

EXPLORING THE EFFECTIVENESS OF
TRADITIONAL CHINESE ACUPUNCTURE
FOR THE TREATMENT OF STRESS
IN ADULTS – A PILOT STUDY

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Abstract

Stress is a physical and psychological response to perceived demands and pressures. Inability to cope can lead to a variety of symptoms of ill health which may eventually lead to serious chronic conditions. The literature review identified the complexity of stress and its management. Traditional Chinese Acupuncture (TCA) has a holistic approach. Its traditional theories have provided a framework over thousands of years and take into account how a poor environment and / or a disturbed mental state has a close connection with disease; therefore symptoms of stress and treatment theory have been an integral part of Chinese medicine over a long history.

This pilot study used a mixed methods approach, combining a randomised controlled trial (RCT), case study reports and focus groups to investigate whether TCA was effective in the treatment of adults experiencing symptoms of chronic stress. This approach helped to compensate for a small sample size and strengthened the understanding of the complex nature of stress. The methods included a number of sequential quantitative measurements covering both physical and psychological aspects of stress, as well as qualitative methods which explored the experience of treatment. This enabled collection of a large amount of data for each participant.

Eighteen volunteers with high self-reported stress levels as identified by the Perceived Stress Scale 14 (PSS-14) >20 were randomised into 3 groups: the TCA group, the attention group and the control group. The PSS-14, the Measure Yourself Medical Outcome Profile (MYMOP), and a diurnal cortisol profile were used as outcome measures in the RCT.

After 5 weeks, the TCA group had significant changes in their total MYMOP profile score and for both reported symptoms ($P<0.05$); the attention group also demonstrated significant changes in MYMOP profile score and for 1 symptom ($P<0.05$); control group showed no change. Comparison between groups demonstrated significant improvements on these scores for the TCA group when compared to the control group ($P<0.05$), whereas the attention group did not. The PSS-14 scores decreased for all 3 groups, but the differences between before and after the intervention period either within or between the groups did not reach

significance in this pilot study. The initial rise in individual cortisol levels after waking (the morning rise) showed an average increase during the intervention in both TCA and attention groups, indicating that for these 2 groups the cortisol response had normalised and they were in a lower state of stress. These trends did not reach statistical significance due to individual variation. The control group showed an overall decrease in the average morning rise over the same period.

This pilot study suggests that TCA could improve perceived stress and its symptoms after 5 sessions of treatment. The relaxation experienced by the attention group also led to some positive outcomes. The most significant improvements were seen in the stress related symptoms as reported in the MYMOP, with the TCA group showing significant improvements over the control group. The effectiveness of TCA treatment for chronic stress and its symptoms is probably via a combination of specific and non-specific effects, with the attention group also showing improvements. However the improvements in symptoms may not relate directly to how a person perceives their stress as there was no correlation between the results of the MYMOP and the PSS-14. The results also suggest that TCA could normalise the diurnal salivary cortisol profile through increasing the morning rise of the cortisol level.

Examination of the case studies showed that TCA treatment was more effective for some individuals than others. The focus group analysis allowed a greater understanding of each individual's perception of stress and its treatment.

This is the first time a combination of quantitative and qualitative research methods was used to explore the role of TCA in moderating chronic stress in adults. The use of the diurnal profile of salivary cortisol concentration as an outcome measure before, during and after TCA treatment was novel and the results indicate that the morning rise alone could be a useful outcome measure. The results of this pilot study contribute to the evidence base in the field of complementary medicine and will be used to inform the design of future research.

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Abbreviation

AA	auricular acupuncture
ACTH	adrenocorticotrophic hormone
ATP	adenosine triphosphate
AR	the alarm reaction
AVP	arginine vasopressin
BUCM	Beijing University of Chinese Medicine
CAM	Complementary and Alternative Medicine
CCHIM	the Centre for Complementary Healthcare and Integrated Medicine
CHD	coronary heart disease
CHKD	China Hospital Knowledge Database
CM	Chinese Medicine
CNKI	China National Knowledge Infrastructure
CNS	central nervous system
CRH	corticotrophin-releasing hormone
CPSR	psychological stress reaction
CRH	corticotrophic releasing hormone
CT	controlled trial
DLE	the Daily Life Experiences Checklist
E	epinephrine
e.g.	exempli gratia
ENRICH	the Evaluating & Nurturing Relationship Issues, Communication, Happiness
EOPs	endogenous opioid peptides
etc.	et cetera
FES	the Family Environment Scale
GAD	generalized anxiety disorder
GAS	General Adaptation Syndrome
GHRH	growth hormone-releasing hormone
hGH	human growth hormone
HPA	the hypothalamic-pituitary-adrenalcortical axis
IBS	irritable bowel syndrome
i.e.	id est

IGFs	insulin like growth factors
ISLE	the Inventory of Small Life Events
JCQ	the Job Content Questionnaire
LEDS	the Life Events and Difficulties Scales
LTE	the List of Threatening Experiences
LTE-Q	the questionnaire version of the List of Threatening Experiences
MAACL	Multiple Affect Adjective Checklist
MACL	Mood Adjective Checklist
MAP	the marital agendas protocol
ME	myalgic encephalomyelitis
MSI	the Marital Situations Inventory
MYMOP	Measure Yourself Medical Outcome Profile
NE	norepinephrine
NIH	National Institute of Health
NIM	neuroendocrine -- immunomodulation network
NPH	nucleus paraventricularis hypothalami
OSI	the Occupational Stress Inventory
PANAS	Positive Affect-Negative Affect Schedule
PGE2	the plasma prostaglandin E2
PNI	psychoneuroimmunology
POMS	Profile of Moods States
PSS	the Perceived Stress Scale
PSS-14	the Perceived Stress Scale - 14
PTSD	Post Traumatic Stress Disorder
RLE	Recent Life Events Questionnaire
RCT	randomised controlled trial
SAM	the sympathetic-adrenal medullary system
SE	the stage of exhaustion
SEPRATE	the Standardized Event Rating System
SNS	sympathetic nervous system
SR	the stage of resistance
SRE	the Schedule of Recent Experiences
SRRS	the Social Readjustment Rating Scale

STRICTA	Standards for Reporting Interventions in Controlled Trials of Acupuncture
TCA	Traditional Chinese Acupuncture
TRH	thyrotropin-releasing hormone
TSH	thyroid-stimulating hormone
TT	Therapeutic Touch
TVU	Thames Valley University
UCT	uncontrolled trial
WES	Work Environment Scale
5-HIAA	5-hydroxyindoleacetic acid
5-HT	5-hydroxytryptamine

Glossary

Acupoints: “Acupoints” is the abbreviation of “acupuncture points”. Acupoints are specific locations where the meridians come to the surface of the skin, and they are throughout the body and correspond to specific organs.

Attention group: The subject in the attention group met with the practitioner, provided outcome data, and lay down for the same amount of time as the TCA group. Attention group in this study acted as a control group to investigate the non-specific effects.

Block randomisation: The most common technique for carrying out random assignment in the random groups design; each block includes a random order of the conditions and there are as many blocks as there are subjects in each condition of the experiment.

Cortisol: Cortisol is a corticosteroid hormone produced by the Zona fasciculata of the adrenal cortex in the adrenal gland. It is a vital hormone that is often referred to as the "stress hormone" as it is involved in the response to stress.

Focus group: A focus group is a form of qualitative research in which a group of people is asked about their attitude towards a product, service, concept, advertisement, idea, or packaging.

Hawthorne effect: Hawthorne effect describes a temporary change to behaviour or performance in response to a change in the environmental conditions, with the response being typically an improvement.

Morning rise of cortisol concentration: It is also called “ Δ cortisol”, which is the change of cortisol concentration between immediately upon waking in the morning and 30mins after waking.

Nocebo: A negative placebo effect as, for example, when patients taking medications experience adverse side effects unrelated to the specific pharmacological action of the drug. The nocebo effect is associated with the person's prior expectations of adverse effects from treatment as well as with conditioning in which the person learns from prior experiences to associate a medication with certain somatic symptoms.

Non-specific effect: Non-specific effect occurs when a patient's symptoms are altered in some way (i.e., alleviated or exacerbated) by a treatment, due to the individual expecting or believing that it will work. It also occurs when a patient is

treated in conjunction with the suggestion from an authority figure or from acquired information that the treatment will aid in healing and the patient's condition improves.

Outcome measure: An instrument, device, or method that provides data on the quantity or quality of the result or product of the experiment; an outcome is the dependent variable of the experiment.

Placebo: In the case of medication studies, a placebo is a substance given to a patient that does not have any direct pharmacological effect. In most studies, the patient does not know whether they are receiving an active medication or a placebo. Any effects seen as a result of taking the placebo are usually attributed to the expectations of the patient, known as the "placebo effect".

Qi: It is energy force running throughout whole body, and consists of all essential life activities.

Randomised controlled trial: It involves the random allocation of different interventions (or treatments) to subjects. This ensures that known and unknown confounding factors are evenly distributed between treatment groups. Randomised controlled trial is considered the most reliable form of scientific evidence in healthcare because it eliminates spurious causality and bias.

Sham: Something false or empty that is purported to be genuine; a spurious imitation.

Salivette: Salivette is a special tube used to collect salivary sample.

Traditional Chinese Acupuncture: It is an important component of Chinese medicine. It is based on Chinese medicine theories, involves the insertion of very fine disposable needles into specific points on the body to treat a wide range of diseases.

Yang: It represents heat, the life functions, and the body's abilities to generate and maintain warmth and circulation.

Yin: It represents cool and the substances of the body, including blood and bodily fluids that nurture and moisten the organs and tissues.

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*: The tables in *Chapter 8 Phase1 Results - Individual Case Studies* are not included in this list.

Names of Acupoints Referred to in this Dissertation*

Point name	Full name	Chinese characters	Pinyin name
LU6	Lung 6	孔最	Kongzui
LU7	Lung 7	列缺	Lieque
LU11	Lung 11	少商	Shaoshang
LI2	Large Intestine 2	二间	Erjian
LI4	Large Intestine 4	合谷	Hegu
LI7	Large Intestine 7	温溜	Wenliu
LI10	Large Intestine 10	手三里	Shousanli
LI11	Large Intestine 11	曲池	Quchi
LI20	Large Intestine 20	迎香	Yingxiang
ST6	Stomach 6	颊车	Jiache
ST9	Stomach 9	人迎	Renyong
ST25	Stomach 25	天枢	Tianshu
ST28	Stomach 28	水道	Shuidao
ST36	Stomach 36	足三里	Zusanli
ST40	Stomach 40	丰隆	Fenglong
SP3	Spleen 3	太白	Taibai
SP4	Spleen 4	公孙	Gongsun
SP6	Spleen 6	三阴交	Sanyinjiao
SP9	Spleen 9	阴陵泉	Yinlingquan
HT3	Heart 3	少海	Shaohai
HT5	Heart 5	通里	Tongli
HT7	Heart 7	神门	Shenmen
BL7	Bladder 7	通天	Tongtian
BL15	Bladder 15	心俞	Xinshu
BL20	Bladder 20	脾俞	Pishu
BL23	Bladder 23	肾俞	Shenshu
BL24	Bladder 24	气海俞	Qihai shu
BL27	Bladder 27	小肠俞	Xiaochangshu
BL40	Bladder 40	委中	Weizhong
BL54	Bladder 54	秩边	Zhibian
KI3	Kidney 3	太溪	Taixi
KI6	Kidney 6	照海	Zhaohai
PC4	Pericardium 4	郄门	Ximen
PC5	Pericardium 5	间使	Jianshi
PC6	Pericardium 6	内关	Neiguan
PC7	Pericardium 7	大陵	Daling
GB5	Gallbladder 5	悬颅	Xuanlu
GB20	Gallbladder 20	风池	Fengchi
GB34	Gallbladder 34	阳陵泉	Yanglingquan
GB40	Gallbladder 40	丘墟	Qiuxu
GB41	Gallbladder 41	足临泣	Zulinqi
LR2	Liver 2	行间	Xingjian
LR3	Liver 3	太冲	Taichong
LR5	Liver 5	蠡沟	Ligou

RN4	Conception Vessel 4	关元	Guanyuan
RN6	Conception Vessel 6	气海	Qihai
RN9	Conception Vessel 9	水分	Shuifen
RN10	Conception Vessel 10	下脘	Xiawan
RN12	Conception Vessel 12	中脘	Zhongwan
RN17	Conception Vessel 17	膻中	Danzhong
RN23	Conception Vessel 23	廉泉	Lianquan
RN24	Conception Vessel 24	承浆	Chengjiang
DU4	Governor Vessel 4	命门	Mingmen
DU14	Governor Vessel 14	大椎	Dazhui
DU20	Governor Vessel 20	百会	Baihui
DU23	Governor Vessel 23	上星	Shangxing
DU24	⁄ Governor Vessel 24	神庭	Shenting
EX-HN3	Extra Point on Head and Neck 3	印堂	Yintang
EX-B2	Extra Point on Back 2	夹脊	Jiaji
EX-B7	Extra Point on Back 7	腰眼	Yaoyan

*: The order of the acupoints in the table follows the 12 regular meridians' circulative order. Sources are from *Standard Acupuncture Nomenclature*, 2nd ed. (WHO Regional Office for the Western Pacific, 1993) and *The National Standard of the People's Republic of China-Location of Points* (State Bureau of Technical Supervision of the People's Republic of China, 1991).

Chapter 1 Introduction

This chapter addresses the background, relevance and significance of the research, and introduces the chapters in this dissertation.

1.1 Introduction to stress in modern life

The human body reacts to stressors in its environment with a variety of biochemical mechanisms which is described as the “fight or flight” response to danger. This was first recognised by Cannon (1914). Observations of this defensive response of the body to stressors applied over longer periods of time led Selye (1956) to develop the model of adaptive response to stress where physiological changes take place in the body that can lead to disturbances in both physical and emotional function. Modern theories of stress and health are related to lifestyle and use a more psychosocial model that includes the individual’s ability to cope with their own perceived stressors (Cassidy, 1999). Lack of ability to cope with perceived stress may lead to a variety of symptoms and may be related to chronic health conditions.

In the last three decades stress has been seen as a contributory factor to the decreased productivity and increased health costs of companies and countries. However, studies of stress-related illness show that stress imposes a high cost on individual health and well-being as well as organizational productivity (Cooper et al., 2001). The Health and Safety Executive (HSE) in the UK (2008) reported the work-related stress accounts for over a third of all new incidences of ill health. Each case of work-related stress, depression or anxiety related to ill health leads to an average of 30.2 working days lost. A total of 13.8 million working days were lost to work-related stress, depression and anxiety in 2006/07. The HSE estimated that one in five employees suffer from high levels of stress, costing UK industry more than £3.7 billion per year in lost production (Clow, 2004). In the UK, the research showed that stress-related work absence costs NHS trusts £450,000 a year on average, with nurses among those most likely to be off sick with the condition (McLaughlin, 2005). The Centre for Disease Control and Prevention reported that up to

90% of the doctor visits in the USA may be triggered by a stress-related illness (Fackelmann, 2005).

If symptoms related to stress are left untreated, chronic stress can lead to serious illness. Chandola et al. (2008)'s research on a total of 10,308 London-based male and female civil servants concluded that work stress may be an important determinant of coronary heart disease (CHD) among working-age populations, which is mediated through indirect effects on health behaviours and direct effects on neuroendocrine stress pathways. Chronic stress has been found to be a contributing factor for hypertension, diabetes, cancer and many other illnesses (National Institutes of Health, 2002; Rosmond and Bjorntrop, 2000). The World Health Organization estimates that mental disease, including stress-related disorders, will become the second commonest cause of disability by 2020 (Greener, 2002).

A person suffering from stress can present with a variety of conditions. This poses problems for a conventional practitioner to treat on a symptomatic basis. Most medication prescribed by the doctors has side effects. A survey of UK general practitioners suggests that stress constitutes an "effectiveness gap" or an area of clinical practice in which available treatments are not fully effective (Fisher et al, 2004). Though there are some stress management techniques to help people to become relaxed, these are not enough for someone suffering from high stress levels to control symptoms induced by stress. It is necessary to find an effective treatment to treat symptoms through improving the general wellbeing, controlling stress levels, and preventing stress from developing into serious illnesses.

1.2 Introduction to Traditional Chinese Acupuncture for stress

Traditional Chinese Acupuncture (TCA) as part of Chinese medicine has been practised in China for several thousand years and is used in the treatment for a wide range of diseases with few reported side effects. Its main focus is to correct energetic imbalances and to improve overall wellbeing. Chinese medicine believes that the interior and exterior, local and general, upper and lower parts of the human body form an organic

whole, closely related to climatic or environmental factors. Diagnosis and treatment should be based on an overall analysis of symptoms and signs, including the nature and other factors of the illness and the patient's physical condition (Huang et al., 1982). According to this theory, TCA uses individual diagnoses and treatment plans, and uses different acupoints on the body to alter the body's qi or vital energy.

The symptoms of stress are varied and may include: insomnia, lack of concentration, lack of energy, headaches, muscular tension, et cetera (etc.). These tend to be connected with the body's general condition. Though the word "stress" (应激, ying ji) is new in Chinese medicine, the traditional theories of zang and fu organs and the seven emotions provided a framework thousands of years ago for understanding that a bad environment or disturbed mental stimulation has a close connection with disease; therefore stress's symptoms and treatment theory have been part of Chinese medicine for a long history. Chinese medicine theory indicates that chronic stress is mainly caused by liver qi stagnation, which could develop to liver qi transforming into fire, liver qi invading spleen and stomach, deficiency of gallbladder qi, or deficiency of both heart and spleen. With its long history and rich clinical experience, TCA can effectively treat stress.

