. (1997). Auricular pressing therapy using Semen Vaccariae on cases with insomnia due to nervous disorders. *Henan Tradtional Chinese Medicine,* **17:6,** 372. (*in Chinese*)[26]

Shang, Y.T. (1996). Clinical observation using auricular therapy on 32 cases with insomnia. *Gansu Journal of Traditional Chinese Medicine,* **9:5,** 34. (*in Chinese*)[27]

Shen, Y.P., Zheng, M.Y. & Pan, L.G. (1997). Low voltage electric current combined with magnetic therapy on treating 150 cases of gallstones. *Fujian Medical Journal,* **19:5,** 35. (*in Chinese*)[28]

Sherwin, D.C. (1992). Traditional Chinese Medicine in rehabilitation nursing practice. *Rehabilitation Nursing,* **17:5,** 253-255.

Shi, X.M. & Zhang, M.C. (1998). *A Chinese-English dictionary of acupuncture & moxibustion* [漢英雙解針灸大辭典]. Beijing: Huaxia Publishing House. (*Chinese-English edition*)

Shuttleworth, A. (1989). Should alternative medicine come into the fold? *The Professional Nurse,* **March,** 277-278.

Singh, N.A., Clements, K.M. & Fiatarone, M.A. (1997). Sleep, sleep deprivation, and daytime activities: a randomized controlled trial of the effect of exercise on sleep. *American Sleep Disorders Association and Sleep Research Society,* **20:2,** 95-101.

Slagle, M.W. (1996). The nurse practitioners and issues of alternative therapies. *Nurse Practitioner,* **21:2**, 16-19.

Sleep research team of NHS (1997a). *Sleep questionnaire* [睡眠狀況問卷]. Hong Kong: Department of Nursing & Health Sciences, The Hong Kong Polytechnic University.

Sleep research team of NHS (1997b). *Sleep log* [睡眠狀況記錄]. Hong Kong: Department of Nursing & Health Sciences, The Hong Kong Polytechnic University.

Soong, Y.S. (1975). The treatment of exogenous obesity employing auricular acupuncture. *American Journal of Chinese Medicine*, **3:3,** 285-287.

Starn, J.R. (1998a). Energy healing with women and children. *JOGNN*, **27:5,** 576-584.

Starn, J.R. (1998b). The path to becoming an energy healer. *Nurse Practitioner Forum*, **9:4,** 209-216.

Steckel, C.M. & King, R.P. (1996). Nursing grand rounds: Therapeutic touch in the coronary care unit. *Journal of Cardiovascular Nursing*, **10:3,** 50-54.

Stone, J. (1999). Using complementary therapies within nursing: some ethical and legal considerations. *Complementary Therapies in Nursing and Midwifery*, **5,** 46-50.

Suen, L.K.P., Wong, T.K.S. & Leung, A.W.N. 'Is there a place for auricular therapy in the realm of nursing?' *Complementary Therapies in Nursing and Midwifery.* 7(3): 132-139, 2001.

Survey conducted by the Hong Kong Baptist University: 80% public support the establishment of Chinese Medicine Outpatient Clinic (2000). *Hong Kong Health Journal* (香港健康報), **No.6.**

Swift, C.G. & Shapiro, C.M. (1993). Sleep and sleep problems in elderly people. *British Medical Journal,* **306,** 1468-1471.

Tanaka, O. & Mukaino, Y. (1999). The effect of auricular acupuncture on olfactory acuity. *American Journal of Chinese Medicine,* **27:1,** 19-24.

Tang, S.Y. (1997). Using auricular therapy on 3 cases with chronic disorders. *Journal of Massage and Dao-Yin,* **5,** 40-41. (*in Chinese*)[29]

Tang, J.L. & Wong, T.W. (1998). The need to evaluate the clinical effectiveness of traditional Chinese medicine. *Hong Kong Medical Journal,* **4:2,** 208-210.

The Computing Services Centre (1996). *Introduction to SPSS for windows.* Hong Kong: City University of Hong Kong.

Todd, B. (1987). The placebo effect: real or imaginary? *Geriatric Nursing,* May/June, 154 &156.

Twelve percent of Hong Kong people suffered from three nights per week of sleep disturbances (20 December, 2001). *Shing Pao Daily News.*

Usui, A., Ishizuka, Y., Obinata, I., Okado, T., Fukuzawa, H. & Kanba, S. (1999). Validity of sleep log compared with actigraphic sleep-wake state II. *Psychiatry and Clinical Neurosciences,* **53,** 183-184.

Vallbona, C., Hazlewood, C.F. & Jurida, G. (1997). Response to pain to static magnetic fields in postpolio patients: A double-blind pilot study. *Archives of Physical Medicine & Rehabilitation,* **78,** 1200-1203.

Wan, D.M. (1998). Auricular magnetic therapy on 240 cases of gallstones. *Traditional Chinese Medicinal Research,* **11:6,** 24-25. (*in Chinese*)[30]

Wang, S.S. (1996). *Advanced textbook on traditional Chinese medicine and pharmacology (Vol. III: Internal medicine).* Beijing: New World Press.

Wang, S.Y. (1998). Discussion on insomnia treated by auricular-plaster with seed of Vaccaria Segetalis. *Journal of Clinical Acupuncture and Moxibustion*, **14:6,** 35-36. (*in Chinese*)[31]

Wang, Y. (1998). Auricular seed pressing therapy using Alpinia Oxyphyllae Fructus on 39 cases with insomnia. *Hebei Journal of Traditional Chinese Medicine*, **20:5,** 303. (*in Chinese*)[32]

Wang, Z., Yu, D.X. & Wang, S.Y. (1993). *Auricular diagnostics of China.* Guangzhou: Zhongshan University Press. (*in Chinese*)[33]

Waxman, H.M., McCreary, G., Weinrit, R.M. & Carner, E.A. (1985). A comparison of somatic complaints among depressed and non-depressed older persons. *Gerontologist*, **25,** 501-507.

Wirth, D.P., Richardson, J.T., Eidelman, W.S. & O'Malley, A.C. (1993). Full thickness dermal wounds treated with noncontact therapeutic touch: a replication and extension. *Complementary Therapies in Medicine*, **1:3,** 127-132.

Wong, F.K.Y. (1998). The integration of traditional Chinese health practices in nursing. *Reflections*, **Second Quarter,** 20-21.

World Health Organization (1991). *Report from the programme on traditional Chinese medicine: Guidelines for the assessment of herbal medicine.* Geneva: World Health Organization.

Wu, X.P. (1998a). Clinical observation using auricular pressing therapy on 60 cases with either insomnia or somnolence. *Chinese Acupuncture and Moxibustion*, **11,** 673-674. (*in Chinese*)[34]

Wu, X.P. (1998b). Clinical observation on the bi-directional regulatory mechanism using auricular pressing therapy on cases with either insomnia or somnolence. *Shanghai Acupuncture and Moxibustion*, **17:4,** 15. (*in Chinese*)[35]

Wu, X.Q., Tian, J. (1998). Auricular pressing therapy using Borneolum combined with scalp acupuncture on treating cases with insomnia. *Shanghai Journal of Acupuncture and Moxibustion,* **17:4,** 47. *(in Chinese)*[36]

Xie, T.X., Dai, X.H. & Zhuang, Y.Z. (1988). *Self study guide on clinical Chinese internal medicine.* Fujian : Fujian Science & Technology Press. *(in Chinese)*[37]

Xing, C.H., Tang T. (1996). Using auricular pressing therapy combined with Chinese herbal medicines on 25 cases with insomnia. *Gansu Journal of Traditional Chinese Medicine,* **17:3,** 49-50. *(in Chinese)*[38]

Xu, B. & Fei, J.Z. (1985). Clinical observation of the weight-reducing effect of ear acupuncture in 350 cases of obesity. *Journal of Traditional Chinese Medicine,* **5:2,** 87-88.

Xu, L.Q. (1998). Combined therapies using acupuncture and auricular pressing therapy on 63 cases with differential diagnosis of insomnia. *Clinical Journal of Anhui Traditional Chinese Medicine,* **10:2,** 80-81. *(in Chinese)*[39]

Xu, Y.W. (1992). Treatment of acute pain with auricular pellet pressure on ear shenmen as the main point. *Journal of Traditional Chinese Medicine,* **12:2,** 114-115.

Yang, C.L. (1988). Clinical observation of 62 cases of insomnia treated by auricular point imbedding therapy. *Journal of Traditional Chinese Medicine,* **8:3,** 190-192.

Yang, J.Q., Zhang, Z. (1998). Using auricular seed pressing therapy on 36 cases with severe insomnia. *Journal of Traditional Chinese Medicine and Chinese Materica Medica of Jilin,* **6,** 41. *(in Chinese)*[40]

Yang, X.B. (1997). Acupuncture combined with auricular pressing therapy on 42 cases with insomnia. *Chinese Acupuncture and Moxibustion,* **17:5,** 284. *(in Chinese)*[41]

Yu, R.H. (1993). *Practical dictionary for Chinese internal medicine.* Beijing: China Science & Technology Press. (*in Chinese*)[42]

Yuan, Y.X., Ren, J.X., Huang, L. & Gao, G.Z. (1996). *Chinese-English dictionary of traditional Chinese medicine.* Beijing: People's Medical Publishing House. *(Chinese-English edition)*

Zhang, D.Z. & Wu, X.L. (1991). *The basic knowledge of traditional Chinese medicine.* Hong Kong: Hai Feng Publishing Company.

Zhang, Y. (1997). Clinical observation using combined therapy of auricular pressing therapy and acupressure on 80 cases with insomnia. *Journal of Fundamentals Traditional Chinese Medicine,* **3,** 80-81. (*in Chinese*)[43]

Zhao, R.X. (1996). Using auricular magnet treating 28 cases with headache. *Chinese Acupuncture and Moxibustion,* **12,** 49. (*in Chinese*)[44]

Zhou, R.X., Zhang, Y.H., Wang, J.L., Chang, H. , Fang, J., Chen, E.Z., Xie, J.G. & Liu, M.R. (1991). Anti-hypertensive effect of auriculo-acupoint pressing therapy: clinical analysis of 274 cases. *Journal of Traditional Chinese Medicine,* **11:3,** 189-192.

Zhu, M.L. & Cao, J.P. (1998). Observation of effect using magnetic treatment and ultra shortwave therapy on treating 156 cases of pseudocyst of pinna. *Jiangxi Journal of Herbal Medicine,* **33:3,** 166-167. (*in Chinese*)[45]

Zhu, J.H. (1998). Using auricular pressing therapy on 38 cases with insomnia. *Journal of Clinical Acupuncture and Moxibustion,* **14:9,** 35-36. (*in Chinese*)[46]

Zomer, J., Pollack, I., Tzinschinsky, O., Epstein, R., Alster, J. & Lavie, P. (1987). Computerized assessment of sleep time by wrist actigraph (Abstract). *Sleep Research,* 16, 592.

REFERENCES (CHINESE)

1 陳植，周萬松，胡梅村 (1998)。磁療法。北京：人民衛生出版社。

2 黨鳳明 (1995)。 耳穴貼壓治療失眠症 58 例。上海針灸雜誌， **14:4,** 162。

3 杜紅 (1996)。耳穴貼壓驚風丸治療不寐 68 例。四川中醫，**14:5,** 54。

4 范婉華、王靜娟 (1996)。針刺加磁珠耳貼治療面癱 83 例。針灸臨床雜誌, **12:12,** 11.