Acupuncture is increasingly popular in the western world (Baldry, 2005). Symptoms of patients presenting for acupuncture are often those relating to stress. A descriptive study on the practice of chartered physiotherapists using acupuncture in the UK has shown stress to be one of the conditions perceived to respond well to acupuncture and recommended this topic as a future area for research (Alltree, 1993). In the U.S. research has revealed that there is the potential for using acupuncture to contribute to caring in the light of contemporary nursing philosophies of care, which include the management of stress (Beal, 1995). In Norway, the study of the association between mental distress and the use of alternative medicine among cancer patients showed that seeking alternative treatment is more common among mentally distressed cancer patients (Risberg and Jacobsen, 2003).

1.3 Introduction to the research project

The aim of the study was to investigate whether TCA was effective in improving stress levels for adults experiencing symptoms of chronic stress. This was an exploratory study which included: a pilot randomised controlled trial (RCT), case study reports and focus groups. This project used the novel approach of using a combination of qualitative and quantitative methods, patient-centred, self-reported questionnaires and salivary cortisol measurements to evaluate the effectiveness of this treatment.

The results of the pilot study contribute to the evidence base in the field of complementary medicine and will be used to inform the design of future randomised controlled trials.

1.4 Structure of this dissertation

There are ten chapters in this dissertation. Chapter 2 defines what is meant by stress, its biological mechanisms and the way humans cope with its demands, discusses the common symptoms of stress and their effects on health, describes the various methods of treatment and management. Chapter 3 introduces the measurement methods used in stress research. Chapter 4 introduces the basic Chinese Medicine theory of health and illness, and discusses the meaning of stress in Chinese medicine, its diagnosis in Chinese medicine and treatment by TCA. Chapter 5 is a systematic literature review of clinical trials on the use of acupuncture for managing stress in order to explore research evidence relevant to this field. Chapter 6 provides the details of the study design and methods in this research project. Chapters 7, 8, and 9 present the results of the RCT, individual case studies, and focus groups respectively. Chapter 10 discusses the findings and the implications of this research, evaluates the design and methods, discusses the limitations and strengths of the approach used, presents the conclusions of this research, and provides recommendations as well as suggested areas for future research.

This dissertation involves terms used in Chinese medicine, Western medicine, psychology, and biology. Abbreviations and glossaries are given at the beginning of the dissertation in order to clarify terms used. The figures, tables and acupoints presented

and used in the thesis are also listed in the front of the dissertation. The appendices in the end of dissertation provide all documents used in this research, data collected in the process of the study, and some of the results which are not included in the main chapters.

In this dissertation, words related to Chinese are written combined with Chinese characters and pinyin, for example, *The Spiritual Pivot* («灵枢», Ling Shu), anxiety (焦虑, jiao lü), ST36 (足三里, Zusanli).

Chapter 2 Theory of Stress

This chapter defines what is meant by stress, its biological mechanisms and the way people cope with its demands. The common symptoms of stress and their effects on health are discussed. It also describes the various methods of treatment and management, including some complementary approaches.

2.1 Concept and definition

The term “stress” was used as early as the 14th century to mean “hardship, straits, adversity, or affliction” (Lumsden, 1981; Lazarus, 1984).

The development of stress as a concept in human health has grown through research into the physiological response of organisms to the external demands and danger, through the relationship of this response to short and long term health issues, and more recently to the interaction between these aspects of stress and individual human social and psychological systems.

Stress research really began with early interest in the variety of biochemical mechanisms that add up to the “fight or flight” response by organisms to danger, first recognised by Cannon (1914). Observations of this defensive response of the body to stressors applied over longer periods of time led Hans Selye to develop the model of adaptive response to chronic stress in which physiological changes take place in the body that can lead to disturbances in both physical and emotional function (Selye, 1956).

As early as 1936, Selye was using the term “stress” in a technical sense which he described as “an orchestrated set of bodily defences against any form of harmful stimulus” (including psychological threats), and the body’s short-term and long-term reactions to stress response which he called the General Adaptation Syndrome (GAS) (Selye, 1946). Later, Selye (1974) explained his choice of terminology as follows: “I call this syndrome “general” because it is produced only by agents which have a general effect upon large portions of the body. I call it “adaptive” because it stimulates defence....I call it a “syndrome” because its individual manifestations are coordinated

and even partly dependent upon each other.” Selye thought that the GAS involved two major systems of the body, the nervous system and the endocrine (or hormonal) system. From the research involving exposing animals to unpleasant or harmful stimuli such as injections, extreme cold and even vivisection, Selye observed that all animals showed a very similar series of reactions, broken into three distinctive stages in the syndrome's evolution. He called these stages the alarm reaction (AR), the stage of resistance (SR), and the stage of exhaustion (SE) (see 2.2 *The stress response*).

Stress was, in effect, not an environmental demand (which Selye called a “stressor” (1950)), but a universal physiological set of reactions and processes created by such a demand. Selye’s work and its spinoffs have played a dominant role in the subsequent expansion of interest in stress (Lazarus and Folkman, 1988).

In the 1940s and 1950s, Harold G. Wolff wrote about life stress and disease, and regarded stress as a “dynamic state” of the body involving adaptation to demands (exempli gratia (e.g.) Wolff, 1953). His work played an important role in the evolution of the stress concept in medicine (Hinkle, 1977). This concept of stress in relation to human health issues led to the development of research into the psychological aspects of stress and ways in which these could be measured. Much stress research was oriented toward studies involving the body’s reaction to stressors (a physiological perspective) and the cognitive processes that appraise the event or situation as a stressor (a cognitive perspective). There was also a growing interest in the epidemiology of diseases thought to result from stress, such as cardiovascular disease (Chandola, 2008) or depression (Steptoe and Whitehead, 2005; Follath, 2003).

Further research on the social perspectives of the stress response noted that different people experiencing similar life conditions were not necessarily affected in the same manner. Pearlin (1982) observed that individuals’ coping strategies were primarily social in nature. The manner in which people attempt to avoid or resolve stressful situations, the cognitive strategies that they use to reduce threat, and the techniques for managing tensions are largely learned from the groups to which they belong. The orientation toward stress research has changed as awareness of the social and cultural contexts

involved in stress and coping have been examined. The current biopsychosocial model of stress incorporates a variety of social factors into its model that can influence the reaction to stress and its perception.

The concept and definition of stress has changed over time. It is defined differently by different branches of science involved in stress research and also has a different meaning between scientists and the general public.

Hans Selye (1982) pointed out that few people define the concept of stress in the same way or even bother to attempt a clear-cut definition. People say they are stressed when taking an examination, or when having difficulties at work or within their personal relationships. Stressful situations can be viewed as harmful, threatening, or challenging. According to Selye, an important aspect of stress is that a wide variety of dissimilar situations are capable of producing the stress response such as fatigue, effort, pain, fear, and even success. Cooper et al. (2001) also reported wide discrepancies in the way that stress has been defined. Examples of definitions of stress are given as follows:

“Stress is the non-specific response of the body to any demand made upon it.” (Selye, 1974)

“Stress is a particular relationship between the person and the environment that is appraised by the person as taxing or exceeding his or her resources and endangering his or her well-being.” (Lazarus and Folkman, 1984)

“Stress is defined as any transactional process in which the organism experiences an alteration of psychological homeostasis.” (Burchfield, 1985)

“Stress is equivalent to a person’s perception of pressure upon them”, or the “three-way relationship between demands on a person, that person’s feelings about those demands and their ability to cope with those demands.” (Richard, 1989)

“Stress reflects the lack of fit between the person and his or her environment, and is an intervening variable between a stimulus (factors provoking stress for a person) and the response (the effects of stress on that person).”(Chambers, 1999)

Chambers (2003) discussed how the concept and definition of stress could develop from various sources, such as:

- External – arising from the environment;
- Internal – arising from within the individual;
- A mixture of internal and external causes.

Other authors (Bartlett, 2002; Lazarus and Folkman, 1984) have further categorised the concepts and definitions as follows:

- Stimulus based;
- Response based;
- Interactional (or relational).

Stimulus based definitions: These identify stress as an aspect of the environment (a stimulus) which causes a “strain reaction” to the individual when they are exposed to it. They focus on events in the environment, for example natural disasters, illnesses, or being made redundant from work. This approach assumes that certain situations are stressful but does not allow for individual differences in response.

Response based definitions: These are common and refer to a state of stress. They focus upon the occurrence of the response as the actual stress itself. Defining stress merely in terms of a physiological response has proved inadequate in accounting for the complexities of the human psychological reaction to the stress process.

Interactional (or relational) definitions: In response to the shortcomings of viewing stress solely as a characteristic either of the external environment (stimulus) or of the physiological response, interactional (or relational) definitions emphasise the relationship between the person and their environment. This parallels the modern medical concept of illness, which is no longer seen as caused solely by an external organism; whether or not illness occurs depends also on the person’s individual susceptibility. The interactional definition of stress is a combination of the stimulus and response models. Stress is therefore seen as the whole process from encountering stressful stimuli in the environment, through to the physiological response of the body and the individual’s experience of stress. The interactional approach does not take into account the causal pathways between the different aspects of the relationship. Lazarus et

al. (1984; 1978) developed this idea as a transaction. Their theory explores the nature of the stressor – response – outcome relationships. This is currently the most frequently used model of stress.

Stress may result either from stressful events themselves or from people's perception of them. A particular event or task may be very stressful for one person on one day but not on another – it all depends on how the person is feeling and what other pressures are being exerted on them. In general, stress occurs in situations where the demands on the person are high, their control over those demands is limited, and they have inadequate support or help.

2.2 The stress response

Stress from everyday life cannot be avoided. Some stress can result in beneficial outcomes, which is called eustress; other stress can be harmful, which is called distress, and its effects can be acute and excessive, as in post-traumatic stress disorder (PTSD), or long-term, leading to chronic ill health. Any stimulus that produces a stress response is called a stressor. The responses to stressors can be experienced as pleasant or unpleasant, depending on an individual's appraisal of the situation in which the stressor acts. This appraisal may change for an individual with changing external conditions, as well as that between different individuals.

The stress response has 2 stages: acute and chronic. When an acute stress response occurs, the body's homeostatic mechanisms try to control its effects. When they are successful, the internal environment remains within normal physiological conditions. If the body does not return to homeostasis, either because stress is extreme, or persistent, then the chronic stress response occurs.

2.2.1 Acute stress

The stress response is the body's normal response to environmental demands or danger to ensure survival of the individual. This is the "fight or flight" response. This response is also the first stage (the alarm reaction (AR)) of the GAS (Selye, 1946).

The “fight or flight” response consists of the following 4 stages (Seaward, 2002):

Stage 1. Stimuli from one or more of the five senses are sent to the hypothalamus.

Stage 2. The brain appraises the stimulus as either a threat or a non-threat. If the stimulus is not regarded as a threat, this is the end of the response; if it is a real threat, the brain activates the nervous and endocrine systems to quickly prepare for defence and / or escape.

Stage 3. The body stays activated and aroused until the threat is over.

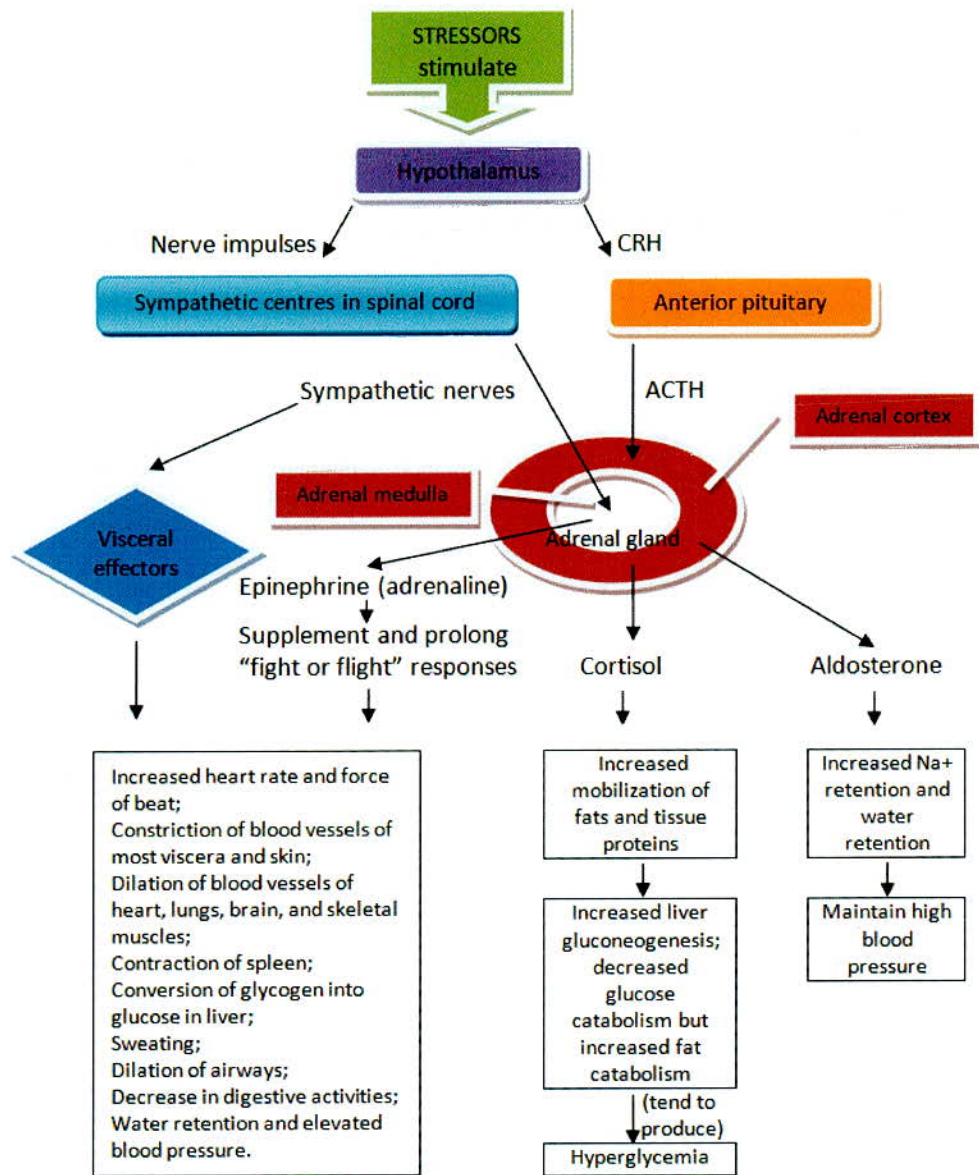
Stage 4. The body returns to homeostasis, once the threat is gone.

When stressors stimulate the hypothalamus, two pathways work at this stage (Thibodeau and Patton, 2007).

1. Nerve impulses increase sympathetic nervous system activity, stimulating the adrenal medulla to secrete epinephrine. The “fight or flight” response quickly arouses the body’s resources for immediate physical activity. This happens within seconds of the stressor being seen as a threat.
2. The adrenal cortex increases its secretion of corticosteroids, primarily the glucocorticoid cortisol and the mineralocorticoid aldosterone. This occurs within minutes if the threat is sustained, to provide energy and increase the blood pressure to maintain the “fight or flight” response.

The two pathways of “the fight or flight response” are detailed in *Figure 2.2.1*.

Figure 2.2.1 The fight or flight response*



Abbreviations: ACTH = adrenocorticotropic hormone.

CRH = corticotrophin-releasing hormone.

*: Sources adapted from *Anatomy and physiology* (sixth edition) (Thibodeau and Patton, 2007) and *Principle of anatomy and physiology* (11th edition) (Tortora and Derrickson, 2007).

The two major stress hormones, cortisol and epinephrine, facilitate the movement of immune cells from the bloodstream and storage organs such as the spleen into tissue where they are needed to defend against infection. During this stage, nonessential body functions such as digestive, urinary, and reproductive activities are inhibited.

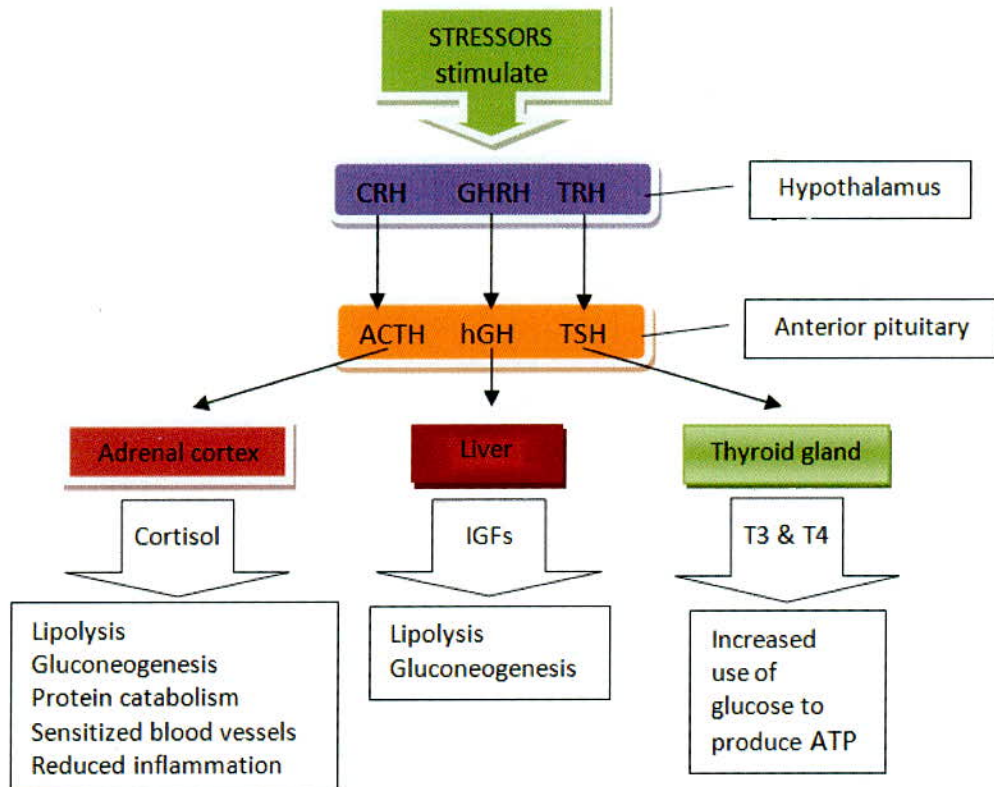
2.2.2 Chronic stress

If a stressor is maintained, the body does not return to homeostasis, and the body's attempts to protect itself may produce long term effects. In the GAS, this is the second stage called "the stage of resistance" (SR). Further hormones released by hypothalamic activity are corticotrophin-releasing hormone (CRH), growth hormone-releasing hormone (GHRH), and thyrotropin-releasing hormone (TRH) (Tortora and Derrickson, 2007).

During this stage, the activity of the sympathetic nervous system declines and epinephrine secretion is less, but corticosteroid secretion continues at above normal levels. As in the acute response, CRH which is released from the hypothalamus stimulates the anterior pituitary to secrete adrenocorticotrophic hormone (ACTH), which in turn stimulates the adrenal cortex to increase release of cortisol. Cortisol then stimulates gluconeogenesis by liver cells, breakdown of triglycerides into fatty acids (lipolysis), and catabolism of proteins into amino acids. Prolonged high cortisol levels reduce inflammation, slow down wound healing, and depress the immune system. This complex set of direct influences and feedback interactions among the hypothalamus, the pituitary gland, and the adrenal gland is called the hypothalamic-pituitary-adrenal axis (HPA axis). This is the major part of the neuroendocrine system that controls reactions to stress and regulates many body processes and the common mechanism for interactions among glands, hormones, and parts of the midbrain that mediate the GAS (Dinan, 2004; Engelmann, 2004).

GHRH causes the anterior pituitary to secrete human growth hormone (hGH). Acting via insulin like growth factors (IGFs), hGH stimulates lipolysis and glycogenolysis, the breakdown of glycogen to glucose, in the liver. TRH stimulates the anterior pituitary to secrete thyroid-stimulating hormone (TSH). TSH promotes secretion of thyroid hormones (T3 and T4), which stimulate the increased use of glucose for adenosine triphosphate (ATP) production. The process of stress responses during SR is shown in Figure 2.2.2.

Figure 2.2.2 Responses to stressors during SR*



Abbreviation: ACTH= adrenocorticotrophic hormone, ATP= adenosine triphosphate,
 CRH= corticotrophin-releasing hormone, GHRH= growth hormone-releasing hormone,
 hGH= human growth hormone, IGFs= insulinlike growth factors,
 TRH= thyrotropin-releasing hormone, TSH= thyroid-stimulating hormone

*: Adapted from *Principle of Anatomy and Physiology* (11th edition) (Tortora and Derrickson, 2007).

“The stage of resistance” (SR) helps the body continue fighting a stressor after the “fight or flight” response has finished. It helps prevent excessive bleeding and slows the inflammatory and healing processes which prevent them becoming overwhelming. This stage also provides the energy, enzymes, and circulatory changes needed to meet emotional crises and perform strenuous tasks in everyday life. If it is successful in combating the stressor, the body returns to normal; if it fails, the body moves to “the stage of exhaustion” (SE) in the GAS.

During the SE, stress has continued for some time, and the body has been unable to return to homeostasis. Some organs are locked into a pattern of overactivity whilst others are becoming inactive. Mental, physical and emotional resources suffer heavily.

The body experiences "adrenal exhaustion" as the glands struggle to maintain high levels of hormone production. The blood sugar levels decrease as the adrenals become depleted, leading to decreased stress tolerance, progressive mental and physical exhaustion, which in turn has a negative feedback effect. Other significant effects occur to the circulatory system, with tissue damage to the blood vessels and heart. The immune system is suppressed, the digestive system functions poorly and other pathological changes can occur throughout the body. These changes can persist even when the stressors have been removed.

In conclusion, the acute stress response allows the body to protect itself when threatened, particularly by physical and environmental stressors. The resistance stage allows the body to deal with a more prolonged stressful episode. Full recovery is possible from both these responses. However, sustained and uncontrolled stress responses can lead to chronic and even permanent physiological changes which may develop into ill health. In modern life stressors are as likely to be psychological, emotional or social, as the physical threats that evolution has prepared us for. Although the stress response is the same for all individuals, it is the way human beings appraise different stressors which leads to our individual stress and health issues. Personal coping mechanisms are needed to help to remove stressors, control stress responses, and return the body to homeostasis.

2.3 Cognitive appraisals and coping mechanisms

Cognitive appraisal is a process through which the person evaluates whether a particular encounter with the environment is relevant to his or her well-being, and if so, in what ways (Kolkman et al., 1986). Current research indicates that the way in which an individual appraises a situation may be more important to psychological well-being than the actual presence of stress (Oliver and Brough, 2002). Cognitive appraisal is central to the stress and coping processes, for it determines how an event is perceived and therefore mediates between the stressor and the outcome.

Cognitive-relational theory defines stress as a particular relationship between the person and the environment that is appraised by the person as making demands or exceeding his

or her resources and endangering his or her well-being, and emphasizes the continuous, reciprocal nature of the interaction between the person and the environment (Lazarus & Folkman, 1984). Appraisals are determined simultaneously by perceiving environmental demands and personal resources. They can change over time due to coping effectiveness, altered requirements, or improvements in personal abilities.

Within the transactional model of stress, Lazarus and Folkman have described two component processes of cognitive appraisal (1984). In the first -- "primary appraisal", a situation is perceived as being stressful or not, and whether a stressor is likely harmful (negative) or exciting (positive). The second type of cognitive appraisal, "secondary appraisal", occurs when an event is appraised as stressful and involves an evaluation of what can be done in a situation, including an assessment of the availability of resources and coping options.

The word "coping", as defined by Lazarus and Folkman (1984), is the "the person's constantly changing cognitive and behavioural efforts to manage specific external and/or internal demands that are appraised as taxing or exceeding the person's resources". Coping has two widely recognized major functions:

- Regulating stressful emotions (emotion-focused coping) ;
- Altering the relationship between the person and the stressor (problem-focused coping).

Two previous studies (Folkman and Lazarus, 1985; 1980) have provided strong empirical support for the idea that coping usually includes both functions. Coping strategies can be either positive, leading to improved health outcomes (e.g. TCA, relaxation, yoga), or negative, leading to negative health outcomes and possibly increased stress (e.g. smoking, drinking alcohol, or substance misuse).

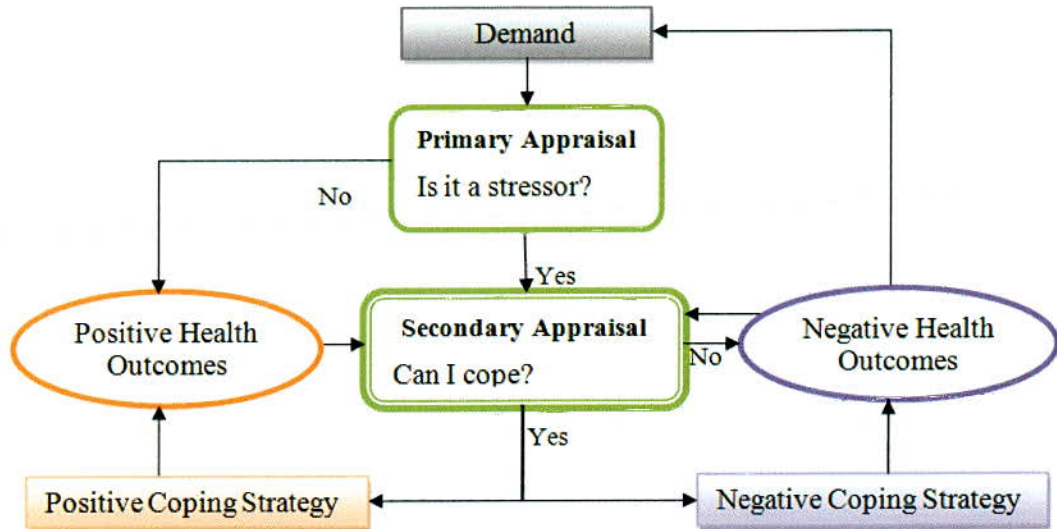
The purposes of positive coping skills (Lazarus and Folkman, 1984; cited by Taylor, 1995) are shown by:

1. Reducing harmful environmental conditions;
2. Tolerating or adjusting to negative events or realities;
3. Maintaining a positive self-image;

4. Maintaining an emotional equilibrium;
5. Continuing a satisfying relationship with another person.

Reviewing the literature on coping, Lazarus (1993) concluded that coping is complex, depends on whether people perceive that something can be done, is generally consistent across genders, and acts as a powerful mediator of emotional outcomes. For example, Taylor et al. (2000) suggested that females respond differently to a threat by seeking social support and protection of their offspring, which has been termed “Tend or Befriend”. This process may be triggered by the addition of sex hormones to those produced by the stress reaction. Some coping strategies are consistent from situation to situation while others depend on the current context, and the effectiveness of a coping strategy depends on the situation, the person and the outcome people are considering. Therefore what might produce a good health outcome might not necessarily produce a good emotional outcome. Giving up smoking is likely to produce better health but may not make some one happier (at least in the short term). What seems clear is that the coping behaviour adopted depends on the cognitive appraisal and the cognitive style in stressful contexts. *Figure 2.3* illustrates cognitive appraisals, coping mechanisms and their possible health outcomes.

Figure 2.3 Cognitive appraisals, coping mechanisms and their possible health outcomes*



*: Adapted from Howie's work (2008)

Positive health outcomes occur when either a demand is not appraised as a stressor at primary appraisal, or that at secondary appraisal a positive coping strategy is employed. Positive health outcomes can also lead to a positive feedback in the coping strategy.

Negative health outcomes occur when a demand is recognised as a stressor at primary appraisal, and either no coping strategy is available or a negative coping strategy employed at secondary appraisal. Negative health outcomes can lead to a negative feedback loop. Any treatment or management is aimed at reducing the appraisal of stressors, improving positive coping mechanisms or reducing the negative feedback by treating symptoms of ill health.

Psychologists have developed theories as to why stress and ill health affect some individuals more than others. Individual differences in personality, which result partly from genetic influences, significantly impact on individual appraisal and coping strategies (Rutter and Silberg, 2002). These differences make individuals more or less likely to experience stressful events and to have poor quality interpersonal relationships, which in turn feedback on the individual, influencing their risk for subsequent illness (Kendler et al., 2003). Certain personality types appear to be stress-prone whereas others

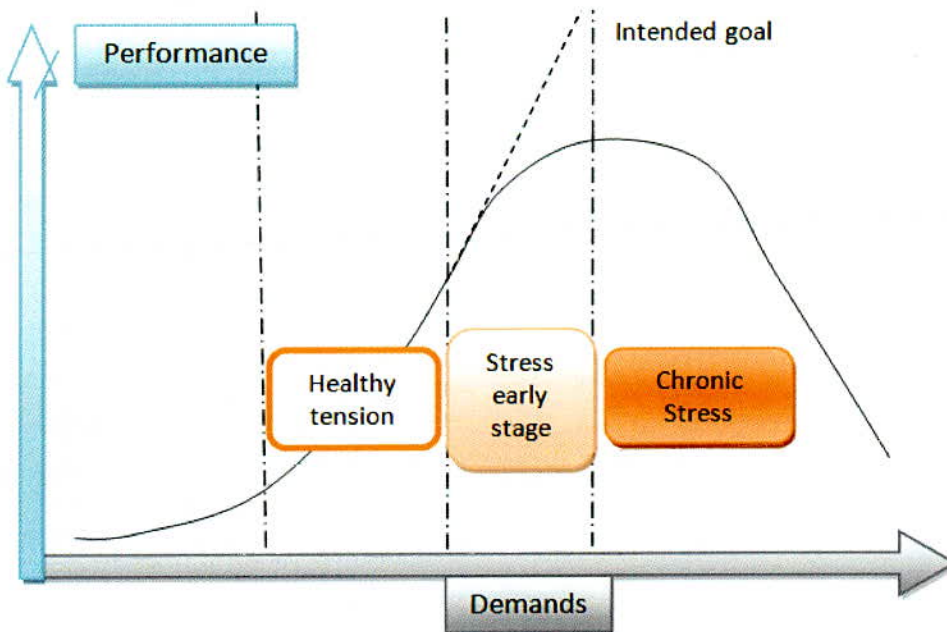
appear to be stress-resistant. Stress-prone personalities include type A behavior (a rushed or hurried lifestyle) (Ursano et al., 2002; Heilbrum and Friedberg, 1988; Friedman and Rosenman, 1974), type D or distressed personality (Pedersen and Denollet, 2003; Denollet and van Heck, 2001; Denollet, 2000), codependency (Beattie, 1989), and the helpless-hopeless personality (Seligman, 1975). The hardy personality and the sensation seeker are believed to be stress-resistant (Kobasa and Puccetti, 1983; Zuckerman, 1971). Various studies indicate that the level of self-esteem is a critical factor in how people respond to stress (Hughes, 2007; Abraham, 1999; Branden, 1992; Clemes et al., 1990). Low self-esteem appears to attract stress; high self-esteem can repel it.

2.4 Symptoms of stress and their relationship to ill health

The previous sections have shown how the chronic stress response can lead to ill health, but individual's appraisal what is stressful for them and their behaviour in coping with stressors in their lives have an important effect on how they manifest symptoms of stress related to illness. The "fight or flight" response can lead to emotions of anger and fear, which if unresolved produce a negative feedback stress cycle (Middelton-Moz, 1999; Handly and Neff, 1987). Acutely stressful life events can lead to health issues long after the event is over, as seen in post-traumatic stress disorder (PTSD). For most people however stress arises from everyday demands and pressures.

All people have to deal with a range of demands in their lives, which affect their output or performance. These demands can include work, relationship, or social pressures. The resources a person is available to deal with these demands will determine their ability to perform which in turn will determine whether these demands are perceived as stressors or not. This is illustrated in *Figure 2.4*.

Figure 2.4 Human performance curve*



*: Sources adapted from the work of Dhillon (2006), Long (2000), Anderson et al. (1989), Yerkes and Dodson (1908)

When the demands start to outstrip the resources, early signs of stress may be observed. These symptoms can be physical, mental, or behavioural in nature. The common symptoms and signs of stress are listed in *Table 2.4-1*.

Table 2.4-1 Symptoms and signs of stress*

Physical symptoms	Mental/cognitive, emotional signs	Behavioural symptoms
tiredness	anxiety	inability to sit still
headache	panic	frequent crying
light-headedness	increased worrying	change in usual behaviour
muscle tension	depression	increased substance use
palpitations	fearfulness	changes in eating patterns
stomach upsets	negative outlook	loss of appetite
indigestion	feeling of unreality	eating more sweets
skin problems	feeling unable to cope	changes in sleep patterns
weight gain or less	feeling of depersonalization	loss of sex drive
trembling	feeling anger, hurt or unhappy	increased smoking or drinking
sweating	feeling helpless	making mistakes
frequent cold	lacking confidence	changes in bowel movements
dry mouth	not wanting to socialise	being argumentative
more infections	loss of interest in anything	shouting
insomnia	frustration	aggression
disturbing dreams	restlessness	violent outbursts
poor balance	despair	pacing
hyperventilation	irritability	hand-wringing
high blood pressure	dread of future	having minor accidents
peripheral tingling	indecision	being accident prone
	poor concentration	biting fingernails
	low self-esteem	
	forgetfulness	
	reduction in problem solving	
	ruminating	

*: Sources adapted from: *Beating Stress in the NHS* (Chambers et al., 2003), *The Everything Stress Management Book* (Adamson, 2002), *Stress Management for Primary Health Care Professionals* (Rout and Rout, 2002), *Stress Management in Primary Care* (Hambly and Muir, 1997), *Managing Stress* (Looker and Gregson, 1997), *The Complete Guide to Stress Management* (Patel, 1996), *Living with Stress* (Cooper et al., 1988), and *The Stress of Life* (Selye, 1976).

Further demands can then lead to a chronic state of stress, and therefore the more serious aspects of ill health are related to the stage of resistance in the GAS. The common serious disorders in which stress may be a factor are summarised in *Table 2.4-2*.

Table 2.4-2 Common serious disorders in which stress may be a factor*

Body's system	Disorders
Nervous system	Myalgic encephalomyelitis (ME), stroke, nervous rash, migraines, backache
Cardiovascular system	Coronary heart disease, hypertension, myocardial infarction
Digestive system	Peptic ulcer, irritable bowel syndrome (IBS), ulcerative colitis, eating disorders
Respiratory system	Asthma
Urinary and reproductive system	Impotence, irregular menstruation
Endocrine system	Acne
Immune system	Arthritis, hay fever, eczema, allergies, lupus, herpes, adult-onset diabetes, cancer
Psychological illnesses	Mental health disorders

*: sources are from the papers of Groot (2002), Seaward (2002), Cohen and Williamson (1991), Laudenslager (1988), Rabin et al. (1989), and Herd (1986).

Symptoms of ill health can also occur as an indirect result of the human response to stressful demands. Behavioural changes occurring as adaptations or coping responses to stressors as negative coping strategies (see *Figure 2.4 Cognitive appraisals and coping mechanisms*) may also influence disease risk. For example, people exposed to stressors or who view themselves as being under stress tend to engage in poor health practices (Cohen and Williamson, 1988; Conway et al., 1981). Smoking more, drinking more alcohol, eating poorly, exercising less, and sleeping less have been established as risk factors for a range of different physical illnesses. Both stressors and negative effects have also been associated with failure to comply with medical regimens. Such failure could result in more severe and longer-lasting illness, either because undesirable behaviours which can aggravate existing problems or because failure to perform desirable behaviours (e.g. following medication regimens) result in disease progression. Other stressor-elicited behaviours, e.g. unsafe sexual practices or poor hygiene practices, could also increase exposure to infectious agents (Cohen et al., 1997).