5 裴良才(1996)。耳穴刺血配合耳穴磁珠壓迫法治療流行性腮腺炎 150 例療效觀察。針灸臨床雜誌，**12:7-8,** 60。

6 馮淑紅 (1998)。針刺配合耳壓治療失眠症臨床觀察。實用中西醫結合雜誌，**11:7,** 646。

7 管遵信、李惠芳、管鍾潔 及 管鍾浚編著 (1994)。 常見病耳針療法。 北京：金盾出版社。

8 高姬偉，孫玉霞 (1996)。耳穴壓丸治療頑固性失眠。陝西中醫學院學報，**19:4,** 27。

9 高揚 (1995)。 耳穴貼壓治療失眠 128 例。上海針灸雜誌， **14:4,** 161-162。

10 郭永紅 (1996)。耳穴貼壓治療失眠症 。江蘇中醫，**17:7,** 35-36。

11 郭玉紅 (1997)。磁鐵治療非化膿性耳廓軟骨膜炎。實用醫技雜誌，**4:11,** 883。

12 胡素萍 (1997)。耳穴貼壓治療不寐 166 例臨床觀察。湖南中醫雜誌，**13:3,** 36。

13 黃迪，袁萍，袁莉，李炳慧 (1996)。耳穴壓丸治療頑固性失眠 30 例。中國中醫葯科技 ，**4:5,** 302。

14 黃麗春編著 (1995)。 耳穴診斷治療學。 北京：科學技術文獻出版社。

15 蔣建平、鄧登和、李長生、謝伯福、楊秋風、吳敬周、武青萍 (1995)。耳穴磁珠麻醉法在甲狀腺手術的臨床研究和應用。針刺研究，**20:3,** 4-8。

16 鞠錄升 (1997)。耳穴貼壓治療失眠 53 例。上海針灸雜誌， **16:3,** 15。

17 李景玉、宋國艷、李明子、孫啓海、張靜波、王春萍 (1995)。低頻脉冲電和耳穴敷磁等綜合治療胆結石。中華理療雜誌, **18:3,** 159。

18 李曉岩 (1997)。耳壓法治療失眠症的護理。天津護理，**5:4,** 178。

19 劉福官、倪霞紅 (1997)。鼻鼽湯加耳穴磁貼治療過敏性鼻炎 42 例初步觀察。中國中西醫結合耳鼻咽喉科雜誌，**5:3,** 135。

20 劉玉梅 (1998)。耳壓針刺並治療失眠 60 例。中醫函授通訊，**17:3,** 33-34。

21 毛麗珍、鞏曉燕 (1994)。耳穴磁珠按摩預防藥物性胃腸道反應。山西護理雜誌，**9:1,** 35。

22 齊鳳軍 (1999)。人體全息診療大法。北京：中國醫藥科技出版社。

23 邱海雲 (1996)。耳穴貼壓治療失眠 65 例。陝西中醫，**17:3,** 126。

24 秦榮華 (1998)。耳穴貼壓治療失眠症 126 例。山西中醫，**14:6,** 31。

25 向麗 (1995)。 耳穴壓丸法治療失眠 35 例。雲南中醫中葯雜誌，**16:4,** 23。

26 尚良翠 (1997)。王不留行耳穴貼壓治療神經衰弱性失眠。河南中醫，**17:6,** 372。

27 尚亞婷 (1996)。耳壓法治療不寐 32 例臨床觀察。甘肅中醫 ，**9:5,** 34。

28 申玉萍、鄭明瑩、潘良國 (1997)。耳穴低頻脉冲電和旋磁治療胆石症 150 例。福建醫學雜誌，**19:5，**35。

29 唐仕勇 (1997)。耳穴除頑疾 3 例。按摩與導引，**5,** 40-41。

30 萬冬梅 (1998)。耳穴貼壓合磁力治療胆結石 240 例。中醫研究，**11:6,** 24-25。

31 王紹英 (1998)。耳穴按壓王不留籽治療不寐症的探討。針灸臨床雜誌，**14:6,** 35-36。

32 王堯 (1998)。益智仁籽耳壓治療失眠 39 例。河北中醫，**20:5,** 303。

33 王正、余德賢、王素雲 (1993)。中國耳穴診治學。廣州：中山大學出版社。

34 伍曉萍 (1998a)。耳穴貼壓治療失眠、嗜睡 60 例臨床觀察。中國針灸，**11, 673-674**。

35 伍曉萍 (1998b)。耳穴貼壓對失眠、嗜睡的雙向調節觀察。上海針灸雜誌，**17:4, 15**。

36 吳錫強，田健 (1998)。冰片耳壓配合頭針治療失眠症。上海針灸雜誌，**17:4, 47**。

37 謝天熙、戴西湖、庄玉柱 (1988)。中醫內科臨証自學必讀。福建：福建科學技術出版社。

38 邢崇慧，唐濟 (1996)。耳穴貼壓配合中葯治療失眠 25 例。雲南中醫中葯雜誌，**17:3, 49-50**。

39 徐立群 (1998)。刺加耳穴貼壓辨証治療不寐 63 例。安徽中醫臨床雜誌，**10:2, 80-81**。

40 楊集群，張姝 (1998)。耳穴壓籽法治療頑固性失眠 36 例。吉林中醫葯，**6, 41**。

41 楊曉碧 (1997)。針刺加耳穴貼壓治療不寐 42 例。中國針灸，**17:5, 284**。

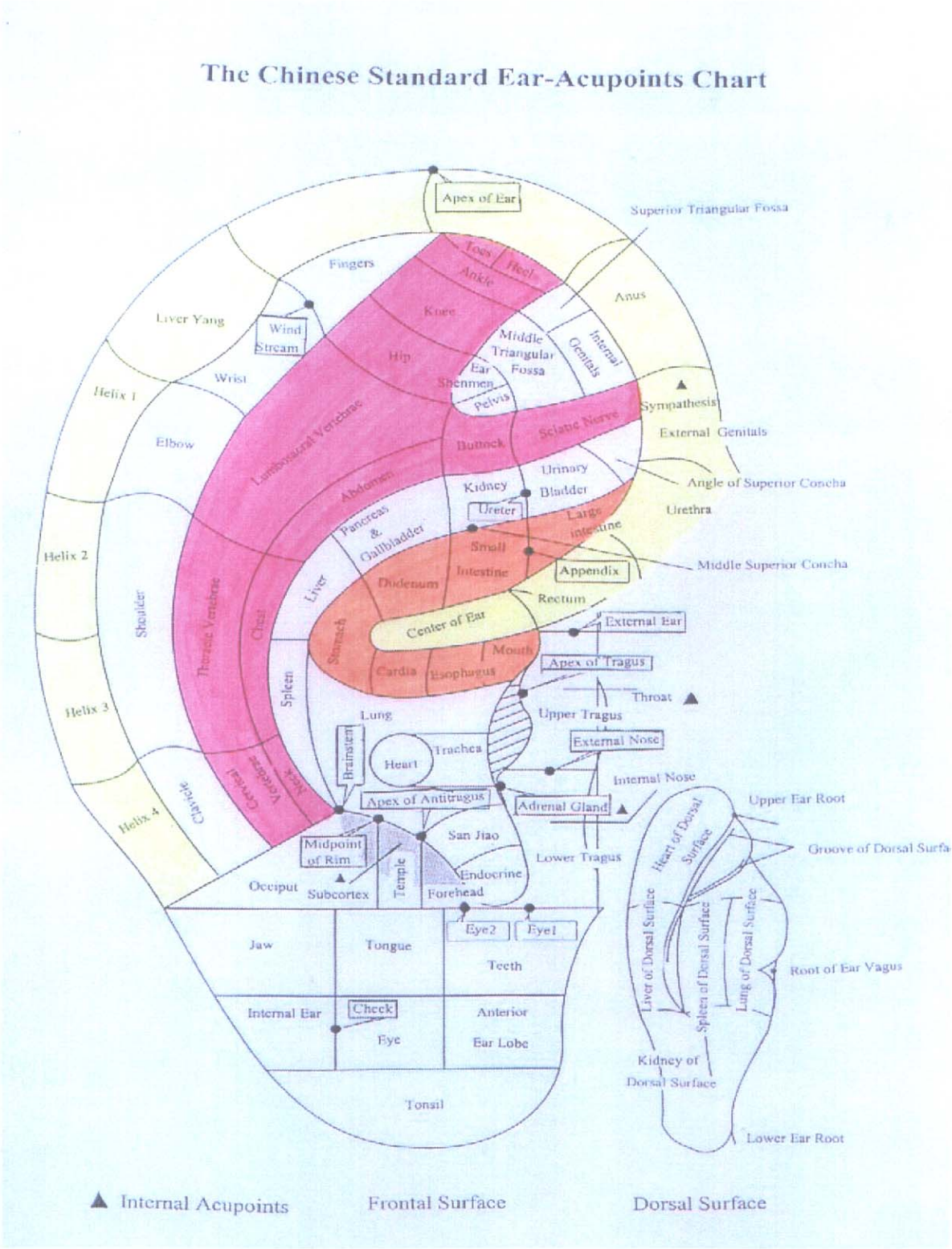
42 余海若 (1993)。實用中醫內科表典。北京：中國科學技術出版社。

43 張燕 (1997)。耳穴貼壓配合指針治療失眠 80 例臨床觀察。中國中醫基礎醫學雜誌，**3, 80-81**。

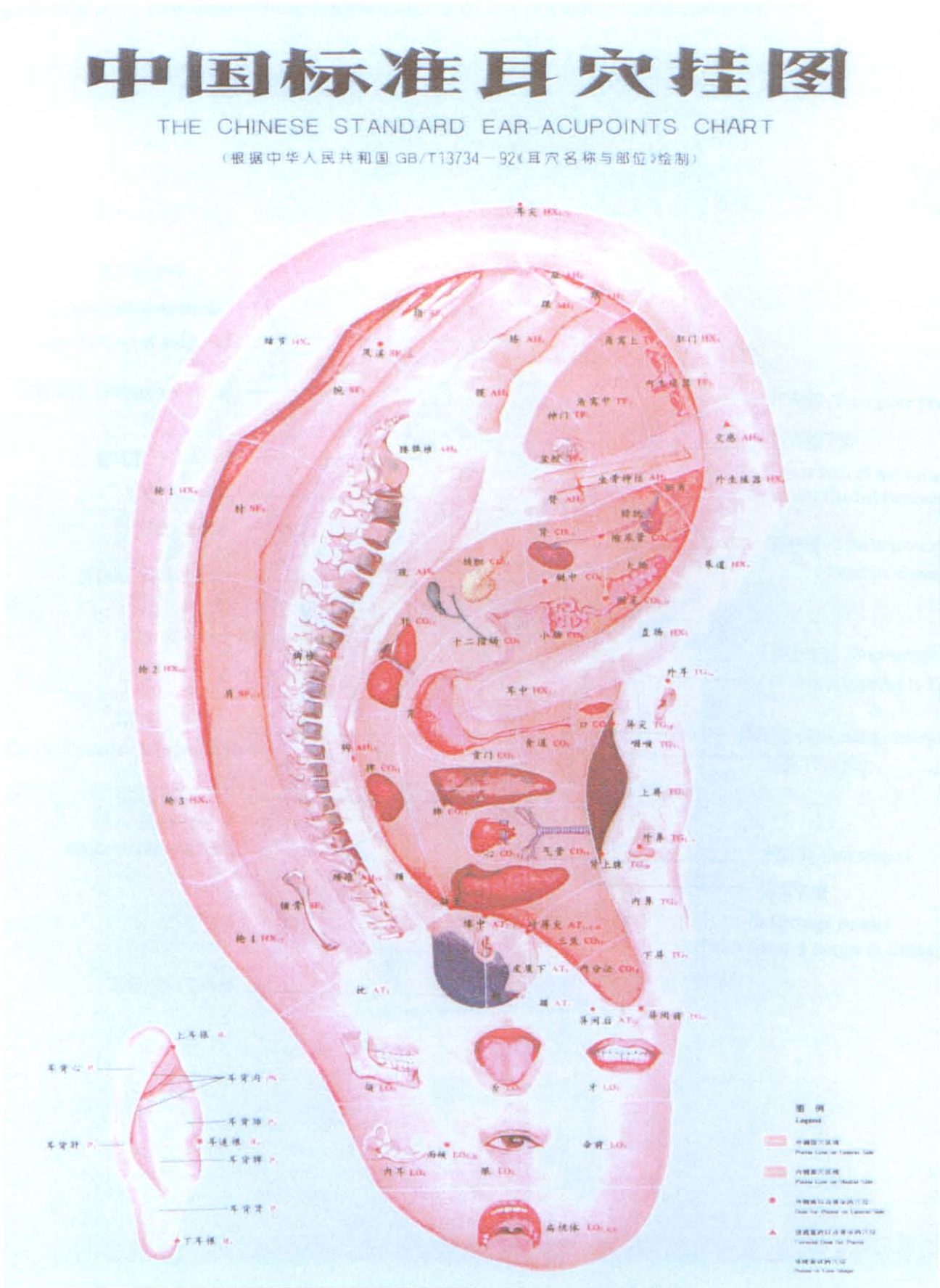
44 趙瑞雪 (1996)。耳穴貼磁治療頭痛 28 例。中國針灸，**12, 49**。