In conclusion, perceived stress increases the chances of an individual becoming ill. Positive coping strategy, treatment and management are needed to control stress levels,

release stress symptoms, or treat stress-induced illnesses in order to decrease the risk of illness and prevent bad health from deteriorating further.

2.5 Treatment and management

In this dissertation, the definition of “treatment” and “management” proposed by Lazarus and Folkman (1984) is adopted. Treatment or therapy is the word preferred by those who work one-on-one with individual clients, families, or small groups; stress management refers to formal programmes for people in general, less often for special groups characterized by some shared problems.

2.5.1 Conventional treatment

A patient approaching their GP with various health issues that are diagnosed as stress related are likely to be treated on symptomatic basis or referred for counselling or psychotherapeutic treatment. The literature outlines the range of psychotherapeutic approaches to the treatment and management of stress. Some approaches have their focus on particular syndromes of stress and distress such as anxiety, phobias and depression (Gardner-Abbate, 2002; Nakao et al., 2001; Jacobs and Nadel, 1985), some centre on problems of adapting and controlling impulses such as smoking or excessive eating, and others focus on the inadequacies of coping skills such as lack of assertiveness.

Generally one-on-one approaches to treatment can be broadly classified as biological or psychological. Biological approach focuses on biochemical imbalance and uses pharmacotherapy and / or somatic therapies to reach the restoration of normal physiological processes. The psychological approach can be divided into 3 categories.

1. Dynamic: This originated in Freudian psychoanalysis. This kind of approach centres on anger directed against the self, following real or symbolic loss. The treatment is an attempt to help the client discover the origins of poor coping and how it is perpetuated and / or to acquire more effective coping strategies.
2. Behavioural: All behavioural approaches emphasise some form of conditioning or deconditioning process. The client monitors his or her own behaviour, uses

reinforcement to learn self-control, and shapes behaviour patterns in the desired direction.

3. Cognitive-behaviour: This emphasises the mediating role of cognitive processes in sustaining or eliminating patterns of behaviour. The therapy encourages changes by employing an examination of current beliefs and behaviour, followed by training in self-monitoring and cognitive restructuring.

It is not clear which strategy works best, and in all likelihood multiple strategies increase the odds of producing the necessary changes for improved health. One way or another psychological approach believes that if there is to be therapeutic change, there must be changes in cognitive appraisal and coping.

By applying the theoretical approach to intervention psychotherapeutic treatment regards stress related illness as transactional, which must be seen as a product of the interplay between the person and his or her environment (Lazarus and Folkman, 1984).

2.5.2 Stress management programmes

Stress management is used to cultivate and strengthen personal resources and improve coping strategies. It can be used at variety of levels including reducing environmental demand, improving the processes of appraisal and coping, or improving positive health outcomes. Stress management can also be used as preventative strategy.

There are different types of stress management using the different techniques. For example, Training in behavioural techniques can improve work satisfaction and reduce work stress (Milne et al., 1986). Personal stress management relaxation techniques can significantly improve people's ability to cope with anxiety and stress (Laingen, 2002; Watson, 1986). Stress management workshops have been showed to be effective in reducing levels of burnout (Kunkler & Whittick, 1991).

Some stress management programmes are designed for large groups of people, they are not tailored to what the individual needs. Their effectiveness may be limited for people

whose troubles stem from individual conflicts or personal agendas that these programmes do not address. Problem – focused stress management programmes also inadequate for people who suffer distress because of the concerns that may be realistically related to their troubles (Bond and Bunce, 2000).

There is an argument which believes that stress management programmes usually only last for a short period. The suggestion is that there can never be a simple procedure for generating the cognitive, behavioural, and emotional processes that can propel the person toward better self-confidence, social and work functioning, and physical health. (Lazarus and Folkman, 1984). A systematic literature review (Ong et al., 2004) showed that stress management techniques were inconsistently labelled and were often poorly described and that comparisons of stress management outcome studies are not meaningful at that time due to their high variability.

In conclusion, in order to achieve more effective results, any stress management programme must stimulate the person to appraise the situation and / or cope with their demands in new ways.

2.5.3 Complementary and Alternative Medicine approaches

Besides conventional western treatment and management, and often in combination with these health strategies, complementary and alternative medicine (CAM) offers approaches that can be used to treat stress and its symptoms. In practice, there is a huge range of different CAM strategies that are used to treat and manage stress and its symptoms. However, there has only been limited scientific research into CAM strategies which have demonstrated that there are measurable changes in levels of stress and stress related health issues (NCCAM, 2007; Krebs, 2001). Some examples of research into CAM used to treat stress are discussed below.

Acupuncture: A National Institute of Health (NIH) panel (1997) in the US concluded that acupuncture was an acceptable alternative to conventional therapy for headaches, low back pain, fibromyalgia, asthma, and carpal tunnel syndrome. The panel stressed

that acupuncture had minimal side effects compared to conventional treatments and further noted considerable evidence that acupuncture causes the release of natural pain relieving substances (endorphins) in the brain. In 1993, a NIH-funded study evaluated the use of acupuncture in the treatment of unipolar depression in 33 women (NIH, 1994). Based on the results of the samples, though small, acupuncture appeared to offer significant symptom relief comparable to conventional interventions such as psychotherapy or pharmacology. The use of acupuncture as an effective treatment for depression was substantial enough to warrant a large-scale clinical trial.

More details on acupuncture are given in *Chapter 4 & 5*.

Aromatherapy: Smell can evoke a variety of emotional states. Aromatherapy involves releasing the aromas of pure essential oils to promote health. Relieving anxiety, reducing stress, and promoting relaxation are perhaps the most common uses of aromatic essential oils. Aromatherapy can be employed in baths, as a diffusion or inhalation, or in massage therapy. Examples are as follows.

Essential oils have major effects on decreasing pain and depression levels (Kim et al., 2005). The main essential oils used were lavender, marjoram, eucalyptus, rosemary, and peppermint. Kim et al. (2005) suggested that aromatherapy could be a useful nursing intervention for arthritis patients. Researchers (Dunn et al., 1995) in the intensive care unit at the Royal Berkshire Hospital NHS Trust, Reading, found patients in the aromatherapy group reported significantly greater improvements in their mood and perceived levels of anxiety. Patients who received aromatherapy were found to be less anxious and more positive immediately after the treatment. Although the improvements were temporary, the results revealed a demonstrable improvement in the aromatherapy group in perceived anxiety.

Guided imagery: This technique teaches people to imagine scenarios that may help relieve certain physiological conditions. The research carried out by Mannix et al. (1999) showed that in the guided imagery group patients had significantly more improvement than the control group in three of the SF-36 domains: bodily pain, vitality and mental health. A pilot study from the University of South Florida College of

Nursing (Lengacher et al., 2008) found significant differences in biochemical assays of natural killer cell function between relaxation/guided imagery and the control groups at 4 weeks post surgery. This suggested that a relaxation / guided imagery intervention may indeed have an effect on heightening immune function and certainly NK cell cytotoxicity for patients undergoing surgery for breast cancer.

Massage: Massage therapy includes an array of manual therapies that manipulate the soft tissues of the body in order to reduce anxiety, tension, stress, and depression. It increases circulation, controls pain, and promotes a sense of overall wellbeing. Touch is the main ingredient of massage therapy, which conveys a sense of caring – an important component in the healing partnership.

A study of the use of massage in cancer patients found that those who received massage had a 60% lower level of pain perception and 24% decrease in anxiety. More than half reported feeling more relaxed as well (Ferrell-Torrey and Glick, 1993).

Meditation: This is often practiced as transcendental meditation and taps into an innate relaxation response. Individuals employ a simple technique of concentrating on breathing or the repetition of a word or sound while sitting comfortably. The repetition blocks thought and prompts deep relaxation.

Harvard's Mind / Body Medical Institute found that as a result of a programme of meditation, 80% of hypertensive patients had lowered blood pressure and required decreased medication and 16% were able to discontinue all antihypertensive medications (Benson, 1996). They also found that chronic pain patients reduced their physician visits by 36% following regular practice of meditation. Equally impressive is their finding that 75% of insomniacs who practised regular meditation became normal sleepers, while 90% reduced or eliminated sleeping medication.

Therapeutic Touch (TT): It is a technique in which hands are passed over the body without touching to restore energy imbalances as well as innate healing forces. One of first studies to be funded by the Office of Alternative Medicine at NIH monitored the effects of TT on 20 very stressed nursing and medical students facing professional

board examinations (NIH, 1994). This study documented measurable changes that occur following TT. Differences between the TT and non-TT groups were found to be significant for IgA, IgM, and apoptosis. In a study of 60 patients with tension headaches, those who received TT reported an average pain reduction of 70% (Keller and Bzdek, 1986). The control group receiving “mock” TT reported an average pain reduction of only 37%.

As stress and its symptoms are individual, and each treatment and management approach whether conventional treatment, management or CAM strategies has its particular strength. One person may find some of those suitable to his own current coping style. As time moves on and effectiveness of some approaches may diminish, and there will be a need for the individual to reacquaint themselves with other coping techniques so that these can be sustainable through whole life.

It is necessary to explore the full array of strategies for coping with stress and minimising its negative effects, no matter whether it is conventional or complementary. In addition, a life balanced with nutrition, rest, exercise, work, and play to manage the effects of stress is an intrinsic part of stress treatment and management.

Chapter 3 Measurement Methods in Stress Research

This chapter describes the various methods of measurement used in stress research and discusses the rationale for the methods used in this study.

3.1 Measurement methods

The definition of stress used in the past has “determined” the type of outcomes used in the attempt to quantify stress and its contribution to illness (Cohen et al., 1997). The stimulus based definition led to the development of an environmental approach, focusing on the assessment of environmental events or experiences that are objectively associated with the need to adapt to the demand. The response based definition led to a focus on a biological approach to measure the physiological response to a state of stress. The transactional definition required a greater emphasis on psychological aspects of individuals’ subjective evaluations of their abilities to cope with the demands posed by specific events or experiences and their resulting response.

3.1.1 The environmental approach

The goal of this approach is to discover the environmental conditions that promote stress and lead to disease. There is considerable disagreement regarding the characteristics of the stressors that place people at risk of disease, and different methods used to measure these stressors reflect the importance of some characteristics compared with others. Characteristics that have received the most attention are reflected in the common measurement techniques and include the amount of change created by the stressor, the extent to which the stressor and its resolution are under the control of the respondent. The traditional measurement of stress caused by “environmental conditions” has also focused on their degree of severity and length of time they have affected individual.

Four types of methods of measuring stress using the environmental approach were identified by Cohen et al. (1997).

3.1.1.1 Life-events – checklists

The idea that physical and mental illness are often preceded by, if not causally linked to, stressful life events has a long history. For example, LeShan (1959) reviewed the clinical anecdotal evidence linking stressful events and the onset of various cancers, originally reported as far back as the fifteenth century.

Interest in the role of life events in illness began with the work of Adolf Meyer in the 1930s, who believed that by using the checklist approach life events could be shown to have etiologic importance for a variety of physical illness (Lief, 1948; Meyer, 1951). One of the early life events lists, the Schedule of Recent Experiences (SRE) (Hawkins et al., 1957), was further developed by Holmes and Rahe's publication of the Social Readjustment Rating Scale (SRRS) in 1967. A panel of judges were employed to rate the amount of adjustment they thought each event would typically require. This process generated normative data that incorporated events of very different severities and took account of their relative importance. The SRRS became the best known and the most widely used questionnaire approach to measuring life events (Turner and Wheaton, 1997). There have been various developments from Holmes and Rahe's original checklist including the List of Threatening Experiences (LTE) (Brugha et al., 1985) and the Recent Life Events Questionnaire (RLE) (Department of Health, 2000).

Major stressful life events instruments ask respondents to report which of a list of events happened to them within a specific time line. The events on the list are representative of the population of major stressful life events that occur in people's lives. Life events instruments rate the effect of major events to individuals. The effect accumulates as the number of events accumulate, *id est* (i.e.) the more events, the greater the stress. Some scales make explicit assumptions about the underlying cause by weighting events on certain dimensions instead of just counting the number of events. Weighting schemes, no matter what their underlying assumption, have not proven to add substantially to the prediction of either mental or physical health outcomes. Many of the studies of stressful life events and health have used the SRE

or the SRRS. There is apparently no life event checklist instrument that is appropriate for all populations or one that is generally accepted in the field (Turner and Wheaton, 1997).

3.1.2.2 Stressful life events -- interviews

Intensive personal interviews employ qualitative probes in order to specify more precisely the characteristics of life events believed to produce stress. Most importantly, the interview techniques are designed to elicit reports of specific events that may put people at risk for disease. Although they provide a much richer description of the nature of stressful events in persons' lives and have better psychometric characteristics (both validity and test-retest reliability), interviews are time consuming (for both respondent and interviewer), expensive, and require training of interviewers and require consensus (Wethington et al., 1997).

There are two major interview techniques which have been employed in research:

- The Life Events and Difficulties Schedule (LEDS) (Brown & Harris, 1978);
- The Standardized Event Rating System (SEPRATE) (Dohrenwend et al., 1993).

The primary scores from the LEDS are based on whether an acute stressful event (termed "events") or chronic stressful condition (termed "difficulties") is experienced during the last year. Events and difficulties that are thought to play a role in health are those that are rated by the judges as having marked or moderate long-term threat. The SEPRATE attempts to identify objectively the events that are independent of the situational and individual characteristics and that determine individual vulnerability. Narratives of each event that strip them of any material that might be used to infer "social vulnerability" are documented. The narratives are then rated by two independent raters on the dimensions mentioned and consensus achieved.

3.1.1.3 Chronic stress measures

Chronic stress measures questionnaires were designed specifically to assess chronic stress in specific role domains, e.g. work and marriage (Lepore, 1997). In the work

domain there are many fairly reliable and multidimensional measures of role stressors, e.g. Work Environment Scale (WES) (Moos, 1981); the Occupational Stress Inventory (OSI) (Osipow & Spokane, 1987); and the Job Content Questionnaire (JCQ) (Karasek, 1985). The work stressor questionnaires typically include items or scales related to role conflict, quantitative and qualitative demands or overload, role ambiguity, lack of control or autonomy, lack of support or cohesion, inadequate career opportunities, job insecurity, and interpersonal conflict. Questionnaires in the marital domain include the Family Environment Scale (FES) (Moos & Moos, 1981), the Marital Situations Inventory (MSI) (Smolen et al., 1985), the Evaluating & Nurturing Relationship Issues, Communication, Happiness (ENRICH) (Fournier et al., 1983), and the Marital Agendas Protocol (MAP) (Notarius & Vanzetti, 1983). The marital role stressor questionnaires typically include items related to problems in communication, verbal and physical abuse, lack of emotional closeness and affection, infidelity or sexual problems, excessive role demands, or inequity in division of labour.

3.1.1.4 Daily event measures

Stressful experiences on the daily level are assessed by self-report using a daily diary / record. These diaries allow the investigator to examine stress on an everyday basis, rather than the more encompassing events assessed with major stressful life events instruments. Such measures can be used to tackle important theoretical problems such as the nature of chronic stress, the mechanisms through which major stressors exert their effects, and the role of personality and social structure in the stress process (Eckenrode and Bolger, 1997).

There are a number of standardised daily event measures, e.g. The Daily Life Experiences Checklist (DLE) (Stone & Neale, 1982) and The Daily Stress Scale (e.g. Bolger & Schilling, 1991). Several daily event scales have been designed as retrospective reports of "hassles" that have occurred over the last month or so. This includes the "revised" Hassle Scale (DeLongis et al., 1988) and the Inventory of Small Life Events (ISLE) (Zautra et al., 1986).

As with major stressful life event checklists, daily event instruments are presumed to contain items that represent the population of daily events that occur in the lives of people they sample.

3.1.2 The psychological approach

The psychological approach of stress emphasises the perception of a threat which arises when the demands imposed upon an individual, by a stressor, are perceived to exceed their ability to cope with those demands. This imbalance gives rise to labelling oneself as being stressed and results in a negative emotional response. So the psychological tradition of assessing the role of stress assumes that stress arises totally out of a person's perceptions (whether accurate or inaccurate) of their relationship to their environment. The measurements of appraisal and effect have been closely linked to the psychological state (Cohen et al., 1997; Derogatis and Coons, 1993; Lei and Skinner, 1980).

Measures of appraisal focus on individuals' evaluations of events, of their own coping resources, and their perceptions of "stress". Monroe and Kelly (1997) identified a variety of appraisal measures used in the existing literature.

3.1.2.1 Measures derived from life event scales

A number of the later scales designed to assess recent life events make provisions for assessing the subject's perceptions about events that may have occurred in their lives, e.g. the Life Experiences Survey (Sarason et al., 1978) and the Impact of Event Scale (Horowitz et al., 1979). These measures can be used as a general index of appraised stress. Also the stressful life events interview, as used in the environmental approach, can be adapted to take account of individual's appraisal of the situation.

3.1.2.2 Single-item questions designed to measure appraisal of specific stressors

Most of these scales have been specifically developed for a particular study. These measures tend to be situation specific, and thereby assume that the immediate context

of the stimulus is very influential in individual's appraisal of the event. This type of measure is commonly used in laboratory experiments or in studies of daily events using diary methods. Although such measures are quite simple and convenient, there are basic psychometric limitations due to lack of evidence for their reliability and validity (Monroe and Kelly, 1997).

3.1.2.3 Self-report stress scales

These instruments attempt to assess the degree to which the specific or collective situations in one's life are appraised as stressful, and typically are composed of multiple-item inventories.

The instrument used most often is the Perceived Stress Scale (PSS) (Cohen & Williamson, 1988; Cohen et al., 1983). Items were designed to identify how unpredictable, uncontrollable, and overloaded respondents find their lives. There are three versions of the scale, with 4-items, 10-items, or 14-items. This scale assesses the amount of stress in an individual's life rather than in response to a specific stressor and has been used widely in studies of both mental and physical health. As a general measure of perceived stress, the scales are influenced by a wide variety of factors. Of greatest concern is the likelihood of overlap between psychological symptoms and what is measured by the PSS.

The Stress Appraisal Measure was developed to assess the dimensions of primary appraisal (threat, challenge, and centrality) for a specific anticipated stressor (Peacock & Wong, 1990). Unfortunately, this scale has been only used with college students, and its applicability and usefulness for broader populations is therefore questionable.

3.1.2.4 Measurement of negative response

Appraisal of events as threatening is presumed to cause a negative affective response. This provides a link to behavioural and biological responses thought to be responsible for illness susceptibility. There has been considerable effort in the area of measuring negative effect.

The most commonly used mood measures are adjective checklists. In this procedure, a number of adjectives representing mood states are presented and the respondents are instructed to indicate whether the presented mood reflects their own feelings. There are many variations on this basic theme, involving different response scales, different sets of adjectives, and different instruction sets. Popular scales include the 36-item Nowlis Mood Adjective Checklist (MACL) (Nowlis & Green, 1965); the 132-item Multiple Affect Adjective Checklist (MAACL) (Zuckerman & Lubin, 1965); the 65-item Profile of Moods States (POMS) (McNair et al., 1971); and the 20-item Positive Affect -- Negative Affect Schedule (PANAS) (Watson et al., 1988). The choice of scales depends on the level of differentiation required (e.g. separate measures of anxiety, depression, anger or just negative mood), and the theoretical approach taken to the structure of moods (Stone, 1997).

3.1.3 The biological approach

The biological approach focuses on the activation of biological systems which are particularly responsive to physical and psychological demands. Two interrelated systems that are viewed as the primary indicators of stress response are the autonomic nervous system, especially the sympathetic-adrenal medullary system (SAM), and the hypothalamic-pituitary-adrenocortical axis (HPA) (see *Chapter 2 Theory of stress*). The measures of SAM activation usually include the cardiovascular and endocrine systems; the measurement of HPA activation is primarily endocrine. The effects of stress on the immune system can also be measured.

In addition, skin conductance and muscle tension have been used as biological markers of stress in laboratory. In studying diseases of the gastrointestinal system, gastrointestinal peptides and measures of gastric motility have been involved. As technology develops in areas such as brain scanning, the variety and specificity of biological measurement of the stress responses in the central nervous system will increase.

Modern human stress research rarely relies on physiological data alone. Current researchers use a combination of psychometric and biological measurement in order to investigate more complex physiological responses to stress and illness in humans (Taylor-Vieira, 2008).

The most frequently used biological measurements relate to the endocrine, cardiovascular, and immune responses.

3.1.3.1 The endocrine response

Cannon (1914) discussed the role of hormones as possible mechanisms for the “fight-or-flight” response. Selye (1976) proposed a model of stress which was based on neuroendocrine changes with stress induced changes considered to be consequences of extended and intense activity in the HPA axis and the resulting massive release of corticosteroids. Since these early investigations, models of stress that focus on neuroendocrine mediators have become more common. Many of those neuroendocrine changes are thought to be mechanisms by which stress may affect other systems or contribute to pathogenesis and disease.

The following are the most frequently measured neuroendocrine changes reported in the literature studying on how stress affects disease or how stress related changes interact with other symptoms.

1. The catecholamines, epinephrine (E) and norepinephrine (NE), as well as corticosteroids, particularly cortisol, and their metabolites, have been the most commonly studied neuroendocrines in stress research and are of considerable importance in the initiation and regulation of stress responses (e.g. Rosochacki et al., 2001; Taylor et al., 1989)
2. Endogenous opioid peptides (EOPs) have been implicated in the pain response, stress-related drug use, eating behaviours, affective responses, and immune system changes (e.g. Bowe et al., 2005; Davidson et al., 1991).
3. The central nervous system (CNS) neurotransmitter serotonin (5-hydroxytryptamine (5-HT)), its precursors (e.g. tryptophan), and its primary

metabolites (e.g. 5-hydroxyindoleacetic acid (5- HIAA)) have also become the focus of many studies addressing a variety of psychological phenomena related to stress, including depression and other affective disorders, obsessive-compulsive disorders, eating disorders, and drug abuse (e.g. Emerson et al., 2000; Bastani et al., 1991; McBride et al., 1991).

4. In addition to these chemicals, prolactin, thyroid hormones, growth factor, insulin, gonadal hormones, and other peptides show changes associated with stress (e.g. Beisel, 1994; Mason et al., 1990).

The basis for using hormonal measures in stress research results from the observation that although most systems in the body show changes during stress, changes in hormonal markers are the most reliably associated with stress. Conceptually, the central role of SNS and HPA activation in stress provides ample justification for measuring hormonal changes. Because it is basic to arousal and related bodily changes, endocrine activity may be a better marker of physiological changes during stress than are more readily obtainable measures such as blood pressure, heart rate, finger temperature, or sweating of the palms (Baum and Grunberg, 1997).

3.1.3.2 The cardiovascular response

The cardiovascular system is highly responsive to a variety of psychological and behavioural states. Ancient Egyptian physicians and philosophers believed that the heart was the seat of emotion (Hassett, 1978). In the 17th century William Harvey (Willis, 1965) discovered that the primary function of the heart was pumping blood throughout the body. The increasing attention devoted to the effects of acute and chronic stress in the development of cardiovascular disorders such as hypertension and coronary artery disease, make it unsurprising that cardiovascular variables are important and widely used measurement tools employed in modern stress research (Krantz et al., 1983; Matthews et al., 1987; Schneiderman et al., 1989).

Heart rate, blood pressure and peripheral vasoconstriction are the three cardiovascular parameters that are commonly and most easily utilized in stress research. These

measurements are helpful to recognise the homeostatic role of the cardiovascular system, as well as the connections among the various parts of the system. But in being nonspecific physiological response to stress these measures tend to be less sensitive to the complex interactions involved in the physiological stress response (Forsyth, 1974).

3.1.3.3 The immune response

There are two pathways between stress and the immune system. Firstly, sympathetic fibers descend from the brain into both primary (bone marrow and thymus) and secondary (spleen and lymph nodes) lymphoid tissues (Felten and Felten, 1994). These fibers can release a wide variety of substances that influence immune responses by binding to receptors on white blood cells (Rabin, 1999; Ader et al., 1995). Though all lymphocytes have adrenergic receptors, differential density and sensitivity of adrenergic receptors on lymphocytes may affect responsiveness to stress among cell subsets. Secondly, the HPA axis, the SAM axis, and the hypothalamic–pituitary–ovarian axis secrete the adrenal hormones epinephrine, norepinephrine, and cortisol; the pituitary hormones prolactin and growth hormone; and the brain peptides melatonin, β -endorphin, and enkephalin. These substances bind to specific receptors on white blood cells and have diverse regulatory effects on their distribution and function (Ader et al., 2001).

Seegerstrom and Miller (2004) carried out a literature review on the relationship between psychological stress and parameters of the immune system in human participants over the last 30 years. The results indicated that acute stressors (lasting minutes) were associated with potentially adaptive up-regulation of some parameters of natural immunity, such as the granulocytes, the natural killer cell, and the complement protein, and down-regulation of some functions of specific immunity, such as lymphocytes (e.g. Bosch et al., 2002; Delahanty et al., 2000; Benschop et al., 1996). Short stressors in natural settings (such as exams) tended to suppress cellular immunity (Th1 cytokines) while preserving humoral immunity (Th2 cytokines) (e.g. Gruzelier et al., 2001; Kiecolt-Glaser et al., 2001; Maes et al., 1999). Chronic

stressors have been associated with suppression of both cellular and humoral measures (e.g. Stowell et al., 2001; Bauer et al., 2000; Mills et al., 1999).

The field of psychoneuroimmunology (PNI) has rapidly grown over the last three decades. This incorporates psychology, immunology, and neurosciences amongst many other fields (such as physiology, molecular biology, psychiatry, behavioral medicine, and infectious diseases) (Vedhara and Irwin, 2005).

Immunological research is expensive, and also they require more special technical requirements, e.g. blood sample collecting time and sitting time, and technical skill to perform the immunological assay (Cohen et al., 1997). Immunological data varies with the health behaviour. For example, people's efforts to manage the demands of stressful experience sometimes leads them to engage in behaviours -- such as alcohol use or changes in sleeping patterns—that also could modify immune system processes (Kiecolt-Glaser & Glaser, 1988).

3.2 Rationale for using measures of stress in this study

The following section outlines the particular measures chosen for this study in greater detail and presents the rationale for their choice.

As a result of the literature review, the RLE, the PSS-14, the Measure Yourself Medical Outcome Profile (MYMOP), and salivary cortisol concentration were selected to assess stress in this study. The RLE (from the environmental approach) was used as a screening tool to ensure that the participants were experiencing chronic stress rather than acute stress. The PSS-14 (from the psychological approach) was used to measure perceived stress. Salivary cortisol concentration (from the biological approach) was used as an objective measure because it is non-invasive, and can be easily collected. In addition, the MYMOP, a patient-centred instrument developed for use in complementary medicine, was used to identify specific symptoms and whether they changed during the study.

3.2.1 The Recent Life Events Questionnaire (RLE)

Many life events are short-lived but may have more enduring consequences. Negative life events involve the experience of loss, or threat of loss, and may include the loss of self esteem. Some apparently positive events such as job promotion may act as positive stressors, which can affect people's general stress levels. Stressful life events play a role in the etiology of various somatic and psychiatric disorders (Dohrenwend and Dohrenwend, 1974). Since the original work of Holmes & Rahe (1967), research into stressful life events on human subjects has tended towards the development of longer and more complex inventories. The List of Threatening Experiences (LTE) of Brugha et al. (1985) has 12 items and overcomes difficulties of clinical application because it is relatively brief. In a study (Brugha and Cragg, 1990), the questionnaire version of the list (LTE-Q) was shown to have high test-retest reliability with good agreement with informant information. Concurrent validity, based on the criterion of independently rated adversity derived from a semi-structured life events interview, made use of the Life Events and Difficulties Scales (LEDS) method developed by Brown and Harris (1978), showed both high specificity and sensitivity. The LTE was recommended by the authors for use in etiological studies of adult psychiatric disorders, and of psychological dysfunction, where cost or other practical considerations precluded the use of methods which required extensive interviewing time and detailed training of users. The LTE has been used in other research projects (Brugha and Conroy, 1985; Duncan and Campbell, 1988; Morris, 1988) supporting the scale's construct validity.

The Recent Life Events Questionnaire (RLE) (Department of Health, 2000) was developed from the LTE with 9 additional items. The inventory includes recent life events, those occurring in the last 12 months and whether the respondents think they have a continuing influence. However it can be used to evaluate events and their impact over a longer period if desired. The RLE is a short inventory and has 21 items (see *Appendix 7.1*). There are 2 boxes following each item – “Yes” box if the event has occurred; a “still affects me” box if the event is still having an effect on one's life. It

can contribute to the social history, and can provide an opportunity to re-evaluate that known events are continuing to exert an influence.

In this research project, the RLE was felt to be an appropriate instrument for use as a screening tool and as a monitoring tool. The questionnaire was amended to monitor recent life events that had occurred over the last month rather than the last 12 months in the original scale.

1. The aim of the research was to study a group of people suffering from chronic stress. One of exclusion criteria was that no life event which might result in an acute stress response had happened during the last month. The RLE was therefore used as a screening tool for the exclusion criteria. If a participant reported a severe life event in the previous month at the interview stage they were excluded from the study.
2. The RLE was also used as a monitoring tool, rather than an outcome measure, to monitor whether life events happen during the study and help the interpretation of the clinical and laboratory data. If a participant experienced an acute severe life event during the study, and their cortisol response and other outcome measures would be affected, they would have to be excluded from the study.

3.2.2 The Perceived Stress Scale – 14 (PSS-14)

The PSS has been proven to possess good reliability and validity. Cohen et al. (1983) found that the PSS was correlated with “number of life events” and had a slightly greater correlation with “impact of life events”. The PSS is more successful in predicting a variety of health and health care outcomes than are measures of specific life events which focus on the number rather than the appraisal of the stressful nature of events as does the PSS.

Since 1983, the PSS has been widely used in research.

1. The PSS and the relationship between the effects of perceived stress and cortisol levels.

Some of research showed that the PSS was associated with cortisol concentrations. The research (Miller et al., 2002) indicated that parents of cancer patients reported more psychological distress than parents of healthy children and they also had flatter diurnal slopes of cortisol secretion. The results of the study (West et al., 2004) showed that both African dance and Hatha yoga groups had reduced the PSS score while cortisol increased in the African dance group but decreased in Hatha yoga group. The data from Ebrecht et al. (2004)'s research hinted at a considerable influence of stress on wound healing, and suggested that elevated cortisol levels, rather than altered health behaviours, played a role in this effect.

There have also been some negative results using the PSS as an outcome measure. Schwarz (2001) found that in family caregivers of older adults there were no significant associations between salivary cortisol and the PSS. In van Eck et al. (1996)'s research, multilevel analysis revealed associations with trait anxiety and depression, but not perceived stress, and there were associated with small but statistically significant salivary cortisol elevation, and stressful daily events were associated with increased cortisol secretion. Dedert et al. (2004)'s research indicated that patients reporting medium or high engagement with religious activities had rhythmic cortisol profiles characterized by high morning and low evening levels while no significant effects of religiosity or spirituality on perceived stress were observed. Ruiz et al. (2001)'s research suggested the possibility of stress reduction as an appropriate intervention for lengthening gestational age and its result indicated that cortisol is a poor predictor of either preterm labour or preterm birth.

2. The PSS has been used to measure the stress levels and investigate the effects of stress on the body or on other illnesses.

Kuiper et al. (1986)'s study on 120 subjects in the University of Western Ontario indicated that The PSS provided a measure of global perceived stress level, or the general tendency to view one's life as being unpredictable, out of control, and overwhelming. Sitz and Poche (2002) carried out a research into gender differences in the relationship between optimism and perceived stress, and found that there was

a strong relationship ($p < 0.001$) between optimism and perceived stress which was measured by the PSS. The PSS has been commonly used in the research into the effects of psychological stress on the immune system (Song et al., 1999; Vedhara et al., 1999; Maes et al., 1997). Smolderen et al. (2007)'s research found psychological stress measured by the PSS and negative mood were related to an increased vulnerability to influenza-like illness. Golden-Kreutz et al. (2004) used the PSS to assess stress in 111 women following breast cancer surgery, while the PSS was used in Lev et al. (2004)'s research into the quality of life of men treated with brachytherapies for prostate cancer. Remor and Carrobes (2001) in Spain and Koopman et al. (2000) in America used the PSS to examine the perceived stress in HIV-positive samples. Kanazawa et al. (2004) used the PSS and other outcome measure to find the patients and nonconsulters with irritable bowel syndrome reporting a parental history of bowel problems have more impaired psychological distress. Groer et al. (1993) examined the relationships between symptoms of common infectious illnesses, cycle phase and menstrual-cycle-related distress which partly measured by the PSS. The PSS was also used to explore the relationship between smoking behavior or treatment and perceived stress (Warner et al., 2004; Shiffman and Waters, 2004; Siqueira et al., 2000).

3. The PSS has been used as one of the outcome measures in studies on the effectiveness of different treatments or interventions.

Robinson (2005) used the PSS and demonstrated the success of complementary health activities offered by a centre for Healthy Living to reduce stress in 175 adults. Stewart et al. (2005)'s research into comparing the effectiveness of occupational therapist-led assessments of older people on dependency and service costs with that of social worker-led assessments used the PSS as one of secondary outcomes, and found there was no clear difference in patient-centred effectiveness measures between occupational therapists and social workers in assessing frail older people and their carers in the community.

The PSS-14 is a 14-item self-report instrument with a five-point scale (See *Appendix 7.2 the PSS-14*). The instrument was designed to identify the extent to which individuals feel that their lives are unpredictable, uncontrollable, and overloaded. As such, the PSS-14 explains cognitions and emotions relating to general stress levels, rather than specific events or situations. The items are easy to understand and the responses are simple to grasp. The higher the scores are, the higher the perceived stress is.

As this project concentrated on self-reported stress, the aim of using the PSS-14 in this study was to assess psychometric properties of the PSS-14 scale in chronic stressed adults. It is an appropriate outcome measure of perceived levels of stress which could be used to test the effect of the intervention.

The researcher carried out a literature review and consulted with the psychologists in the university with the aim of identifying how a clear diagnosis for chronic stress could be used to identify stressed individuals for inclusion into the study. The literature research demonstrated that the PSS was designed for use with community samples (Cohen et al., 1983), and was previously not used for diagnostic purposes. There are no specific categories or cut-off in the PSS suggested by Cohen et al. (Johnston et al., 1995). The sample size was small for this pilot study therefore it was necessary to ensure that all participants could be considered to have higher than average stress levels. An inclusion criterion for participants' high stress levels, as identified by the PSS-14, was needed. The criterion of the PSS-14 cut off was based on previous research which had used the PSS-14 as an outcome measure of experienced levels of stress. The details are given in *Table 3.2.2*.

Table 3.2.2 The mean score of the PSS-14 in the previous research

Author (year)	Sample and its size (N)	Mean (SD)
Cohen et al. (1983)	College Student Sample I: 332	23.18(7.31)
	College Student Sample II: 114	23.67(7.79)
	Smoking-Cessation Sample: 64	25.00(8.00)
Kuiper et al. (1986)	University students: 120	22.88 (8.01)
Cohen and Williamson (1988)	General population by telephone: 2,387	19.62 (7.49)
Sitz and Poche (2002)	University students: 60	26.7(8.30)
Boury et al. (2004)	Low-income women: 151	27.2*
Robinson (2005)	Participants in the Centre for Healthy Living: 175	23.94(7.90)

* Standard deviation was not given in that article.