45 朱美蘭、曹建平 (1998)。敷磁和超短波治療耳廓假性囊腫 156 例療效觀察。江西醫藥，**33:3, 166-167**。

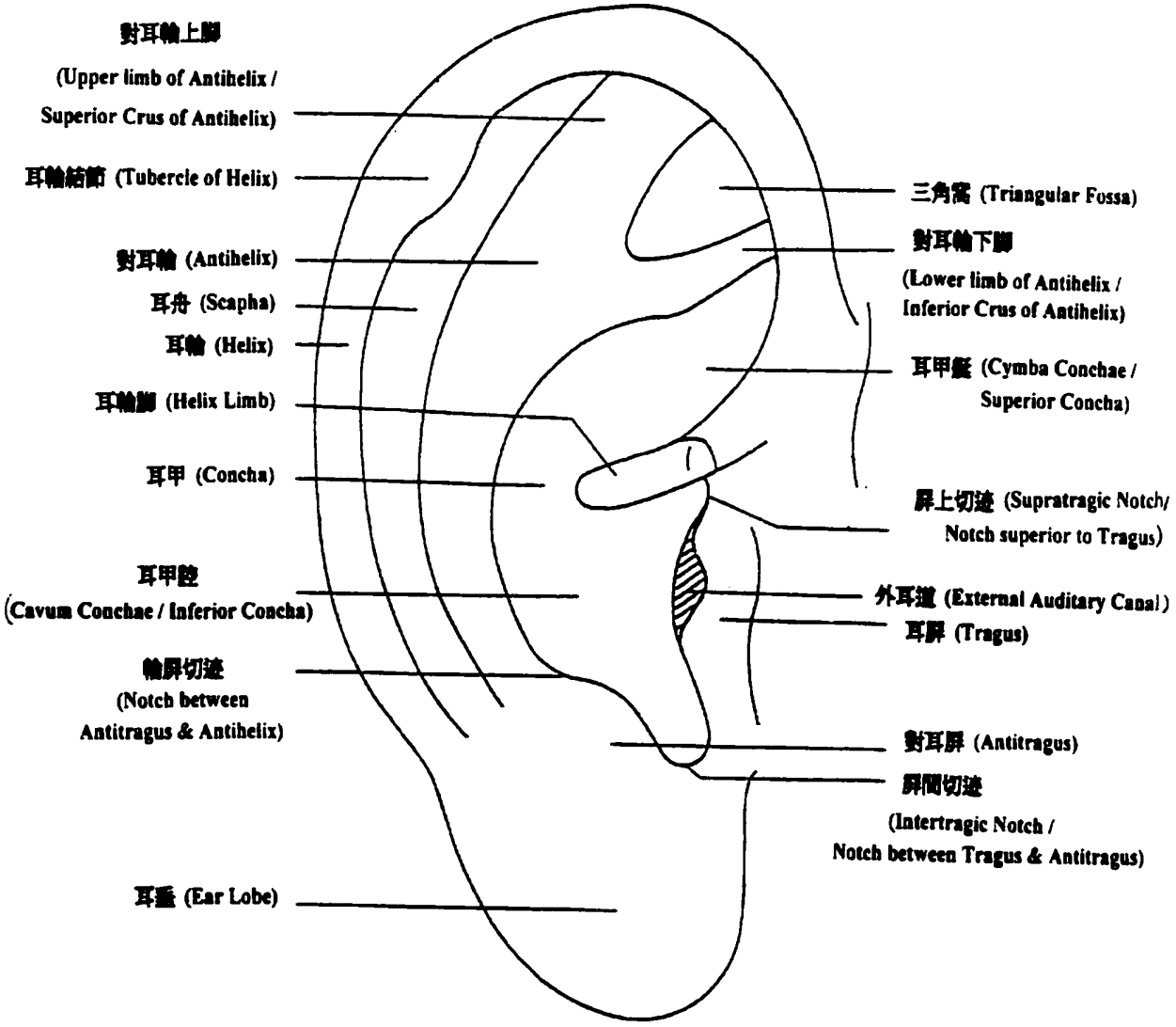
46 朱金宏 (1998)。耳穴貼壓法治療失眠症 38 例。針灸臨床雜誌，**14:9, 35-36**。


The Chinese Standard Ear-Acupoints Chart
Apex of Ear
Superior Triangular Fossa
Fingers
Toes
Heel
Ankle
Knee
Anus
Liver Yang
Wind Stream
Hip
Middle Triangular Fossa
Internal Genitals
Wrist
Ear Shenmen
Pelvis
Sympathesis
Helix 1
Elbow
Lumbosacral Vertebrae
Buttock
Sciatic Nerve
External Genitals
Urinary Bladder
Kidney
Angle of Superior Concha
Abdomen
Ureter
Urethra
Pancreas & Gallbladder
Large intestine
Helix 2
Small Intestine
Middle Superior Concha
Appendix
Duodenum
Rectum
Shoulder
Thoracic Vertebrae
Chest
Liver
Center of Ear
External Ear
Stomach
Mouth
Apex of Tragus
Cardia
Esophagus
Throat
Helix 3
Spleen
Upper Tragus
Lung
External Nose
Brainstem
Trachea
Heart
Internal Nose
Cervical Vertebrae
Neck
Clavicle
Helix 4
Apex of Antitragus
Adrenal Gland
Upper Ear Root
Midpoint of Rim
San Jiao
Groove of Dorsal Surface
Heart of Dorsal Surface
Lower Tragus
Occiput
Subcortex
Temple
Endocrine
Forehead
Eye2
Eye1
Jaw
Tongue
Teeth
Root of Ear Vagus
Liver of Dorsal Surface
Spleen of Dorsal Surface
Lung of Dorsal Surface
Internal Ear
Cheek
Anterior Ear Lobe
Eye
Kidney of Dorsal Surface
Tonsil
Lower Ear Root
▲ Internal Acupoints
Frontal Surface
Dorsal Surface

The Chinese Standard Ear-Acupoints Chart (Chinese version).
[標準耳穴定位示意圖]



Appendix 3 The anatomical nomenclature of the auricle (frontal surface).



Appendix 4 Sleep questionnaire (English version).

The Hong Kong Polytechnic University Date : _____
Department of Nursing and Health Sciences Code: _____

Sleep Questionnaire

Part I Demographic Information

Please put a (tick) in the appropriate box.

1. Age: _____

2. Sex: _____

3. Total years of stay: _____

4. How do you describe your present health status?

   1 ☐ Very good
   2 ☐ Good
   3 ☐ Acceptable
   4 ☐ Poor
   5 ☐ Very poor

5. Do you have any physical or mental illness(es)?

   _____

6. Are you taking any medication(s)? Please specify the medication(s) with dosage, frequency, date of commencement & any reaction(s) related to the medication(s).

   _____

   _____

7. How do you describe your sleep status at night?

   1 ☐ Very good
   2 ☐ Good
   3 ☐ Acceptable
   4 ☐ Poor
   5 ☐ Very poor

8. How do you feel upon arising?

1 ☐ Refreshed
2 ☐ Acceptable
3 ☐ Still tired
4 ☐ Sleepy

9. Did you feel dizzy or headache after arising?

1 ☐ Most of the time
2 ☐ Yes. but not very frequent
3 ☐ No

10. Do you sleep alone?

2 ☐ Yes
1 ☐ No

11. Do you use any sleep aids? Please describe.

_____

Part II Sleep History

1. How long have you been suffering from sleep disturbance?

_____ month(s) / year(s)

2. How many night(s) a week do you have sleep disturbance?

_____ nights per week

3. What will exacerbate your sleep disturbance?

1 ☐ Go to toilet frequently
2 ☐ Too Noisy
3 ☐ Temperature: too cold or too hot
4 ☐ Physical discomfort
5 ☐ I don't know
6 ☐ Others: _____

4. What is the usual time for you to sleep at night? _____

5. How long do you usually take to fall asleep at night? _____ minute(s) / hour(s)

6. How often do you usually wake up during the night? _____

6.1 How long do you usually take to fall asleep again?

1 ☐ A very short period of time (fall asleep again immediately)
2 ☐ A short period of time
3 ☐ A long period of time
4 ☐ A very long period of time
5 ☐ Once awake, can't fall asleep again
6 ☐ I don't know/ No fixed mode

6.2 What is/are the usual cause(s) of the awakening(s)?

1 ☐ Go to toilet frequently
2 ☐ Too Noisy
3 ☐ Temperature: too cold or too hot
4 ☐ Nightmare
5 ☐ Physical discomfort
6 ☐ I don't know
7 ☐ Others: _____

6.3 What will you usually do in the awakening(s)?

1 ☐ Still rest on bed
2 ☐ Get up to do something (eg go to toilet, etc) till sleepy
3 ☐ Take sleeping pills
4 ☐ Others: _____

7. What is your usual final awakening time? _____

8. What is your usual final arising time? _____

9. How many hours do you usually sleep at night? _____

10. Do you usually make dreams during sleep?

1 □ Frequently
2 □ Sometimes
3 □ Rarely
4 □ Never

11. Do you go to bed in daytime?

1 □ Frequently
2 □ Sometimes
3 □ Rarely
4 □ Never

How long do you sleep in daytime? (Asleep) _____ minute(s) / hour (s)

12. Do you doze?

1 □ Frequently
2 □ Sometimes
3 □ Rarely
4 □ Never

How long do you usually doze?

1 □ A very short period of time
2 □ A short period of time
3 □ A long period of time
4 □ A very long period of time
5 □ I don't know/ No fixed mode
6 □ Others: _____

13. In the last six months, have you been particularly worry or anxious?

2 □ Yes
1 □ No

14. For the past couple of years, have you been bothered by depressed mood?

1 ☐ Frequently
2 ☐ Sometimes
3 ☐ Rarely
4 ☐ Never

Part III Life style

1. Do you smoke every day?

2 ☐ Yes.
1 ☐ No.

2. Do you consume any caffeinated food or drink every day?

2 ☐ Yes. The caffeinated food or drink is/are: Chinese Tea, Coffee, Western Tea,
Others: _____

1 ☐ No.

3. Do you drink alcohol every day?

2 ☐ Yes.

1 ☐ No.

4. Do you consume dairy product(s) every day?

2 ☐ Yes.

1 ☐ No.

5. Do you do exercise every day?

2 ☐ Yes. I usually do exercise for _____ minute(s) / hour(s).
I usually do exercise in: indoor / outdoor.

1 ☐ No.

6. When do you usually have your dinner? _____.

7. Do you eat snack every night before bedtime?

2 ☐ Yes.

1 ☐ No.

** End **

Appendix 5 Sleep questionnaire (Chinese version).

香港理工大學 編號:_____

醫療科學學系 日期:_____

睡眠情況問卷

第一部份 個人資料

請在適當的方格內加以「✓」號。

1. 年齡：_____

2. 性別：_____

3. 住在這院舍多少年? _____

4. 你目前的健康狀況：

   1 ❑ 很好

   2 ❑ 好

   3 ❑ 普通

   4 ❑ 差

   5 ❑ 很差

5. 你的身體及精神上，有沒有什麼疾病？

   _____

6. 你有否長期服食藥物？*(請列明其名稱、劑量、每日的服食次數、該藥已服用的年期及被研究者對該藥的有關反應)*

   _____

   _____

7. 通常你晚間睡得好嗎？

1 ❑ 很好

2 ❑ 好

3 ❑ 普通

4 ❑ 差

5 ❑ 很差

8. 通常朝早起身時，你的精神好嗎？

1 ❑ 精神奕奕

2 ❑ 普通

3 ❑ 精神不足

4 ❑ 重係好想睡

9. 你睡醒後，有沒有頭暈或頭痛之現象出現？

1 ❑ 大部份時間

2 ❑ 有，但不太頻密

3 ❑ 沒有

10. 你是否獨睡一床？

2 ❑ 是

1 ❑ 否

11. 你有否要用其他東西協助入睡？請列明。

_____

第二部份　過去睡眠狀況

1. 你的睡眠困擾已持續了多久？ _____個月/年

2. 你的睡眠困擾狀況，通常一星期會有多少晚發生？

_____（日）

3. 在什麼情況下，你在晚上的睡眠困擾情況會惡化？

1 ❑ 經常要去廁所

2 ❑ 太嘈

3 ❑ 太凍或太熱

4 ❑ 身體不適

5 ❑ 不清楚

6 ❑ 其他：_____

4. 你通常幾點鐘上床睡？ _____

5. 通常需要多少時間才能入睡？_____分鐘/ 小時

6. 入睡之後，你通常半夜會醒多少次？_____

6.1 半夜醒後，通常要多久才可以再入睡？

1 ❑ 好快（醒一醒轉頭立刻可以再入睡）

2 ❑ 一陣間（要一段短時間才可以再入睡）

3 ❑ 都幾耐（要一段頗長的時間才可以再入睡）

4 ❑ 好耐（要一段好長的時間才可以再入睡）

5 ❑ 醒後就不可以再入睡

6 ❑ 不知道／無一定

6.2 通常，半夜醒的原因：

1 ❑ 要去廁所

2 ❑ 太嘈

3 ❑ 太凍或太熱

4 ❑ 發惡夢

5 ❑ 身體不適

6 ❑ 不清楚

7 ❑ 其他：_____

6.3 通常，你半夜醒後會做些什麼？

1 ❑ 仍在床上休息

2 ❑ 起身做其他事（如去廁所等），等想睡才再上床

3 ❑ 食安眠藥

4 ❑ 其他：_____

7. 通常，你幾點鐘睡醒？_____

8. 通常，你幾點鐘落床？_____

9. 你通常一晚可睡多少個小時？_____

10. 你睡覺時是否經常造夢？

1 ❑ 經常是

2 ❑ 間中是

3 ❑ 不常是

4 ❑ 不是

11. 你有否在日間上床睡?

1 ❑ 經常有

2 ❑ 間中有

3 ❑ 不常有

4 ❑ 沒有

大約共睡多少時間？(真正睡著了)_____分鐘/小時

12. 你有否瞌睡(瞌眼瞓)？

1 ❑ 經常有

2 ❑ 間中有

3 ❑ 不常有

4 ❑ 沒有

每次大約瞌幾耐？

1 ❑ 極短，轉頭就醒

2 ❑ 瞌一陣

3 ❑ 都幾耐

4 ❑ 瞌好耐

5 ❑ 不知道／無一定

6 ❑ 其他：_____

13. 在過去半年，你是否試過很憂慮或緊張？

2 ❑ 是

1 ❑ 否

14. 在過去兩年，你有否情緒低落？

1 ❑ 經常有

2 ❑ 間中有

3 ❑ 不常有

4 ❑ 沒有

第三部份　生活習慣

1. 你有沒有每天抽煙的習慣？

2 ❑ 有。

1 ❑ 無。

2. 你有沒有每天進食含咖啡因的食品的習慣？（如奶茶、咖啡、中國茶）

2 ❑ 有。

1 ❑ 無。

3. 你有沒有每天飲酒的習慣？

2 ❑ 有。

1 ❑ 無。

4. 你有沒有每天飲用奶類食品的習慣？

2 ❑ 有。

1 ❑ 無。

5. 你有沒有每天做運動的習慣？

2 ❑ 有。　每天會做多少時間？_____分鐘/小時

在那裏做？　室內／室外

1 ❑ 無。

6. 你通常幾點食晚飯？_____

7. 你睡前，有沒有食些東西才睡的習慣？

2 ❑ 有

1 ❑ 無

- 完 -

Appendix 6 Sleep diary (English version).

The Hong Kong Polytechnic University
Department of Nursing and Health Sciences

Date : _____
Code: _____

Sleep Diary

Please put a (tick) in the appropriate box.

(A) Items related to the sleeping pattern of last night

1. When did you go to bed yesterday evening? _____

2. How long did you take to fall asleep? _____ min(s) / hour(s)

3. Did you awake during the night?

1 ☐ No.
2 ☐ Yes. How often? _____

4. How long do you usually take to fall asleep again?

1 ☐ A very short period of time (fall asleep again immediately)
2 ☐ A short period of time
3 ☐ A long period of time
4 ☐ A very long period of time
5 ☐ Once awake, can't fall asleep again
6 ☐ I don't know/ No fixed mode

5. How did you describe your sleep?

1 ☐ Very good
2 ☐ Good
3 ☐ Acceptable
4 ☐ Poor
5 ☐ Very poor

6. Did you dream last night?

1 ☐ Most of the time
2 ☐ Yes, but not very frequent
3 ☐ No

7. What was your final awakening time? _____

8. What was your final arising time? _____

9. How did you feel upon arising?

1 ☐ Refreshed
2 ☐ Acceptable
3 ☐ Still tired
4 ☐ Sleepy

10. Did you feel dizzy or headache after arising?

1 ☐ Most of the time
2 ☐ Yes, but not very frequent
3 ☐ No

(B) Items related to yesterday

1. Did you go to bed yesterday (from awaken up in the morning till nocturnal bedtime)?

1 ☐ No.
2 ☐ Yes. How often? _____

2. Did you doze yesterday (from awaken up in the morning till nocturnal bedtime)?

1 ☐ No.
2 ☐ Yes. How often? _____

3. Had you taken any medication(s)? Please describe.

_____

(C) After receiving auricular therapy

1. Did you feel any positive effect(s) after receiving auricular therapy?

   1 ☐ No.
   2 ☐ Yes. _____ (Please specify)

2. Did you feel painful to any of the auricular points after receiving auricular therapy?

   1 ☐ No.
   2 ☐ Yes. _____ (Please specify)

3. Is there any negative local effect to the pinna after receiving auricular therapy? (For example: local irritation, inflammation, bleeding etc).

   1 ☐ No.
   2 ☐ Yes. _____ (Please specify)

4. Did you experience any bodily discomfort after receiving auricular therapy? (For example: headache, nausea etc).

   1 ☐ No.
   2 ☐ Yes. _____ (Please specify)

- The End -

Appendix 7 Sleep diary (Chinese version).

香港理工大學　　日期： / /00 Day_____

醫療科學學系　　編號：_____

睡眠日記

(A) 昨晚睡眠情況

1. 昨晚，你幾點鐘上床瞓？_____

2. 你需要多少時間才能入睡？_____分鐘/小時

3. 入睡之後，你半夜有沒有醒？

1 □ 無。

2 □ 有。多少次？_____次

4. 半夜醒後，通常要多久才可以再入睡？

1 ❑ 好快（醒一醒轉頭立刻可以再入睡）

2 ❑ 一陣間（要一段短時間才可以再入睡）

3 ❑ 都幾耐（要一段頗長的時間才可以再入睡）

4 ❑ 好耐（要一段好長的時間才可以再入睡）

5 ❑ 醒後就不可以再入睡

6 ❑ 不知道／無一定

5. 你晚間睡得好嗎？

1 ☐很好

2 ☐好

3 ☐普通

4 ☐差

5 ☐ 很差

6. 你昨晚睡覺時有否造夢？

1 ☐大部份時間

2 ☐有，但不太頻密

3 ☐沒有

7. 你今早幾點鐘睡醒？_____

8. 你今早幾點鐘落床？_____

9. 今朝早起身時，你精神好嗎？

1 ☐精神奕奕

2 ☐普通

3 ☐精神不足

4 ☐重係好想睡

10. 你睡醒後，有沒有頭暈或頭痛之現象出現？

1 ☐大部份時間

2 ☐有，但不太頻密

3 ☐沒有

(B) 昨天情況

1. 昨天(早上起床後至晚上睡覺前)，你有否上床瞓？

1 □ 無。

2 □ 有。多少次？_____次

時間	躺了多久	真正瞓着了多久
_____	_____分鐘	_____分鐘
_____	_____分鐘	_____分鐘

2. 昨天(早上起床後至晚上睡覺前)，你有否打瞌睡(瞌眼瞓)？

1 □ 無。

2 □ 有。多少次？_____次

時間	瞌了多久
_____	_____分鐘
_____	_____分鐘

3. 昨日你有否服食任何藥物？請列明。

_____

(C) 關於接受耳穴治療後的情況

1. 接受耳穴治療後對你的身體情況有沒有正面反應或改善？

1 □ 無。

2 □ 有。_____(請列明)

2. 穴位有否出現局部疼痛之現象？

1 □無。

2 □有。_____（請列明）

3. 治療有否對耳廓產生局部不良反應？(如：過敏、發炎、出血等)

1 □無。

2 □有。_____（請列明）

4. 治療後有否出現身體不適之現象？(如：頭痛、噁心等)

1 □無。

2 □有。_____（請列明）

＊ 完 ＊

Appendix 8 Insomnia types assessment form.

參加者 _____ 年齡/性別_____ 編號 _____

	症狀 (請圈上合適)	其他
睡眠	不寐 / 多夢 / 多夢易醒 / 多夢易惊 / 正常	
心情	急躁易怒 / 胸悶 / 心煩 / 胆怯心悸 / 正常	
口	不思飲食/ 噯氣吞酸 / 脘腹脹滿 飲食無味 / 口苦 / 口干津少 / 正常	
舌	舌紅 / 苔黃 / 苔膩 / 舌淡苔薄 / 舌淡 / 正常	
脉搏	脈弦數 / 脉滑數 / 心悸 / 脉細 / 脉細數 / 脉弦細 / 正常	
小便	小便黃赤 / 小便清長 / 正常	
大便	大便秘結 / 大便泄瀉 / 正常	
體力	面色少華 / 四肢倦苔 / 倦怠少力 / 正常	
神經系統	目赤 / 頭重目眩 / 頭痛 / 健忘 / 神疲 / 五心煩熱 / 頭暈 / 耳鳴 / 遺精 / 腰酸 / 正常	
其他	痰濁上扰 / 氣短 / 正常	

失眠分型:

實証	(1) 肝郁化火 (2) 胃氣不和 (3) 痰熱內擾
虛証	(1) 心脾兩虛 (2) 心腎不交 (3) 心胆氣虛

過往病歷 / 備註：

_____

_____

_____

Appendix 9 Consent form (English version).