According to the results of above research, generally the mean score of the PSS-14 was higher than 20. This suggests that when the PSS-14 scores are greater than 20, people are likely to have high stress levels. In this project, a PSS-14 score greater than 20 was used as a criterion to recruit participants with a high stress level.

In summary, the PSS-14 in this project was used as one of the criteria for subject recruitment and in addition as one of the outcome measures to measure the self-reported stress levels during the study period.

3.2.3 The Measure Yourself Medical Outcome Profile (MYMOP)

As mentioned in 2.4 *Symptoms of stress and their relationship to ill health*, people with stress exhibit different symptoms and their quality of life can be affected, it is necessary to have an instrument to measure all these changes and in combination with other stress measures.

The MYMOP is a patient-centred instrument, which aims to measure the outcomes that the patient considers the most important (Paterson, 1998). The MYMOP has been validated and found to be responsive in a general practice environment (Paterson, 1996).

The current version of the MYMOP, as of April 1998, was labelled MYMOP2. This version can collect additional information about new symptoms, medication, and other things which may affect outcome during the study. The MYMOP consists of 4 items, each scored by the patient on a seven point scale (see *Appendix 7.3*). The first two items – “Symptom 1” and “Symptom 2” are for the 2 symptoms which the patient specifies as the most important that they are experiencing at that time. The third item “Activity” relates to an aspect of daily living which is being disrupted or prevented by the health problem, and which is also specified by the patient. The fourth item “Wellbeing” asks the patient to rate their feeling of general well-being. Those 4 items are recorded symptoms and feeling for the previous week. On the second and subsequent MYMOP profile, the wording of the previously chosen items is unchanged but there is an optional fifth item for a new symptom. A “MYMOP Profile Score” is calculated as the mean of the scored items. The scores of MYMOP were found to be more sensitive to change than the SF-36 which is the best-known questionnaire amongst experts for measuring health status (Paterson, 1996).

The MYMOP is a well accepted quality of life instrument that is particularly good for assessing the effect of complementary therapies and is sensitive to change. In the evaluation of complementary treatments, a patient generated measure may overcome the problem of the different diagnostic frameworks of different disciplines (McGourty, 1993). For example, a group of patients labelled by conventional medicine as homogeneous in suffering from migraine would consist of a heterogeneous mix of various of diagnoses according to traditional Chinese medicine diagnosis. Taking the definition of the problem back to the patient’s concerns for the purpose of outcome evaluation means that the complementary medicine intervention will not be falsely constrained by the assumptions of other types of medicine with different theories about symptoms. As a patient-centred outcome measure, the advantage of MYMOP is that it measures the change in symptoms which are important to the patient and the change in activity which occurs as a result of these symptoms. Various research studies in complementary therapies have used the MYMOP, for examples, acupuncture (Day et

al., 2004; Paterson et al., 2003; Chapman et al., 2001; Stellon, 2001), spa treatment (Hill et al., 1999), spiritual healing (Abbot et al., 2001) and complementary medicine in the primary health care (Robinson et al., 2006; Paterson, 1997) all have shown that the MYMOP is a useful tool for measuring change as a result of using complementary therapies.

In this project, the MYMOP was used in the 3 periods of the study to assess the effects of TCA for chronic stress for adults (see 6.2.8 *Collection of data for questionnaires*).

3.2.4 The diurnal profile of salivary cortisol concentration

Since Selye's (1936) work, it has been known that high levels of cortisol occur during states of stress. The assessment of circulating or excreted cortisol is one of the common endocrine measures of stress.

Glucocorticoids are synthesized in the zona fasciculata of the adrenal cortex (see 2.2 *The stress response*). Cortisol is the primary glucocorticoid for humans, whereas corticosterone, produced in small amounts in humans, is the primary glucocorticoid in some animal species. As with the catecholamines, a small amount of cortisol is excreted as free cortisol in urine and can be measured by radioimmunoassay. Most of the excretory products of cortisol are in the form of metabolites; cortisol and corticosterone are metabolized primarily in the liver and excreted as tetrahydrocortisol and tetrahydrocortisone (Brook and Marshall, 2001).

Plasma, urinary and salivary measures of cortisol are used in stress research. There are fewer problems or limitations on the use of cortisol measures than of catecholamine measures (Baum and Grunberg, 1997). Cortisol is neither very sensitive to movement and effort nor immediately responsive and unstable. Blood-samples of cortisol exhibit more stable arousal patterns which represent an hour or more of mood and experience.

Salivary cortisol was first introduced to psychobiological stress research more than two decades ago by Stahl and Dörner (1982) who investigated changes in cortisol levels in

response to medical diagnostic procedures in several patient populations. Saliva is considered to be a mirror of the parts of the body. The tissue fluid levels of natural substances indicate emotional status ranging from high anxiety to depression. Hormonal status, immunological responsiveness, neurological status, and nutritional and metabolic influences can also be monitored. The cortisol concentration in saliva closely reflects the levels of unbound cortisol in blood (Vining and McGinley, 1984; Hiramatsu, 1981) and there is a good correlation between serum free and saliva cortisol concentration (Kirschbaum and Hellhammer, 1989; Riad-Fahmy et al., 1982).

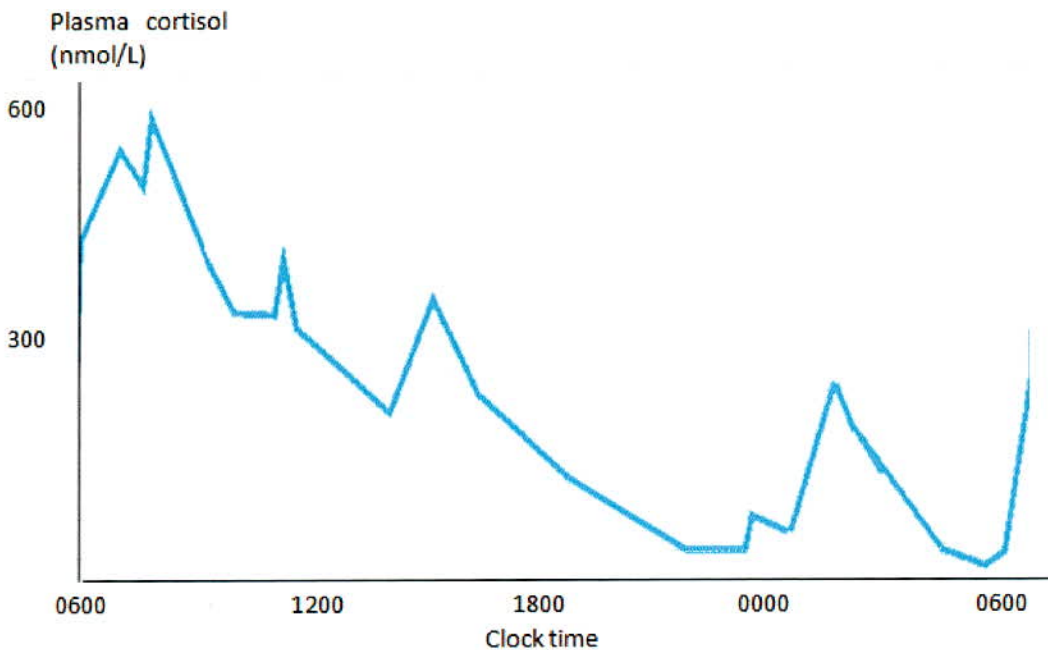
Of major importance for use in stress research is the non-invasiveness and more accessible method of measuring stress-related HPA response in humans than do blood and urine samples (Mandel, 1993). It provides an easy method to measure the stress responses from subjects of all age groups. Sampling saliva for 20-60 seconds is usually sufficient, since sensitive assay systems often require only 200µl of sample volume or less for duplicate analysis (Kirschbaum and Hellhammer, 1999).

Cortisol is a fairly stable molecule in saliva. Cortisol concentration in saliva does not depend on salivary flow rate (Kiess et al., 1995; Kahn et al., 1988; Vining et al., 1983) or other variables such as cigarette smoking (Cherek et al., 1982). Saliva can be kept at room temperature for at least four weeks without a significant drop in cortisol levels (Kirschbaum and Hellhammer, 1999). Moreover, since saliva can be collected in unlimited amounts and short intervals, the time course of the stress responses is easily assessed in situ.

Cortisol and corticosterone release show clear diurnal rhythms. While dependent on ACTH, cortisol release appears to peak at about 8am, with a low point around midnight. The normal diurnal profile is characterised by a marked increase in cortisol concentration on waking, peaking after about 30 min, and then subsequent declining to lower levels for the remainder of the day (Edwards et al., 2001; Pruessner et al., 1997). However, cortisol is released in bursts, and measurement over a 24-hour day can reveal 15 or more pulse release of cortisol, with the largest peak during the early morning,

normally 30 minutes after waking. Figure 3.2.4 is an example of a 24 hours profile of plasma cortisol from a healthy individual without fasting.

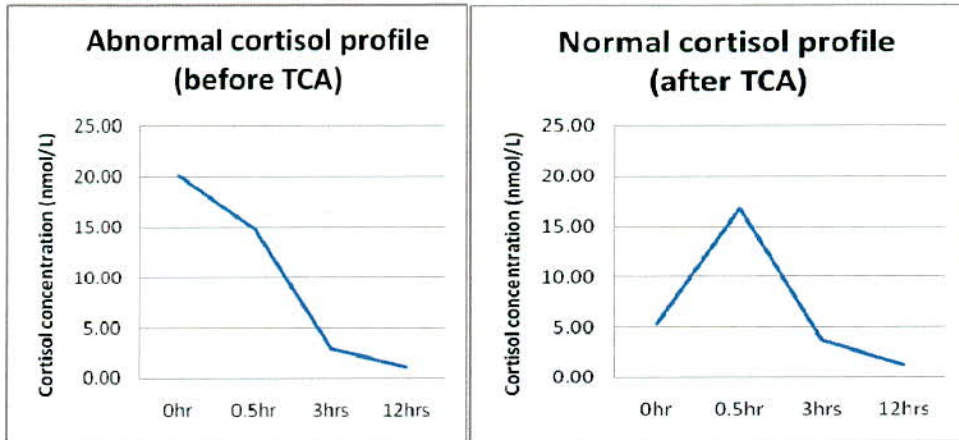
Figure 3.2.4 A 24 hours profile of plasma cortisol*



*: Source adapted from the studies of Caufriez et al. (2002) and van Cauter et al. (1996)

When an external threat is perceived, the brain sends a signal to the pituitary gland, which alerts the adrenal glands to produce cortisol. The impact of repeated life stress in susceptible individuals can be detected by a disrupted cortisol circadian cycle (Clow, 2004). Schulz et al. (1998) showed that adults reporting a high level of chronic stress due to work overload had a significantly greater cortisol increase after wakening compared with a low stress group. Individuals with stress have a flattened cortisol profile with loss of the morning surge. It is thought that the salivary cortisol awakening response (or morning rise of the cortisol concentration, which is called “delta (Δ) cortisol” (Daniel et al., 2006; Marik, 2006)) can serve as a reliable marker of hypothalamic-pituitary-adrenocortical activity (Kunz-Ebrecht et al., 2004). Table 3.2.4 provides examples of abnormal and normal diurnal profiles of salivary cortisol concentration.

Table 3.2.4 Abnormal and normal diurnal profiles of salivary cortisol concentration*



*: These two diurnal cortisol profiles were chosen from the results of one participant in the TCA group in this study before and after acupuncture treatment

There are some points to be taken into account while performing saliva sampling to help ensure accurate results. Appropriate controls should be taken when taking saliva samples as contamination of saliva with some substances, like food (Toda et al., 2004) and blood from tooth brushing (Kivlighan, 2005) can interfere with the results. Despite these facts, salivary cortisol determination could provide an easily accessible index of the HPA function under circumstances where blood sampling may be ethically or technically difficult to accomplish.

Various studies have been carried out and have demonstrated the heterogeneity and complexity of cortisol stress responses (Kudielka et al., 1998; Kirschbaum et al., 1994; Kirschbaum et al., 1993). Firstly there is a gender difference: female sex hormones appear to exert a more profound influence on the cortisol stress response; Women using estrogen-containing oral contraceptives show blunted or absent salivary cortisol responses to stress (Kirschbaum et al., 1996; Kirschbaum et al., 1995); Schulz et al. (1998) found a significant sex difference with larger increases in chronically stressed women compared to stressed men. Secondly the difference between weekdays and weekend: Participants' awakening cortisol response profiles differ between the weekdays and weekend with trends revealing a steeper rise on weekdays compared to the weekend (Thorn et al., 2006; Kunz-Ebrecht et al., 2004). Finally there are a number

of psychological variables (e.g. social support (Kirschbaum et al., 1995)) and personality traits (Pruessner et al., 1997; Kirschbaum et al., 1992) which have been found to be closely associated with the individual salivary cortisol stress response.

In recent years, cortisol concentration has been used as an objective biochemical parameter, and is also used in research into complementary medicine, cognitive behavioural therapy, mindfulness-based stress reduction and transcendental meditation for stress. The results have shown those relieved some of the negative psychological consequences of stress and correspondingly lower levels of the hormone cortisol (Carlson et al., 2004; Antoni, 2003; Smyth et al., 2001; Perna, 1998; McCraty et al., 1998; Maclean et al., 1997; Walton et al., 1995). Field et al. (2005)'s study showed there were significant decreases in cortisol concentrations after massage therapy. The research with a mixed cross-sectional and longitudinal repeated measures design found salivary cortisol secretion in kinaesthetic meditation group was lower in the afternoon on the day of the final kinaesthetic meditation session compared to on a typical day in the same week (Bullen et al., 2006). Other research has indicated that there were instantaneous decreases of cortisol concentration after Tai Chi (Jin, 1992 & 1989), Yoga (West et al., 2004) and a brief lunch time visit to an art gallery (Clow and Fredhoi, 2006). Facchinetti et al. (2004), Gaab et al. (2003) and Maclean et al. (1997) have reported that the size of the cortisol response to a standard stressor can be attenuated by interventions like transcendental meditation and cognitive behavioural therapy.

There has been laboratory research into the effect of acupuncture on cortisol concentration in studies which have modelled stressful circumstances in animals and have suggested that acupuncture can decrease cortisol concentrations (Li et al., 2006; Li et al., 2000; Shen et al., 1995 & 1994; Xu et al., 1994; Xiang et al., 1993). Few studies have been carried out to investigate the effectiveness of acupuncture on cortisol concentration on stressed humans (see *Chapter 5*).

The literature indicated that the diurnal profile of the salivary cortisol concentration could potentially be of use as an objective measure. This was the first time it has been used as a biochemical parameter to monitor any changes of cortisol concentrations with TCA for chronic stress on adults and explore whether TCA could normalise the diurnal salivary cortisol profile of chronically psychologically stressed adults. Using the above literature, the sample collection time points (4 points in time on each day of 9 separate days) were established as appropriate in order to demonstrate the diurnal profile of salivary cortisol concentration (see 6.2.9 *Collection of salivary samples*) in this study.

Chapter 4 Traditional Chinese Acupuncture in the Treatment and Management of Stress

Traditional Chinese Acupuncture (TCA) is an important part of Chinese Medicine (CM) that has been practiced in China for several thousand years for the treatment of a wide range of diseases.

This chapter introduces concepts of yin and yang and other theories and integrates this into the basic CM theory of health and illness, and discusses the meaning of stress in CM, its diagnosis in CM and treatment by TCA.

The language used in this chapter is expressed using *The Proposal on Chinese-English CM Nomenclature* (World Federation of Chinese Medicine Society, 2007) and *The Foundations of Chinese Medicine: A Comprehensive Text for Acupuncturists and Herbalists* (Maciocia, 2005).

The names of acupoints in this dissertation were based on *Standard Acupuncture Nomenclature Second Edition* (WHO Regional Office for the Western Pacific, 1993).

4.1 Basic theory related to emotion

4.1.1 Yin – yang and qi

4.1.1.1 Yin – yang

According to traditional Chinese philosophy, yin and yang are the two primal cosmic principles of the universe. *The Plain Questions* (《素问》, Su Wen) (Shandong College of CM & Hebei Medical College, 1982) says “Yin and yang are the laws of heaven and earth, the greater framework of everything, the parents of change, the root and beginning of life and death...” They represent two separate phenomena with opposing natures, as well as different and opposite aspects within the same phenomenon. Yin and yang are rooted in each other: they are interdependent, inter-consuming-supporting, and inter-transforming (Cheng, 1987). CM applies the yin-yang principles to the human body to explain its physiology and pathology and guide clinical diagnosis and treatment. The differences between yin and yang are described below.

“Yin moistens, softens, stabilises, and roots life, and keeps the body’s qualities of rest, tranquillity, and quiescence” (Kaptchuck, 1983). When yin is sufficient, the body “lacks the qualities of receptivity and contemplation and becomes easily disturbed, unsettled or nervously uneasy; the control over the dynamic manifestations of heat and activity is lost” (Kaptchuck, 1987). Yin represents the latent potential that awaits to be expressed and organised (Seem, 1987).

Yang, by contrast, “expands and disperses outwardly”. It “provides the body with the capacity to engage life, to react, and to respond, and keeps the invigorating quality of life”. When yang is insufficient, the person finds himself in fear, confused and indecisive, unable to express what he wants, hopeless. When the quickening power to move is lost, the expression of life becomes “congested, inactive, and frozen” (Kaptchuck, 1987).

The human being is a small system living with a large system. Individual’s relationships to their environment are of the greatest importance in the development of illness. Every one experiences events and reacts to a stressor in a different way. The tendency to develop a disorder at any given time depends on the individual experience of being in the world. Situations that create a conflict between the internal needs and desires and the demands placed upon people precipitate personal patterns of reaction based on their relative “vacuity” or “repletion” of either yin or yang (Seem, 1987).