THE HONG KONG
POLYTECHNIC UNIVERSITY
香港理工大學

Department of Nursing
and Health Sciences
護理及醫療科學系

CONSENT TO PARTICIPATE IN RESEARCH

Auricular therapy and insomnia in the elderly

I _____ hereby consent to participate in the captioned research conducted by Ms. Lorna Suen Kwai Ping.

I understand that information obtained from this research may be used in future research and published. However, my right to privacy will be retained, i.e. my personal details will not be revealed.

The procedure as set out in the attached information sheet has been fully explained. I understand the benefit and risks involved. My participation in the project is voluntary.

I acknowledge that I have the right to question any part of the procedure and can withdraw at any time without penalty of any kind.

Name of participant _____

Signature of participant _____

Name of researcher _____

Signature of researcher _____

Date _____

Appendix 10 Consent form (Chinese version).

THE HONG KONG
POLYTECHNIC UNIVERSITY
香港理工大學

Department of Nursing
and Health Sciences
護理及醫療科學系

參與研究同意書

耳穴療法與老人失眠症

本人 _____ 同意參加由孫桂萍女士負責執行的研究項目.

我理解此研究所獲得的資料可用於未來的研究和學術交流.然而我有權保護自己的隱私,我的個人資料將不能泄漏.

我對所附資料的有關步驟已經得到充分的解釋.我理解可能會出現的風險.我是自願參與這項研究.

我理解我有權在研究過程中提出問題,并在任何時候決定退出研究而不會受到任何不正常的代遇或責任追究 .

參加者姓名_____

參加者簽名_____

研究人員姓名_____

研究人員簽名_____

日期 _____

Appendix 11 Research study information sheet (English version).

THE HONG KONG
POLYTECHNIC UNIVERSITY
香港理工大學

Department of Nursing
and Health Sciences
護理及醫療科學系

Research Study Information Sheet

Title of research: Auricular therapy and insomnia in the elderly.

Researcher:
Lorna Suen Kwai Ping,
Doctoral student,
Department of Nursing & Health Sciences,
The Hong Kong Polytechnic University.
Tel no: 2766 6758

Why is the study being performed?

To identify the effects of auricular therapy on improving the sleep quality in the elderly.

What can I (as a volunteer) do for this study?

1. To sign an informed consent form that states you understand the information presented on this sheet.

2. To fill in a sleep questionnaire the first time you meet the researcher. The researcher will invite an experienced TCM practitioner to conduct an assessment on you to determine the type of insomnia (differentiated by traditional Chinese diagnosis) you are now having via history taking, pulse palpation and tongue inspection.

3. To wear a watch-like actigraph on either the left or right hand during sleep at night for some days during the research period.

4. The whole research process is divided into **three parts**:
   a) Wearing the actigraph at night for **three days** without receiving the auricular therapy.
   b) Auricular therapy (any 1 out of 3 different treatments) will be given to you by the researcher for three weeks (**21 days**) and she will meet with you at a regular interval. You also need to wear the actigraph at night in the middle of the treatment course for **three days**.
   c) Continue to wear the actigraph for **three days** after the therapy is over.

5. The staff in your hostel will make an inquiry the next day after you wear the actigraph in order to understand your sleeping conditions and related activities over the past 24 hours.

6. You are advised to stop all sleep-inducing medications during the study period to facilitate the monitoring of the single effect of the auricular therapy.

7. Please don't massage the beads which are applied on your ear.

What is auricular therapy being used in this study?

Seven vital points on the ear that are thought to have an effect on promoting sleep are selected. Small round beads will be applied on each selected point of a single ear. To avoid the possibility of local irritation of auricular points under treatment, the beads will be peeled off after three to four days and new beads will be reapplied on alternate ear. The total treatment course consists of 21 days. It is expected that the using of beads for auricular therapy will be less traumatic, more hygienic and convenient than many other approaches of auricular therapies, such as auricular acupuncture. Side effects arise from this therapy are rare. Normal reactions to auricular pressing therapy that may appear includes localized sensations of pain, heat, numbness, and distention. However abnormal phenomena such as allergic reactions to the adhesive tape or infection of the auricle may be possible. In severe situation, you can peel off the beads and such reverse reaction(s) will be diminished very quickly.

Can I withdraw from this study?

You are invited to participate in this study on a voluntary basis, and can withdraw from the study at any time if you don't feel comfortable with no penalty.

Will my data be disclosed to the others?

All information related to you will remain confidential, and will be identifiable by codes only known to the researcher.

Can I get more information on this study?

You can contact the researcher who invites you to participate before, during and after the data collection process and he/she will try to answer any questions you may have.

If you have any complaints about the conduct of this research study, please do not hesitate to contact Miss Milly Koo, Secretary of the Human Subjects Ethics Sub-Committee of The Hong Kong Polytechnic University in person or in writing (c/o Human Resources Office in Room AG426 of the University).

Appendix 12 Research study information sheet [睡眠研究簡介] (Chinese version).

THE HONG KONG POLYTECHNIC UNIVERSITY
香港理工大學

Department of Nursing and Health Sciences
護理及醫療科學系

睡眠研究簡介

♦研究名稱：

『耳穴療法與老人失眠症』。

♦研究員：

香港理工大學
護理及醫療科學系
博士課程研究生
孫桂萍女士 (電話：2766 6758)

♦是項研究的目的是什麼?

用科學研究去証實耳穴療法可改善失眠情況及提高老人之睡眠質素，並希望將來可應用於臨床護理中。

♦我(作爲參加者)可以如何配合這項研究?

i) 明白是項研究的資料及簽署同意書。

ii) 第一次會見研究員時，在研究員協助下填寫睡眠問卷一份。此外，她亦會邀請一位富經驗的中醫從中醫角度透過詢問病史、脉診及舌診替您辨別您的失眠類型。

iii) 於研究期間某些指定晚上，參加者需要於睡眠期間戴上手錶樣的睡眠測量儀於右手或左手中。

iv) 整項研究分三部份：

(甲) 晚上睡眠期間配戴睡眠測量儀**三日**，暫不接受耳穴治療。

(乙) 接受耳穴治療(三種不同治療之其中一種)及定時約見研究員。整個療程爲**三個星期**(二十一天)。參加者亦需於治療中期晚上睡眠期間配戴睡眠測量儀**三日**，

(丙) 療程完畢後**三天內**仍需於晚上睡眠期間配戴睡眠測量儀。

v) 一位你的院舍職員會於你配戴睡眠測量儀之翌日詢問你簡短之

問題以了解你前一晚的睡眠情況。

vi) 爲免防碍治療果效，參加者需於整項研究期間停服安眠藥物。

vii) 請勿按摩貼在你耳朵上的小圓粒。

◆ 在這個研究使用的耳穴治療是什麼？

研究員會在數個被認爲會改善睡眠情況的耳部的穴位貼上圓形小粒。每次只在單側耳朵貼上圓粒。爲免圓粒引起局部不良刺激，圓粒會三至四天更換一次，而新的小圓粒會貼在對側耳朵。整個療程共二十一天。此種耳穴治療會較其他同類治療，如耳針療法，較少傷害性、更衛生及方便，副作用亦非常少見。常見的正常反應有局部酸、麻、脹、痛、熱。不正常的反應計有穴位局部因膠布而產生過敏現象或炎症反應等。若情況嚴重的話，你自己可以撕去圓粒，此類反應會很快消失。

◆ 我可以中途退出這項研究嗎?

參予是項研究乃出於自願，故閣下可根據你自己的個人意願，在任何時間退出，而不需負上任何責任。

◆ 我的個人資料會被外洩嗎?

凡有關閣下的資料均會保密，一切資料的編碼只有研究人員知道.

◆ 我可以獲得更多關於是項研究的資料嗎？

當然可以。你可以於參與是項研究期間或前後隨時詢問研究員關於是項研究之問題，她會非常樂意地爲你解答。

如果閣下有任何對這項研究的不滿,請隨時與香港理工大學人事倫理委員會秘書親自或寫信聯絡(地址：香港理工大學人力資源辦公室 AG426 室轉交).

Appendix 13 : Courses on complementary therapies attended by the researcher.

Courses on Complementary Therapies Attended.

From Mth/Yr	To Mth/Yr	Total hours	Nature of Training	Name & address of organization	Mode of assessment
Jan/98	March/98	1 1/2 hr/session; 6 sessions; Total : 9 hours	Intensive theory and practical course on the Rwo-Shr Health Method of foot reflex zone therapy (Mid-level) [若石健康法 – 足部反射學中級訓練]	Rwo-Shr Health Institute International (Hong Kong Branch) [國際若石健康研究會 – 香港分會]	Theory & practical examination
March/98	August/98	2 1/2 hr/session; 20 sessions; Total : 45 hours	Intensive theory and practical course on the Rwo-Shr Health Method of foot reflex zone therapy (High-level) [若石健康法 – 足部反射學高級訓練]	Rwo-Shr Health Institute International (Hong Kong Branch) [國際若石健康研究會 – 香港分會]	Theory & practical examination
January/98	February/98	1 1/2 hr/session; 6 sessions; Total : 9 hours	Ear Vital Point Training [耳穴療法]	Spare-time study center [業餘進修中心]	Attendance only
Januray/98	April/98	1 1/2 hr/session; 12 sessions; Total : 18 hours	Chiropractor Training [推拿、按穴療法]	Spare-time study center [業餘進修中心]	Attendance only
August/98	September/98	2 hr/session; 4 sessions(theory); 4 sessions (practice); Total : 16 hours	Ear Vital Point Training (Elementary level) [耳穴療法班]	Auricular Acupuncture Association [耳穴療法促進會]	Practical examination
September/ 98	November/98	2 hr/session; 6 sessions(theory); 6 sessions (practice); Total : 24 hours	Ear Vital Point Training (Intermediate level) [耳穴療法進修班]	Auricular Acupuncture Association [耳穴療法促進會]	Practical examination

From	To	Total hours	Nature of Training	Name & address of organization	Mode of assessment
January/99	February/99	2 hr/session; 3 sessions (theory & practice); Total : 6 hours	Hand reflexology [手掌反射區療法]	Auricular Acupuncture Association [耳穴療法促進會]	Attendance only
March/99	May/99	2 hr/session; 6 sessions(theory); 6 sessions (practice); Total : 24 hours	Ear Vital Point Training (Advanced level) [耳穴療法研究班]	Auricular Acupuncture Association [耳穴療法促進會]	Practical examination
July/99	July/99	20 hrs (theory); 160 hrs (practical) Total : 180 hours	Acupuncture & Moxibustion (Short course)	China Guangzhou University of Traditional Chinese Medicine [廣州中醫藥大學]	Theory examination
January/00	April/00	1 1/2 hr/session; 12 sessions (theory); Total : 18 hours	The principle of Dietotherapy in Traditional Chinese Medicine and common soup formulas [食療原理簡介及常用湯方]	Spare-time study center [業餘進修中心]	Attendance only
Feb/00	May/00	4 hrs/session; 14 sessions (theory); Total : 52 hours	Certificate course in common disorders in TCM & Chinese medicinal nursing [中醫內科常見病與中西結合護理証書課程]	College of Nursing, Hong Kong [香港護理學院]	Theory (test and examination)
March/00	May/00	1 1/2 hr/session; 6 sessions (theory); Total : 9 hours	Traditional Chinese Natural Therapies [中國民間自然療法]	Spare-time study center [業餘進修中心]	Attendance only

using magnetic pearls.