4.1.1.2 Qi

Qi is the fundamental substance constituting the universe, and all phenomena are produced by the changes and movement of qi. In CM, qi denotes both essential substances of human body which maintain its vital activities, which include the spiritual, emotional, mental, and the physical aspects of life, and the functional activities of the zang-fu organs (Cheng, 1987). The concept of qi is much broader, sometimes referred to as “vital energy” or simply “energy”.

According to CM, qi has six functions: promotion, warming, defence, restraint, transformation, and nourishing (Cheng, 1987). Although these six functions of qi are different, they cooperate with and supplement each other. Qi runs throughout whole body and motivates all movement, transformation, and change in the body. All physical and mental activities are manifestation of qi, and qi is perceived functionally by what it does (Beinfeld and Korngold, 1991).

4.1.2 Body, mind and spirit

In CM theory, the body is the substance, the physical body; the mind is insubstantial, which consists of thoughts, feelings and emotions (Jahnke, 2002). The body is the material basis for the mind, and the mind is seen as the natural expression of the functions of the body. The concept of body-mind is one of the main characteristics of Eastern thought. In CM, therefore, mental activity has always been considered to be inseparable from bodily functions, and mental diseases were generally not treated differently from any other disorder. Weber and Hoedeman (1993) state because there is no duality between “psyche” and “soma”, and they are accorded equal status and treatment in CM, physiological events within the body may result in mental-emotional sensations, experiences, and predispositions, while psychological events may have “either a beneficial or deleterious effect on the body’s physiology”. The causative relationship between “psyche” and “soma” in CM is completely “bi-directional”.

The combination of the body and mind is the “spirit” (精神, jing shen) (Ke, 2008). Spirit is the translation for the Chinese word “shen” (神). It is the fundamental texture that is unique to human life (Kaptchuk, 2000). Within CM, spirit can have three basic meanings:

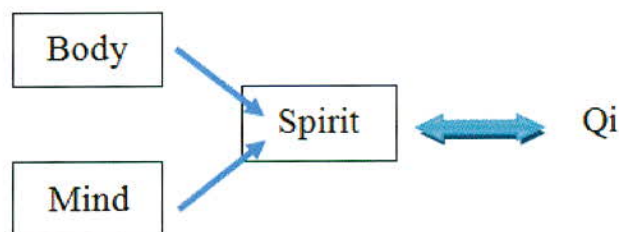
1. Spirit refers to the outward manifestations of the body’s life activities, including the manifestations of both normal physiological and pathophysiological activities. *The Plain Questions* (《素问》, Su Wen) (Shandong College of CM & Hebei Medical College, 1982) says “Obtaining spirit is prosperity (i.e., life); losing spirit is death.” The signs of having spirit or physiologic vitality include bright eyes, normal bearing,

clear speech, coherent responses to questions, a normal facial complexion, and normal excretions.

2. Spirit refers to consciousness and the function of thinking-feeling. In CM, there is no distinction between thoughts and emotions. Both are merely sensations within consciousness. The spirit and its outward manifestation as one's emotional affect are referred to by the collective term "spirit affect". When the word "spirit" is used in this way within CM, it refers to a person's sensations, cognitive abilities and functions, and to one's experience of emotions.
3. Spirit also refers to that which is responsible for all movement and change in the phenomenal world. It is the creative and motivational force of nature "whose substance cannot be seen, but whose function can be seen." (*The Great Treatise* («荀子», Xun Zi or HsunvTzu or Master Xun).

More particularly, spirit is made from the essence qi of water and grain. Spirit is the home of the qi, and is "all forms of qi" (Jahnke, 2002). *The Spiritual Pivot* («灵枢», Ling Shu) (Nanjing College of CM, 1986) states that "when qi is exuberant, spirit is radiant; when qi is debilitated, spirit becomes diseased; when qi is severed, spirit perishes." The relationship of body, mind, spirit and qi is demonstrated in *Figure 4.1.2*.

Figure 4.1.2 Relationship of body, mind, spirit and qi



In CM theory, the spirit allows a person to tread his or her self-chosen and self-directed path. China's oldest herbal text *The Divine Farmer's Materia Medica* («神农本草», Shen Nong Beng Cao, 150BC) treats spirit when it prescribes herbs that will support a person to self-consciously shape his or her own destiny (Kaptchuk, 2000). Pathological

abnormalities of the spirit include the following disease conditions of the spirit: loss of spirit, restless spirit, spirit failing to keep to its home, clouded spirit, haziness of the spirit, fatigued spirit, lassitude of the spirit, debilitated spirit, abstraction of the spirit, and spirit floating and jumping up. All of these are due to two basic disease mechanisms. Either the spirit is deprived of sufficient energy to build up and nourish or some evil qi is harassing the spirit. Without sufficient blood to nourish it and settle it, the spirit becomes restless; without enough qi, the mental clarity is slowed down and not conscious and aware (Schnyer & Flaws, 1998). Of the types of evil qi which may harass the spirit, the two main ones are fire heat and phlegm turbidity. Heat causes the spirit to stir restlessly, while phlegm turbidity may block and confound the spirit, thus obscuring its light or brilliance (Yin, 1984).

4.1.3 Theory of the seven emotions

Chinese medical practitioners have always recognised that emotional factors play a part in health and illness (Chen, 1174). The emotional life cannot be separated from the physical. Concern for the psychological texture of a patient's being must be part of a physician's examination, as the fundamental substances and the organs are all intimately connected to the emotions, which are the internal causes of disease.

The Yellow Emperor's Canon of Medicine («黄帝内经», Huang Di Nei Jing) (Shandong College of CM & Hebei Medical College, 1982) cites seven emotions that particularly affect the body and that are still considered most important: joy, anger, anxiety, worry, sadness, fear and fright. The differences between two of them e.g. fear and fright to be expressed on different levels; sometimes this pair is combined as one emotion of fear or fright. The seven emotions are also thought to correlate with the five zang-organs: joy with the heart, anger with the liver, worry and anxiety with the spleen, sadness with the lung, and fear and fright with the kidney. For example, anger covers the full range of associated emotions including resentment, irritability, and frustration; it will affect the liver, resulting in the stagnation of liver qi (Williams, 1996). Each of the seven emotions corresponds to one of the five zang-organs which in turn correspond to one of the five elements (wood, fire, earth, metal and water) (see *Table*

4.1.3). According to *The Plain Questions* (《素问·阴阳应象大论》, Su Wen) (Shandong College of CM & Hebei Medical College, 1982) chapter titled *The Great Treatise on the Correspondences and Signs of Yin and Yang*, “Humans have five zang-organs which transform the five qi which, in turn, engender joy, anger, sadness, worry, and fear.” Thus the seven emotions are produced by their corresponding zang organs in response to external and internal stimuli, and they are the subjective experience of the function of these five zang-organs. For example, the liver stores the blood, and the blood is the home of the ethereal soul. When liver qi is full, it leads to anger (*The Spiritual Pivot* (《灵枢》, Ling Shu), Nanjing College of CM, 1986).

Table 4.1.3 Seven emotions, five zang-organs and five elements

Five elements	Wood	Fire	Earth	Metal	Water
Five zang-organs	Liver	Heart	Spleen	Lung	Kidney
Seven emotions	Anger	Joy	Worry Anxiety	Sadness	Fear Fright

Of course, emotional qualities are not in themselves pathological, and all of them appear in healthy individuals. It is only when an emotion is either excessive or insufficient over a long period of time, or when it arises very suddenly with great force, that it can generate imbalance and illness. And the reverse is true: internal disharmony can generate unbalanced emotional states. So *The Great Treatise on the Correspondences and Signs of Yin and Yang in The Plain Questions* (《素问》, Su Wen) (Shandong College of CM & Hebei Medical College, 1982) says “Violent anger damages yin; violent joy damages yang”. In the Qing dynasty, Shen Jin’ao (1773) reiterated that it is excessive emotion that causes disease: “Due to having great fear, great joy, great anxiety, great fight, the result is suffering loss of spirit.”

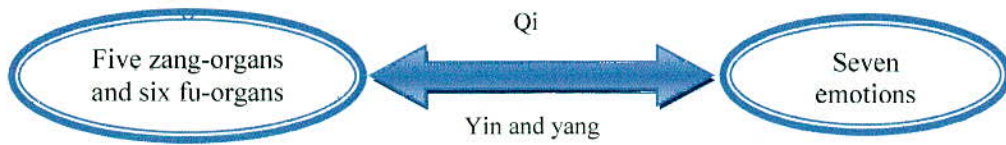
Emotional excess or insufficiency acts on the qi and the other substances. *The Plain Questions* (《素问·举痛论》, Su Wen) (Shandong College of CM & Hebei Medical College, 1982) states that “excess joy is associated with slow and scattered qi; excess

anger induces the qi to ascend; excess sadness weakens the qi; excess anxiety and worry generate knottiness; fear results in descending qi; and fright induces chaotic qi.”

The function of each of the five zang-organs and six fu-organs is associated with and dependent on a particular flow of qi. For instance, the stomach governs downward movement, while the liver governs upward movement. This is referred to as the qi mechanism. Extreme or prolonged emotions cause extreme and prolonged changes of the flow of qi and can inhibit the qi mechanism. When the qi mechanism becomes inhibited, the various zang and fu organs cannot perform their functions correctly. The organs that are affected depend on the emotions involved and their correspondences with those organs.

When a person’s zang and fu organs are relatively exuberant and replete, yin and yang are relatively coordinated and in balance, emotions come and go in response to stimuli, but they do not result in enduring pathological changes. However, if a person’s zang and fu organs are already vacuous and weak or if they habitually tend towards yin or yang excess, extreme or prolonged emotions may further damage those already weakened organs or tip the yin-yang balance even further. In that case, abnormal or excessive emotions can easily cause disease. Conversely, when one’s mind is smoothed and freely flowing and one’s emotions are open and light, the qi mechanism is freely and smoothly flowing, the qi and blood are regulated and harmonious, the zang and fu organs’ function is regulated, and the body’s healthy qi is bright. If the mind is not smoothly flowing and emotions are depressed, the qi mechanism will counterflow (not moving as a normal pattern) and be in chaos, the yin-yang, qi and blood will lose their regulation, and the organs’ function will become abnormal. Then the body’s healthy qi will become diminished and weak. Thus, the relationships between organs and emotions through qi and yin-yang are completely bi-directional, which is shown in *Figure 4.1.3*.

Figure 4.1.3 Relationship between the organs and emotions



When discussing the disease causes and mechanisms of individual diseases, internal damage by the seven emotions is the most common cause of psychological problems in CM. This is also supported in western research where illnesses have been shown to be associated with psychological problems (e.g. Johnson-Laird et al., 2006).

4.1.4 The liver

As it is discussed above, all five zang-organs can be affected by emotions. Since the qi mechanism of the entire body is closely related to the liver's function, extremes of any emotion can result in liver qi stagnation, which has a close connection with stress and its symptoms. So the liver's physiological functions and its pathological changes are addressed in this section.

CM differentiates the liver as the liver yin (its material structures, including the blood stored in it) and the liver yang (its functions and energetic capacity, including the qi of the liver). The chief physiological functions of the liver are as following:

1. Soothing and regulating the flow of qi and blood. Ancient CM practitioners understood that trees tended to grow upwards and spread out freely; so did the liver corresponding to this characteristic (Yin, 1984). In the CM theory, the liver governs the rise and dispersion, and the free flow of qi. This is why the liver is classified as "wood" in the five elements. This function of the liver is shown in the three aspects:
 - Regulating mind and mood – "The liver holds the office of General of the armed force. Assessment of circumstances and conception of plans stem from it" (*Plain Questions* (《素问》, Su Wen), Shandong College of CM & Hebei Medical College, 1982) which explains the relationship of the liver to certain activities of the higher centres of the nervous system in western medicine;

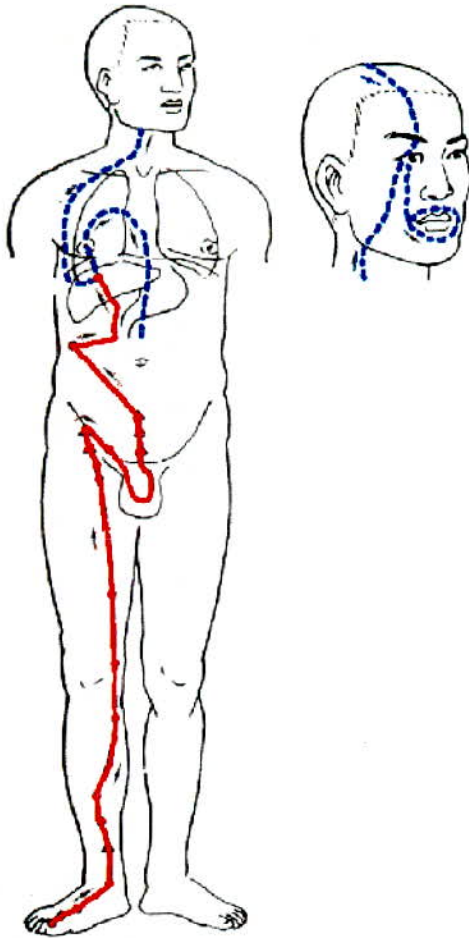
- Promoting digestion and absorption;
 - Keeping qi and blood moving normally.
2. Storing and regulating blood.
 3. Association of the liver and gallbladder. The gallbladder is related to the liver with which it is externally – internally related and mutually affected.
 4. Related to the tendons, nails and eyes. The condition of the liver determines the condition of the tendons. The brilliance of the liver is reflected by the nails. The eyes are the windows of the liver.

The liver regulates the smooth and unobstructed flow of qi and blood, and maintains the uninhibited and free movement of qi throughout the body in order to prevent stagnation. Hammer (1990) states the liver is the first line of emotional defence for the entire organism; when confronted by a noxious emotional stimulus, this energy system is the organism's first choice for coping with the stressor. The liver deals with the stressors by assuring constant movement and circulation of qi, thus preventing stagnation.

The liver network expresses capacity for growth, development, expression and change. Any experience inhibits this potential directly affects the ability of the liver to maintain free flow. Any intense emotion is not released through verbal expression or physical activity increases the demand by the nervous system on qi and blood, and potentially results in the liver incapable of renewing and circulating harmful energy (Hammer, 1990). A condition of blockage or stagnation of qi may set in. Emotions, especially anger and frustration, are the primary causes of liver qi stagnation.

Liver qi stagnation affects, in turn, other functions of the liver such as storing the blood and regulating digestion. It may also manifest as a blockage or pathological change along the pathway of the liver meridian (which traverses the foot, the medial side of the leg, pubic region, lower abdomen, stomach, liver, gallbladder, the costal and hypochondriac region, throat, eye, and the vertex) (see *Figure 4.1.4*).

Figure 4.1.4 The liver meridian of foot-jueyin*



*: Adapted from Chinese Acupuncture and Moxibustion (Cheng, 1987) and Meridians and Collaterals (Li, 1984).

The red part is external to the body; the blue part is internal to the body.

In addition, the qi is yang and, therefore, inherently warm. While unfulfilled desires are the main immediate cause of liver qi stagnation, loss of the liver's control over soothing and regulation may also be due to the liver's not obtaining sufficient blood to nourish and harmonize it, and the liver's not obtaining sufficient yin to enrich and moisten it. When this condition is kept longer inside of body or its level is more serious, liver qi stagnation is easily transformed to heat or fire.

Depending on the viability of the organ systems in a particular individual, liver qi stagnation may negatively impact any of the other zang-organs and fu-organs which play a main role in the creation or perpetuation of mental-emotional illness. First and foremost, liver qi stagnation will invade the spleen and stomach. Liver attacking the spleen results in spleen qi vacuity and, therefore, blood vacuity as well as dampness, phlegm, and/or food stagnation. Liver invading the stomach typically leads to a counterflow rise of stomach qi, which will descend when the stomach is normal.

Therefore, it is easy to see the critical role liver qi stagnation plays in the various disease mechanisms associated with mental-emotional disorders. The main zang-organs associated with mental-emotional disorders in CM are the heart, liver and spleen, and the liver has close relations with each of them. While each of the organs in CM is connected to each of the others, in clinical practice, the liver is simply the most commonly diseased of all the Chinese organs. Hence liver-stomach, liver-spleen, heart-liver, and liver-kidney patterns and, by extension, liver-spleen-stomach pattern are the most commonly seen patterns. So liver qi stagnation plays an important part in the overwhelming majority of patients with mental-emotional disorders.

In CM there is a saying, “In adults, blame the liver.” This is because no adult living in a civilized society can immediately fulfil all their desires. If someone cannot cope with this, stress may be the result and affect the function of the liver. That mainly results in the pathological changes of liver qi stagnation as *The Spiritual Pivot* (《灵枢·本神》, Ling Shu) (Nanjing College of CM, 1986) says “Anxiety and worry lead to qi stagnation.”

The heart is “the residence of the mind” (*The Spiritual Pivot* (《灵枢》, Ling Shu), Nanjing College of CM, 1986), and is therefore considered to be the seat of consciousness and mental functions. Inability of the heart can cause some symptoms of mental and emotional imbalance, such as, sleep disturbances, anxiety and palpitations. More discussion can be found in 4.3.2 *Chinese Medicine pathogenesis and diagnosis in stress*.

4.2 Chinese Medicine theory of health and illness

CM defines health as the balance between yin and yang, which depends on the capacity of an organism to adapt, change and maintain equilibrium. Illness is the result of deficiency or excess of either yin or yang. Deficiency, also is called vacuity or emptiness or xu (虚) in Chinese, is defined as: weakness of the forces (upright qi) which maintain the health of the body and fight disease, an insufficiency of vital substances (qi, blood, body fluids, and essence), or the diminished capacity of physiological processes. Excess, also is called repletion or fullness or shi (实) in Chinese, is defined as: an accumulation of physiological products (phlegm, dampness, blood, qi) that are harmful to the body when present in excessive amounts and obstructing normal functioning, or as the relative excess of either endogenous or exogenous pathogens (which are called “evil qi” and include wind, cold, fire, summer heat, dampness, and dryness) that may threaten the health of the organism. Deficiency and excess are both imbalances between yin and yang.