Baseline measurement (three days before the thera

ACTION data file: a:\36-P.DAT

Report date: May 16, 200

ID:

>>>>>>>>>>>>>>>>>>> **ACTIGRAPH DATA REPORT** <<<<<<<<<<<<<<<<<<<

ACTION data file:	a:\36-P.DAT
Sleep file:	-memory-
Manual sleep scoring:	No
Tag point file:	-memory-
Wake-up time:	12:45:00/284 Oct 10, 2000
End of data recording:	14:21:00/287 Oct 13, 2000
Data collection epoch duration:	30 seconds
Plot time compression:	2.00
Event mode:	Yes
Data collection mode:	Zero Crossing
Packing option:	B
Actigraph serial number:	SN: 352
Plotted data start:	12:45:00/284 Oct 10, 2000
Plotted data end:	14:21:00/287 Oct 13, 2000
Type of data plotted:	Activity & Sleep
Method of plotting:	Single
Plot size setting for activity:	4
Clipping value for activity:	None
Date report generated:	May 16, 2001

ID:

STATISTICS FOR DATA COLLECTION EPOCHS OF 30 SECONDS DURATION

STATISTICS FOR ENTIRE REPORTING PERIOD

Begin interval time	12:59:00/311 Nov 6, 2000
End interval time	15:39:00/314 Nov 9, 2000
Number of epochs of data	8959.0
Number of minutes of data	4479.5
Minimum activity value	0
Maximum activity value	159
Mean activity value	10.7
Standard deviation	32.1
Number of wake epochs	1202.0
Minutes of wake epochs	601.0
Percent of wake epochs	13.4
Number of sleep epochs	7757.0
Minutes of sleep epochs	3878.5
Percent of sleep epochs	86.6
Sleep to wake ratio	6.453
Number of awakenings	47
Avg. length of awakenings	11.9
Sleep latency (min.)	1.0
Min. Wake After Sleep Onset	557.5

STATISTICS FOR INTERVAL 1

Begin interval time	20:21:30/311 Nov 6, 2000
End interval time	04:20:30/312 Nov 7, 2000
Number of epochs of data	959.0
Number of minutes of data	479.5
Minimum activity value	0
Maximum activity value	148
Mean activity value	20.5
Standard deviation	41.5
Number of wake epochs	237.0
Minutes of wake epochs	118.5
Percent of wake epochs	24.7
Number of sleep epochs	722.0
Minutes of sleep epochs	361.0
Percent of sleep epochs	75.3
Sleep to wake ratio	3.046
Number of awakenings	11
Avg. length of awakenings	9.3
Sleep latency (min.)	7.5
Min. Wake After Sleep Onset	102.5

ID:

STATISTICS FOR INTERVAL 2

Begin interval time	20:25:30/312 Nov 7, 2000
End interval time	04:33:30/313 Nov 8, 2000
Number of epochs of data	977.0
Number of minutes of data	488.5
Minimum activity value	0
Maximum activity value	159
Mean activity value	26.9
Standard deviation	46.7
Number of wake epochs	323.0
Minutes of wake epochs	161.5
Percent of wake epochs	33.1
Number of sleep epochs	654.0
Minutes of sleep epochs	327.0
Percent of sleep epochs	66.9
Sleep to wake ratio	2.025
Number of awakenings	14
Avg. length of awakenings	10.0
Sleep latency (min.)	17.5
Min. Wake After Sleep Onset	139.5

STATISTICS FOR INTERVAL 3

Begin interval time	20:09:00/313 Nov 8, 2000
End interval time	04:57:00/314 Nov 9, 2000
Number of epochs of data	1057.0
Number of minutes of data	528.5
Minimum activity value	0
Maximum activity value	150
Mean activity value	18.7
Standard deviation	40.5
Number of wake epochs	237.0
Minutes of wake epochs	118.5
Percent of wake epochs	22.4
Number of sleep epochs	820.0
Minutes of sleep epochs	410.0
Percent of sleep epochs	77.6
Sleep to wake ratio	3.460
Number of awakenings	12
Avg. length of awakenings	8.0
Sleep latency (min.)	23.0
Min. Wake After Sleep Onset	95.5

INTERVAL STATISTICS

Interval: 1 Start: 21:01:00/284 End:04:23:00/285

Activity

Epochs in Interval:	884	Minimum:	0.00
Epoch Length(secs):	30.00	Maximum:	161.00
Mean activity:	30.93	25 Percentile:	0
Std Dev:	49.03	50 Percentile:	0
		75 Percentile:	52

Sleep

Total Interval		Onset - Offset	
Total Minutes Scored:	442.00	First Sleep Onset:	22:41:00/284
Sleep (minutes):	293.00	Last Sleep Offset:	04:12:00/285
percent:	66.29	Duration (min):	331.50
Wake (minutes):	149.00	Sleep (minutes):	293.00
percent:	33.71	percent:	88.39
Total Awakenings:	9	Wake (minutes):	38.50
Avg length:	4.28	percent:	11.61
Sleep/Wake ratio:	1.97	Sleep latency (min):	100.00

PgDn:Next Interval PgUp: Previous Interval ESC:Quit

INTERVAL STATISTICS

Interval: 2 Start: 20:00:00/285 End:04:29:00/286

Activity

Epochs in Interval:	1018	Minimum:	0.00
Epoch Length(secs):	30.00	Maximum:	150.00
Mean activity:	20.00	25 Percentile:	0
Std Dev:	39.75	50 Percentile:	0
		75 Percentile:	13

Sleep

Total Interval		Onset - Offset	
Total Minutes Scored:	509.00	First Sleep Onset:	20:25:00/285
Sleep (minutes):	375.00	Last Sleep Offset:	04:24:00/286
percent:	73.67	Duration (min):	479.50
Wake (minutes):	134.00	Sleep (minutes):	375.00
percent:	26.33	percent:	78.21
Total Awakenings:	12	Wake (minutes):	104.50
Avg length:	8.71	percent:	21.79
Sleep/Wake ratio:	2.80	Sleep latency (min):	25.00

PgDn:Next Interval PgUp: Previous Interval ESC:Quit

INTERVAL STATISTICS

Interval: 3 Start: 20:05:30/286 End:04:27:30/287

Activity

Epochs in Interval:	1004	Minimum:	0.00
Epoch Length(secs):	30.00	Maximum:	153.00
Mean activity:	38.17	25 Percentile:	0
Std Dev:	51.83	50 Percentile:	4
		75 Percentile:	88

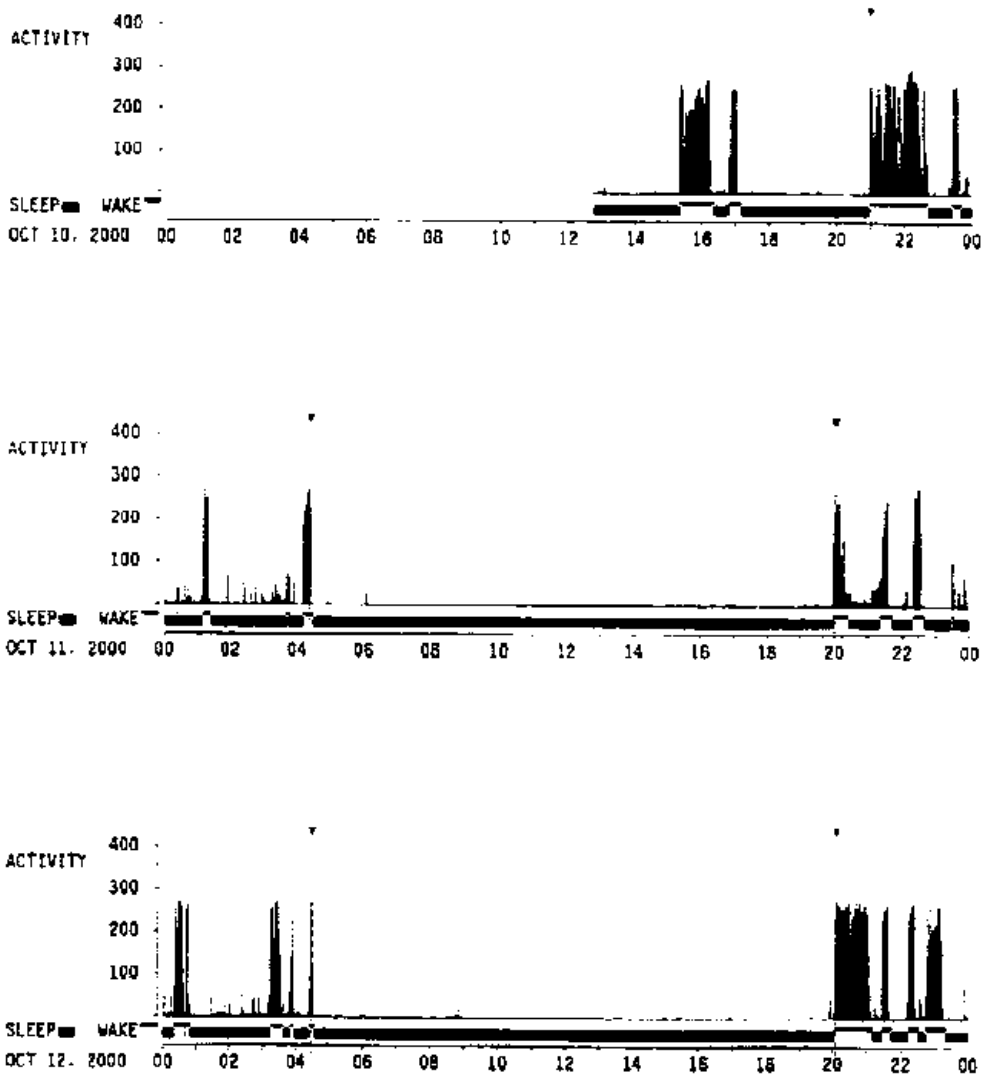
Sleep

Total Interval		Onset - Offset	
Total Minutes Scored:	502.00	First Sleep Onset:	21:12:00/286
Sleep (minutes):	261.00	Last Sleep Offset:	04:17:00/287
percent:	51.99	Duration (min):	425.50
Wake (minutes):	241.00	Sleep (minutes):	261.00
percent:	48.01	percent:	61.34
Total Awakenings:	15	Wake (minutes):	164.50
Avg length:	10.97	percent:	38.66
Sleep/Wake ratio:	1.08	Sleep latency (min):	66.50

PgDn:Next Interval PgUp: Previous Interval ESC:Quit

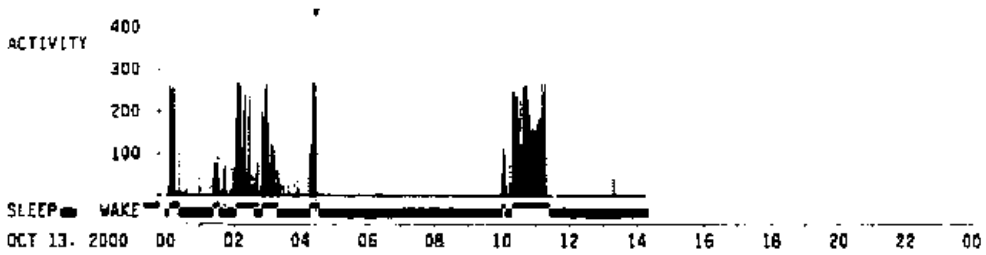
ID:

SINGLE PLOT OF DATA



ID:

SINGLE PLOT OF DATA



ID:

STATISTICS FOR DATA COLLECTION EPOCHS OF 30 SECONDS DURATION

STATISTICS FOR ENTIRE REPORTING PERIOD

Begin interval time	12:45:00/284 Oct 10, 2000
End interval time	14:21:00/287 Oct 13, 2000
Number of epochs of data	8831.0
Number of minutes of data	4415.5
Minimum activity value	0
Maximum activity value	167
Mean activity value	12.8
Standard deviation	34.6
Number of wake epochs	1404.0
Minutes of wake epochs	702.0
Percent of wake epochs	15.9
Number of sleep epochs	7427.0
Minutes of sleep epochs	3713.5
Percent of sleep epochs	84.1
Sleep to wake ratio	5.290
Number of awakenings	44
Avg. length of awakenings	14.4
Sleep latency (min.)	1.0
Min. Wake After Sleep Onset	634.5

STATISTICS FOR INTERVAL 1

Begin interval time	21:01:00/284 Oct 10, 2000
End interval time	04:22:30/285 Oct 11, 2000
Number of epochs of data	884.0
Number of minutes of data	442.0
Minimum activity value	0
Maximum activity value	161
Mean activity value	30.9
Standard deviation	49.0
Number of wake epochs	298.0
Minutes of wake epochs	149.0
Percent of wake epochs	33.7
Number of sleep epochs	586.0
Minutes of sleep epochs	293.0
Percent of sleep epochs	66.3
Sleep to wake ratio	1.966
Number of awakenings	9
Avg. length of awakenings	4.3
Sleep latency (min.)	100.0
Min. Wake After Sleep Onset	38.5

ID:

STATISTICS FOR INTERVAL 2

Begin interval time	20:00:00/285 Oct 11, 2000
End interval time	04:28:30/286 Oct 12, 2000
Number of epochs of data	1018.0
Number of minutes of data	509.0
Minimum activity value	0
Maximum activity value	150
Mean activity value	20.0
Standard deviation	39.8
Number of wake epochs	268.0
Minutes of wake epochs	134.0
Percent of wake epochs	26.3
Number of sleep epochs	750.0
Minutes of sleep epochs	375.0
Percent of sleep epochs	73.7
Sleep to wake ratio	2.799
Number of awakenings	12
Avg. length of awakenings	8.7
Sleep latency (min.)	25.0
Min. Wake After Sleep Onset	104.5

STATISTICS FOR INTERVAL 3

Begin interval time	20:05:30/286 Oct 12, 2000
End interval time	04:27:00/287 Oct 13, 2000
Number of epochs of data	1004.0
Number of minutes of data	502.0
Minimum activity value	0
Maximum activity value	153
Mean activity value	38.2
Standard deviation	51.8
Number of wake epochs	482.0
Minutes of wake epochs	241.0
Percent of wake epochs	48.0
Number of sleep epochs	522.0
Minutes of sleep epochs	261.0
Percent of sleep epochs	52.0
Sleep to wake ratio	1.083
Number of awakenings	15
Avg. length of awakenings	11.0
Sleep latency (min.)	66.5
Min. Wake After Sleep Onset	164.5

ACTION data file: a:\36-A.DAT Report date: May 16, 200

ID:

>>>>>>>>>>>>>>>>>>> **ACTIGRAPH DATA REPORT** <<<<<<<<<<<<<<<<<<<

ACTION data file:	a:\36-A.DAT
Sleep file:	-memory-
Manual sleep scoring:	No
Tag point file:	-memory-
Wake-up time:	13:09:00/300 Oct 26, 2000
End of data recording:	13:09:00/304 Oct 30, 2000
Data collection epoch duration:	30 seconds
Plot time compression:	2.00
Event mode:	Yes
Data collection mode:	Zero Crossing
Packing option:	B
Actigraph serial number:	SN: 352
Plotted data start:	13:09:00/300 Oct 26, 2000
Plotted data end:	13:09:00/304 Oct 30, 2000
Type of data plotted:	Activity & Sleep
Method of plotting:	Single
Plot size setting for activity:	4
Clipping value for activity:	None
Date report generated:	May 16, 2001

INTERVAL STATISTICS

Interval: 1 Start: 20:17:00/300 End:04:19:00/301

Activity

Epochs in Interval:	964	Minimum:	0.00
Epoch Length(secs):	30.00	Maximum:	161.00
Mean activity:	21.41	25 Percentile:	0
Std Dev:	43.28	50 Percentile:	0
		75 Percentile:	10

Sleep

Total Interval		Onset - Offset	
Total Minutes Scored:	482.00	First Sleep Onset:	20:23:00/300
Sleep (minutes):	356.00	Last Sleep Offset:	04:14:00/301
percent:	73.86	Duration (min):	471.50
Wake (minutes):	126.00	Sleep (minutes):	356.00
percent:	26.14	percent:	75.50
Total Awakenings:	14	Wake (minutes):	115.50
Avg length:	8.25	percent:	24.50
Sleep/Wake ratio:	2.83	Sleep latency (min):	6.00

PgDn:Next Interval PgUp: Previous Interval ESC:Quit

INTERVAL STATISTICS

Interval: 2 Start: 20:14:00/301 End:04:49:30/302

Activity

Epochs in Interval:	1031	Minimum:	0.00
Epoch Length(secs):	30.00	Maximum:	147.00
Mean activity:	21.88	25 Percentile:	0
Std Dev:	41.10	50 Percentile:	2
		75 Percentile:	14

Sleep

Total Interval		Onset - Offset	
Total Minutes Scored:	515.50	First Sleep Onset:	20:40:00/301
Sleep (minutes):	379.00	Last Sleep Offset:	04:42:00/302
percent:	73.52	Duration (min):	482.50
Wake (minutes):	136.50	Sleep (minutes):	379.00
percent:	26.48	percent:	78.55
Total Awakenings:	15	Wake (minutes):	103.50
Avg length:	6.90	percent:	21.45
Sleep/Wake ratio:	2.78	Sleep latency (min):	26.00

PgDn:Next Interval PgUp: Previous Interval ESC:Quit

INTERVAL STATISTICS

Interval: 3 Start: 20:19:00/302 End:03:44:30/303

Activity

Epochs in Interval:	891	Minimum:	0.00
Epoch Length(secs):	30.00	Maximum:	153.00
Mean activity:	27.81	25 Percentile:	0
Std Dev:	46.41	50 Percentile:	0
		75 Percentile:	32

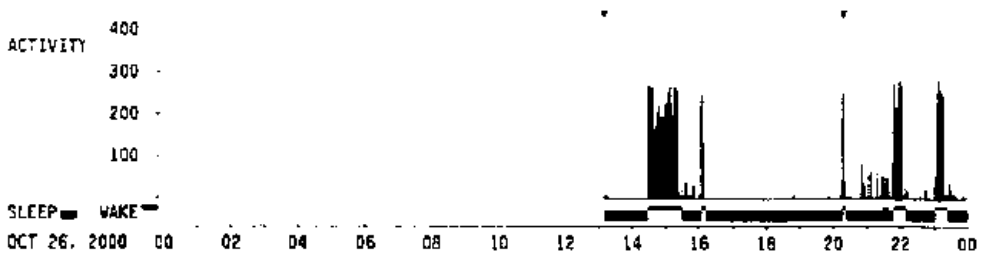
Sleep

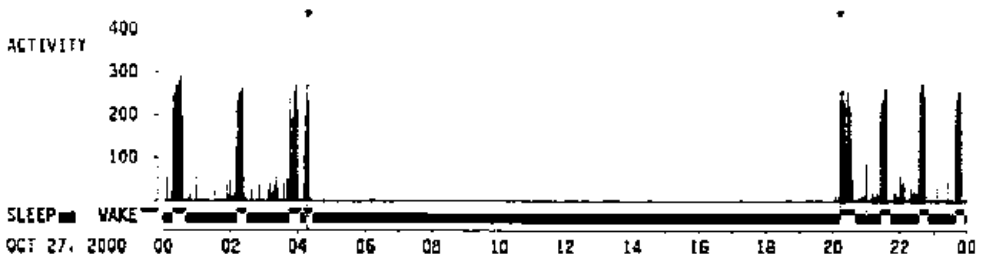
Total Interval		Onset - Offset	
Total Minutes Scored:	445.50	First Sleep Onset:	20:29:00/302
Sleep (minutes):	295.00	Last Sleep Offset:	03:40:00/303
percent:	66.22	Duration (min):	431.50
Wake (minutes):	150.50	Sleep (minutes):	295.00
percent:	33.78	percent:	68.37
Total Awakenings:	9	Wake (minutes):	136.50
Avg length:	15.17	percent:	31.63
Sleep/Wake ratio:	1.96	Sleep latency (min):	10.00

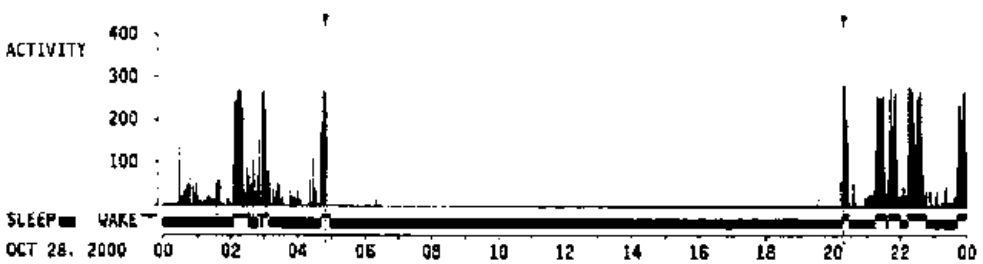
PgDn:Next Interval PgUp: Previous Interval ESC:Quit

ID:

SINGLE PLOT OF DATA

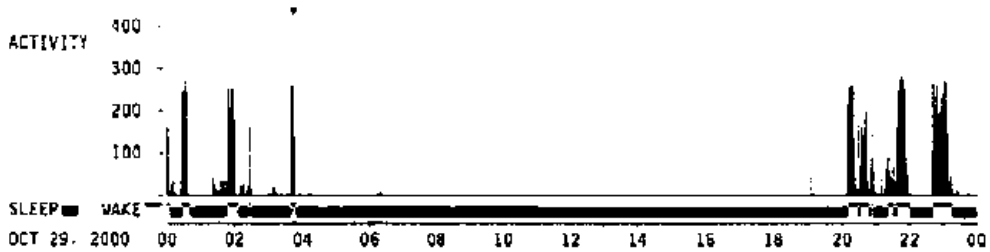






ID:

SINGLE PLOT OF DATA



ID:

STATISTICS FOR DATA COLLECTION EPOCHS OF 30 SECONDS DURATION

STATISTICS FOR ENTIRE REPORTING PERIOD

Begin interval time	13:09:00/300 Oct 26, 2000
End interval time	13:09:00/304 Oct 30, 2000
Number of epochs of data	11519.0
Number of minutes of data	5759.5
Minimum activity value	0
Maximum activity value	177
Mean activity value	10.9
Standard deviation	32.2
Number of wake epochs	1584.0
Minutes of wake epochs	792.0
Percent of wake epochs	13.8
Number of sleep epochs	9935.0
Minutes of sleep epochs	4967.5
Percent of sleep epochs	86.2
Sleep to wake ratio	6.272
Number of awakenings	66
Avg. length of awakenings	11.1
Sleep latency (min.)	1.0
Min. Wake After Sleep Onset	735.5

STATISTICS FOR INTERVAL 1

Begin interval time	20:17:00/300 Oct 26, 2000
End interval time	04:18:30/301 Oct 27, 2000
Number of epochs of data	964.0
Number of minutes of data	482.0
Minimum activity value	0
Maximum activity value	161
Mean activity value	21.4
Standard deviation	43.3
Number of wake epochs	252.0
Minutes of wake epochs	126.0
Percent of wake epochs	26.1
Number of sleep epochs	712.0
Minutes of sleep epochs	356.0
Percent of sleep epochs	73.9
Sleep to wake ratio	2.825
Number of awakenings	14
Avg. length of awakenings	8.3
Sleep latency (min.)	6.0
Min. Wake After Sleep Onset	115.5

ID:

STATISTICS FOR INTERVAL 2

Begin interval time	20:14:00/301 Oct 27, 2000
End interval time	04:49:00/302 Oct 28, 2000
Number of epochs of data	1031.0
Number of minutes of data	515.5
Minimum activity value	0
Maximum activity value	147
Mean activity value	21.9
Standard deviation	41.1
Number of wake epochs	273.0
Minutes of wake epochs	136.5
Percent of wake epochs	26.5
Number of sleep epochs	758.0
Minutes of sleep epochs	379.0
Percent of sleep epochs	73.5
Sleep to wake ratio	2.777
Number of awakenings	15
Avg. length of awakenings	6.9
Sleep latency (min.)	26.0
Min. Wake After Sleep Onset	103.5

STATISTICS FOR INTERVAL 3

Begin interval time	20:19:00/302 Oct 28, 2000
End interval time	03:44:00/303 Oct 29, 2000
Number of epochs of data	891.0
Number of minutes of data	445.5
Minimum activity value	0
Maximum activity value	153
Mean activity value	27.8
Standard deviation	46.4
Number of wake epochs	301.0
Minutes of wake epochs	150.5
Percent of wake epochs	33.8
Number of sleep epochs	590.0
Minutes of sleep epochs	295.0
Percent of sleep epochs	66.2
Sleep to wake ratio	1.960
Number of awakenings	9
Avg. length of awakenings	15.2
Sleep latency (min.)	10.0
Min. Wake After Sleep Onset	136.5

ACTION data file: a:\36-N.DAT Report date: May 16, 200

ID:

>>>>>>>>>>>>>>>>>>> **ACTIGRAPH DATA REPORT** <<<<<<<<<<<<<<<<<<<

ACTION data file:	a:\36-N.DAT
Sleep file:	-memory-
Manual sleep scoring:	No
Tag point file:	-memory-
Wake-up time:	12:59:00/311 Nov 6, 2000
End of data recording:	15:39:00/314 Nov 9, 2000
Data collection epoch duration:	30 seconds
Plot time compression:	2.00
Event mode:	Yes
Data collection mode:	Zero Crossing
Packing option:	B
Actigraph serial number:	SN: 352
Plotted data start:	12:59:00/311 Nov 6, 2000
Plotted data end:	15:39:00/314 Nov 9, 2000
Type of data plotted:	Activity & Sleep
Method of plotting:	Single
Plot size setting for activity:	4
Clipping value for activity:	None
Date report generated:	May 16, 2001

INTERVAL STATISTICS

Interval: 1 Start: 20:21:30/311 End:04:21:00/312

Activity

Epochs in Interval:	959	Minimum:	0.00
Epoch Length(secs):	30.00	Maximum:	148.00
Mean activity:	20.50	25 Percentile:	0
Std Dev:	41.54	50 Percentile:	0
		75 Percentile:	10

Sleep

Total Interval		Onset - Offset	
Total Minutes Scored:	479.50	First Sleep Onset:	20:29:00/311
Sleep (minutes):	361.00	Last Sleep Offset:	04:12:00/312
percent:	75.29	Duration (min):	463.50
Wake (minutes):	118.50	Sleep (minutes):	361.00
percent:	24.71	percent:	77.89
Total Awakenings:	11	Wake (minutes):	102.50
Avg length:	9.32	percent:	22.11
Sleep/Wake ratio:	3.05	Sleep latency (min):	7.50

PgDn:Next Interval PgUp: Previous Interval ESC:Quit

INTERVAL STATISTICS

Interval: 2 Start: 20:25:30/312 End:04:34:00/313

Activity

Epochs in Interval:	977	Minimum:	0.00
Epoch Length(secs):	30.00	Maximum:	159.00
Mean activity:	26.89	25 Percentile:	0
Std Dev:	46.72	50 Percentile:	0
		75 Percentile:	29

Sleep

Total Interval		Onset - Offset	
Total Minutes Scored:	488.50	First Sleep Onset:	20:43:00/312
Sleep (minutes):	327.00	Last Sleep Offset:	04:29:00/313
percent:	66.94	Duration (min):	466.50
Wake (minutes):	161.50	Sleep (minutes):	327.00
percent:	33.06	percent:	70.10
Total Awakenings:	14	Wake (minutes):	139.50
Avg length:	9.96	percent:	29.90
Sleep/Wake ratio:	2.02	Sleep latency (min):	17.50

PgDn:Next Interval PgUp: Previous Interval ESC:Quit

INTERVAL STATISTICS

Interval: 3 Start: 20:09:00/313 End:04:57:30/314

Activity

Epochs in Interval:	1057	Minimum:	0.00
Epoch Length(secs):	30.00	Maximum:	150.00
Mean activity:	18.69	25 Percentile:	0
Std Dev:	40.52	50 Percentile:	0
		75 Percentile:	8

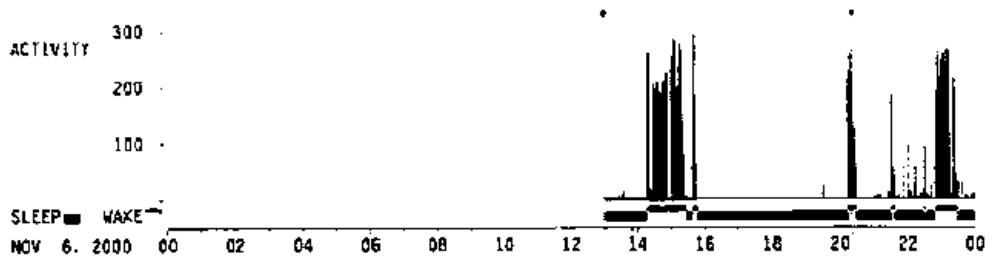
Sleep

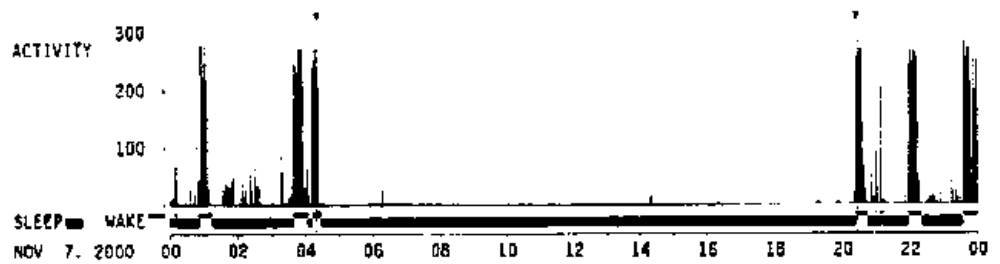
Total Interval		Onset - Offset	
Total Minutes Scored:	528.50	First Sleep Onset:	20:32:00/313
Sleep (minutes):	410.00	Last Sleep Offset:	04:57:00/314
percent:	77.58	Duration (min):	505.50
Wake (minutes):	118.50	Sleep (minutes):	410.00
percent:	22.42	percent:	81.11
Total Awakenings:	12	Wake (minutes):	95.50
Avg length:	7.96	percent:	18.89
Sleep/Wake ratio:	3.46	Sleep latency (min):	23.00

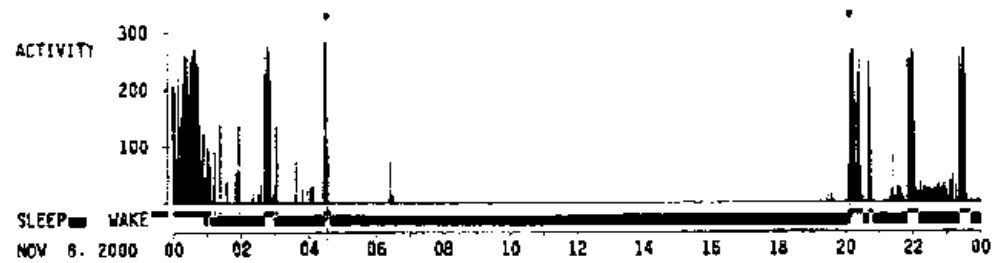
PgDn:Next Interval PgUp: Previous Interval ESC:Quit

ID:

SINGLE PLOT OF DATA





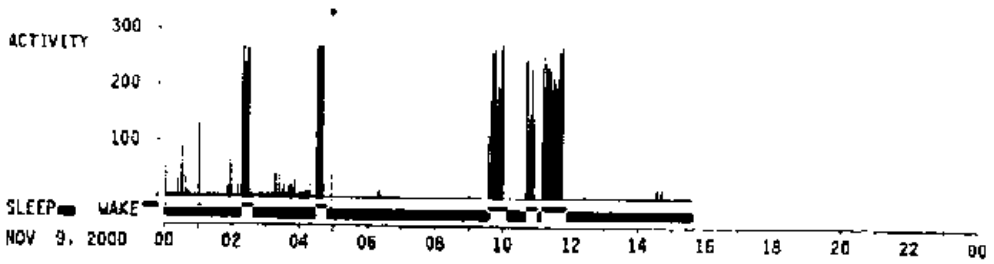


ACTION data file: a:\36-N.DAT

Report date: May 16, 200
Page

ID:

SINGLE PLOT OF DATA



Appendix 15 : Photos of participants in different hostels for the elderly.

Yan Chai Hospital, Li Chan Yuk Sim Hostel for the Elderly
(仁濟醫院，李陳玉嬋老人宿舍)

Sik Sik Yuen, Ho Shin Home for the Elderly (嗇色園，可善護理安老院)

Tsung Tsin Mission, Kwong Fuk Hostel for the Elderly (崇真會，廣福宿舍)

Kowloon Women's Welfare Club, Wong Cheung Kin Memorial for the Elderly
(九龍婦女福利會，黃張見紀念老人之家)

Women's Welfare Club, Eastern District Hong Kong, Wong Fung Ting Hostel for the Elderly (香港東區婦女福利會，黃鳳亭頤安院)

Hong Kong Chinese Young Men's Christian Association, Tin Ping Hostel for the Elderly (香港中華基督教青年會，天平老人宿舍)

Fung Kai Public School, Fung Kai C&A Home for the Elderly – Home section
(鳳溪護理安老院 - 安老部)

Heung Hoi Ching Kok Lin Asso., Buddhist Po Ching Home for the Aged Women
(香港正覺蓮社，佛教寶靜安老院)

Yan Chai Hospital, Hong Kong Peninsula Lions Club Hostel for the Elderly
(仁濟醫院, 半島獅子會老人宿舍)

Hong Kong Christian Service, Cheung Fat Home for the Elderly
(香港基督教服務處, 長發安老院)

Kiangsu & Chekiang Residents' (HK) Association, Kwai Tsing Hostel for the Elderly (蘇浙港同鄉會葵青安老院)

The Hong Kong Society for the Aged, Mrs. Wong Wha Sha Hostel for the Elderly (香港耆康會, 王華湘夫人老人宿舍)

* (No photo taken) *