The homeostasis of an organism – the balance between yin and yang – is sustained by the proper circulation of qi along energetic pathways: the system of meridians and collaterals. The system of meridians and collaterals forms a network that connects the surface of the body with the internal organs (five zang-organs: liver, heart, spleen, lung and kidney; and six fu-organs: gallbladder, small intestine, stomach, large intestine, bladder and triple energizer). This system serves as a two-way communication system, which both conveys messages to the surface about internal malfunctioning and alerts the internal functions about surface phenomena that might be threatening to move deeper into the system (Seem, 1987). The meridians and collaterals are the surface manifestations of the five zang-organs and six fu-organs, and act as an irrigation system that regulates the supply of qi and prevents accumulations. The internal organs in CM are defined by their functions and interrelations, rather than by their somatic structures or specific anatomic locations. They represent a complete set of functions that reflect energetic relationships among physiological and psychological events (Beijing College of TCM et al., 1980).

In short, key principles in CM are that both wellness and illness result from a balance or imbalance of yin and yang. The movement of qi between these opposite forces is considered to be the essential element in the healing system of CM. It is best thought of as energy becoming manifest, a vitalistic force that flows ceaselessly through the meridians and organs of the body. Imbalance in the flow of qi among the meridians and organs is the cause of disease and susceptibility to illness.

Chen Yan published *The three Causes and A Unified Treatise on Diseases, Patterns and Formulas* (《三因极一病证方论》, san yin ji yi bing zheng fang lun) in 1174CE and divided disease causes into three categories: external, internal, and miscellaneous.

1. External disease causes refer to the six environmental excesses (wind, cold, fire, summer heat, dampness, and dryness) and pestilential or epidemic qi. If one or more of these external evils attack and enter the body, they may cause various pathological problems depending upon the nature of the evil qi.
2. The internal causes of diseases are the seven emotions. These have close connection with psychological and emotional changes, as discussed above in *4.1.3 The theory of seven emotions*.
3. The category of miscellaneous causes of disease is comprised of an indefinite number of disease causes. The only thing that links these together into a single category is that they are neither the six environmental excesses nor the seven emotions. The most common miscellaneous causes are unhealthy diet, lack of regulation between activity and stillness, excessive sexual life, drug addiction, wrong treatment, and parasites.

Generally, illness development in CM has three stages (Huang, 2003). In the early stage, the illness often belongs to a disorder of the qi, and could manifest as excess of qi or qi stagnation. The middle stage is very long, complex and changeable. For instance, liver qi stagnation could develop to liver qi invading the spleen and / or stomach, ascendant hyperactivity of liver yang, internal stirring of liver wind, liver yang transforming into fire, and blood stasis. Liver qi stagnation also could induce spleen deficiency which could subsequently involve damp retention, phlegm, deficiency of qi and blood,

deficiency of kidney qi and deficiency of stomach yin, etc. In the third stage, a deficiency of yang is the final manifestation of all chronic depleting severe illness.

These descriptions in CM theory of the three categories of disease causation is similar to the three categories of stress definition (see 2.1 *Concept and definition*). This similarly provides the opportunity to use CM theory to research stress and use CM's treatments to treat stress and its symptoms.

4.3 Chinese Medicine understanding of stress

“Stress” translated into Chinese is “应激 (ying ji)”. “Stress” and its theory were introduced into China in the 1980s. Since then, researchers in China have designed various questionnaires and research methods to carry out studies into stress in different fields (Jiang, 2006).

Although the concept of the word “stress” is relatively new in CM, the traditional theories of zang and fu organs and the seven emotions provided a framework thousands of years ago for understanding how a bad environment or disturbed mental state is closely connected with disease. Therefore symptoms of stress and treatment theory really have been an integral part of CM for a long time. Pathological stress belongs to the category mental-emotional disorders in CM (Yan and Xu, 2005) and CM can recognise and diagnose different types of stress. In the recent two decades, there has been an increasing amount of research into CM including TCA for stress. The research can be divided into three types: (1) theoretical exploration; (2) clinical and epidemiological research; and (3) animal laboratory study.

4.3.1 Relation between the theories of Chinese Medicine and stress

Theoretical research by scholars in CM has explored the correlation between stress theory and CM theory, which is helpful in developing a suitable methodology to carry out research into CM for stress.

Huang (2004) stated that the stress syndrome is caused by many stressors, leading to changes in the internal environment of the nervous system, endocrine system and immune system, which are non-specific. It appears widely in different diseases in clinical practice. This is similar to the general basic syndromes identified in CM diagnosis and treatment. He considered that there was a close relationship between the stress syndrome and basic CM syndromes. In CM, the basic syndromes include general symptoms from all the body. CM's syndromes equate to the non-specific symptoms in stress which were proposed by Selye (1974). Also the syndrome developments in the early stages, middle and later stages of different disease correspond to the three stages of stress syndrome. These two theories support and enrich each other. This provides an opportunity to theoretically integrate CM with western medicine.

Yan and Xu (2005) believe that stress is a state of the interaction between the body's response and stressor, and it follows a process. In CM, syndromes are the response states of different individuals to various disease causes. All these states are integrated responses of physiology and pathology (including function and organism), and they adapt to follow changes in the etiological factors. This process of analysis and induction is called CM syndrome differentiation. Since both stress and CM syndrome development have similar process and stage during their development, they have an essentially high correlation. In particular, stress is a chronic and repeated process, and it is similar to CM understanding of the development of many diseases and syndromes.

Though stress theory was published in western countries in the 20th century and the theory of the seven emotions was proposed several thousand years ago in China, Zhou and Zhu (1996) developed a module (S-R) to explain the similarity of two theories using cognitive method. CM's concept of holism emphasises the correspondence between nature and human beings. Any change of climate, location, time and social environment could become a stressor (S) that impacts on an individual, who will have a psychological and biological response (R). Psychological responses could be the seven emotions through high level subjective mentality; biological changes include the physical responses due to disturbance of the qi dynamic. The theory of stress centres

on how the body develops the physiological, biochemical and psychological responses (R) to the environmental (including biological, social or psychological) changes (S). Therefore, researchers consider the model (S-R) in both theories is the same and this gives a chance to research into CM integrated with western medicine in this field.

Furthermore, Zhou and Zhou (2001) identified the following five shared aspects in the theories of CM seven emotions and stress:

- unity of mind and body;
- non-specific response of many systems of the body;
- positive and negative effects to the body;
- transmitter mechanism;
- individuality.

They believed there were similarities in these two theories, which could supply and enrich each other and this allowed the creation of a new medical model to carry out further and deeper research.

In short, stress is based on a holistic theory, which believes the response to stress is non-specific and involves the symptoms from whole body (see 2.2 *The stress response* and 2.4 *Symptoms and their relationship to ill health*). That is similar to the CM theory. This may be a breakthrough point to encourage researchers to find an integrating way to use modern western medicine techniques to research into ancient CM and its theory.

4.3.2 Chinese Medicine pathogenesis and diagnosis in stress

The researchers used CM theory combined with psychological, biochemical and other modern methods to carry out clinical and epidemiological research to reveal the pathogenesis and diagnosis of stress in CM. Pan (2005)'s study showed that in the general population who suffered from stress, CM diagnosis could be divided into two types. One was the liver and gallbladder depression; another was the deficiency of zang-fu organs. In the first type, liver qi stagnation was the most common diagnosis. The main organs associated with stress were the liver (gallbladder), heart, and spleen

(stomach). Liver pathology is predominant. Furthermore, Gao (2005) studied 2156 cases using a psychological measuring scale and a developed data collection instrument to collect information on the four CM physical examinations. He identified that the top 5 types of CM syndrome for stress were:

- liver depression with qi stagnation,
- liver qi invading spleen,
- gallbladder qi deficiency,
- liver qi invading stomach,
- deficiency of both heart and spleen.

Another study (Yan et al., 2003) on 250 university students investigated the distribution of CM syndromes in examination stress. They found the symptoms came from the heart, liver and spleen. The most common syndrome patterns of stress were the deficiency of heart and spleen, the deficiency of heart qi and yin, the deficient of heart qi, and liver qi invading spleen.

Yue et al. (2005) reviewed the previous studies, which used western medicine methods and techniques to investigate the mechanisms of stress in CM, and concluded that stress is involved in all five zang-organs, but especially the heart, liver and kidney. In respect of stress, the heart is in charge of sensation and perception, and making decisions after cognitive appraisal. Thus it transmits the decision to the subcortical centre, transacts the feedback of organs, and accepts the regulation of adrenal cortical hormones. The liver transmits decisions from the heart, investigates emotional modulation in the limbic system, and reacts on the locus coeruleus -- norepinephrine neuron / sympathetic -- adrenomedullary system, which acts to contract smooth muscle and redistribute the blood, thus performs the physiological and psychological reaction to stress. It also influences the hypothalamic-pituitary-adrenalcortical (HPA) to secrete more cortical hormone, which is the core of the reaction of stress. The kidney mainly organises general adaption via adrenal cortical hormone, and regulates the sensibility of the heart and liver. The liver and kidney each store fire which is called “ministerial fire”, and influence each other in the stress response.

From the current research and theoretical studies, there was a consensus that the liver's function of taking charge of dispersion and regulating mind and mood is closely related to stress. According to CM theory and the result of modern studies, Li et al. (1998) suggested that the change of qi's function and movement is an important physiological characteristic of stress reactions, which could cause other physiological and pathological changes, such as the disorder of the functions of zang and fu organs, and imbalance of yin-yang. The liver is the centre for adjusting stress reactions and it adjusts this kind of reaction by affecting the function of qi, the blood and emotions. The liver's function is directly related to the physiology and pathology of other organs, and to the pathogenesis and prognosis of diseases concerning these organs. Li and his colleagues believed that many CM interventions are aimed at adjusting stress reaction, for example, therapy for relieving liver qi stagnation, and those CM interventions possess important value in prevention and treatment of many diseases. So Wang (2006) stated that whether the liver's function is normal decides the body's damage and severity of damage from stress.

By combining the holistic approach and homeostasis theory of CM with stress theory, Yan and Xu (2005) put forward the hypothesis that the liver's function in CM covers certain mechanisms of central neurobiology, on which basis they established the model of chronic psychological stress reaction (CPSR). The animal model imitated the process of comprehensive pathological changes when the liver's function failed and emotional disorder appeared. From reviewing and analysing previous research results, they considered that the liver's function in CM was related to the regulation of the hypothalamic-pituitary-adrenal gland axis. Concretely, it may be related to the changes in multiple neurotransmitters and their syntheses that are produced in the process of stress, such as neuropeptides, hormones, cyclic nucleotide system and Fos protein expression. This system is characterised by multiple links, multiple levels and multiple targets. Several brain regions, including various clusters of nuclei in the hypothalamus, hippocampus and amygdale, are involved in all those effects.

Besides the liver, other organs also can be related to stress, especially the heart which “the radiance of the spirits stems from” (*The Plain Questions* (《素问》, Su Wen), Shandong College of CM & Hebei Medical College, 1982). In clinical practice, some acupuncturists think the heart is important to treat symptoms of emotional disorder induced from stress, e.g. being upset, irritable. However, mental illnesses and emotional disorders can affect the heart, but rather than originating in the heart itself, damage caused by the emotions begins in other organs eventually affecting the heart (Schnyer and Flaws, 1998). So in clinical practice, the treatment should focus on the root of illnesses, rather than the manifestation from the heart. For chronic stress, which is due to the disorder of qi’s flow, its treatment should concentrate on regulating liver qi’s function, at the same time treating the manifestation of other organs (see 4.4.3*Treatment*).

4.3.3 Research into Chinese Medicine for stress

CM includes Chinese traditional medicine (also called “Chinese herbal medicine”, the researcher prefers “Chinese traditional medicine” because as well as herbs, it also includes metals, minerals, and animal parts, etc.), acupuncture, and other kinds of therapies and exercises. This section briefly reviews some research into Chinese traditional medicine and acupuncture for treating stress and provides an update on the most significant research.

4.3.3.1 Chinese traditional medicine

For decades, the neuroimmunopharmacological research has shown that many single medicines, compound prescriptions and effective component separation of Chinese traditional medicine can holistically regulate the neuroendocrine -- immunomodulation network (NIM) which is the pathological mechanism operating for stress. That is especially manifested in the Chinese traditional medicine compound prescriptions for psychosomatic diseases, such as tonic compound prescriptions (Liuwei Dihuang Bolus (Ma et al., 2002), Shengmai Yin (Li and Zhao, 1999), Baoyuan Jian (Sun and Zhen, 1999)) and liver-regulating compound

prescriptions (Xiaoyao Powder (Dun and Hao, 1999), Sini Powder (Yan et al., 2004), and Chaihujialonggumuli Decoction (Zhang and Nie, 2001)).

Current research uses the advanced molecular biological techniques and focuses on Chinese traditional medicine monomers, such as alkaloids, flavonoids, polysaccharides (Chinese wolfberry polysaccharides), and saponins (ginseng saponins), and shows that their resistance to the damage caused by stress is through regulating NIM (Zhang and Yan, 2002). In addition, there are many kinds of ingredients in Chinese traditional medicine, either as a single medicine or as compound prescriptions, whose effects are wide ranging and non-specific (Xu, 2006).

4.3.3.2 Acupuncture

The research into acupuncture for stress can be divided into clinical research and experimental animal studies. The clinical research is discussed in *Chapter 5*. Experimental studies have involved the use of different types of animal models to explore the mechanism of the effectiveness of acupuncture for stress. In China, most of studies in this area are carried out in the laboratory. They can be divided into 3 main topics:

1. Research into the efficacy of acupuncture for stress

Studies have been carried out to explore the potential acupuncture mechanism operating in stressful circumstances. Li et al. (2005)'s research showed that acupuncture at DU14 (大椎, Dazhui) could improve behaviour in rats exhibiting chronic stress disturbance, and suggested that this effect was likely to be regulated by arginine vasopressin (AVP) in the nucleus paraventricularis hypothalami (NPH). Han et al. (2001) used radioimmunoassay to monitor the levels of plasma cortisol and ACTH in rats with chronic stress and induced depression. They found that electro acupuncture on DU20 (百会, Baihui) and SP6 (三阴交, Sanyinjiao) significantly decreased the levels of ACTH, cortisol and arginine vasopressin, and suggested that the effectiveness may be related to the regulation of the HPA axis. Another study using a chronic stress animal model

showed that compared with the control group electro acupuncture on DU20 and EX-HN3 (印堂, Yintang) significantly increased stressed rats' vertical movement times and sucrose intake volume, and decreased the levels of ACTH and cortisol. These effects were the same for the group where the rats were given hydrochloride fluoxetine. The results suggested that electro acupuncture on DU20 and EX-HN3 could promote recovery from the rats' abnormal behaviour and adjust the secretion of ACTH and cortisol by inhibiting the hyperactivity of the HPA axis (Jia et al., 2004). Huang and Sun (2005) found that acupuncture on PC6 (内关, Neiguan) and RN17 (膻中, Danzhong) on chronic stress rat models to treat depression had similar effects to the above studies in regulating the HPA axis. Although those studies sample sizes were small and only used one or two acupoints in each study, they suggest acupuncture could normalise the cortisol levels, which was helpful supporting the researcher's project. Also all acupoints used in the animal studies were common points used in the clinical practice to treat stress, thus the animal studies provided the theoretical basis for using these points.

There has been a lot of research into acupuncture's regulation of the immune system during stress. For example, Meng et al. (2003) used the enzyme-linked immunosorbent assay technique to investigate the immune system's function under acupuncture on LI4 (合谷, Hegu) and LR3 (太冲, Taichong) in a chronic fatigue rat model induced by chronic stress. Results showed that the use of these points could significantly decrease Interleukin 1 β (IL-1 β) and Interleukin 6 (IL-6) in the serum. Meng et al. (2003) also found that electro acupuncture on DU20, ST36 (足三里, Zusanli), and LR4 significantly reduced β -endorphin in the hypothalamus, which could relieve damage in the chronic fatigue rat model induced by chronic stress. Li et al. (2000)'s research demonstrated that electro acupuncture on ST36 could reduce cortisol concentration and strengthen the immunologic function by increasing the activities of T and B lymphocytes in the spleen.

Some studies were carried out into acupuncture for digestive system dysfunction during stress. For example, Shen et al. (2002) found using electro acupuncture on ST36 could protect against gastric mucosal damage in rats subjected to restrained – cold stress. At the same time there was a significant change of vasoactive intestinal peptide, suggesting that it may act as a signal transducer in this process.

2. Research into acupuncture needling techniques for treating stress induced symptoms

There are a few studies which have investigated different acupuncture techniques for the treatment of stress. For example, Wu et al. (2001)'s research was to investigate the protective effect of warming-dredging needling method on rats with stress lesion of gastric mucosa (80 rats divided into 4 groups; no symptom control group, stress model control group, warming-dredging needling group and twisting-reinforcing needling group). The acupoints used in the study were ST36 (足三里, Zusanli) and RN12 (中脘, Zhongwan). The authors report that compared with the control groups the needling methods could significantly increase the quantity of prostaglandin E2 (PGE2) in plasma and gastric mucosa, decrease the amount of gastrin in blood serum and gastric mucosa, and relieve lesions of the gastric mucosa. The warming-dredging needling method was more effective than the twisting-reinforcing needling method. Authors believed that compared to the twisting-reinforcing needling method the warming-dredging needling method is more easily manipulated. It also takes effect more quickly. Although this small study suggests that specific needling techniques may increase the effectiveness of treatment, these techniques tend to cause increased discomfort and were not considered suitable for the western subject of this study.

These animal studies suggest that acupuncture on particular points has a physiological effect on stress induced symptoms. Most studies only used one or two acupoints aimed at limited physical symptoms. Electro-acupuncture is more frequently employed in all these studies. This is in order to standardise the protocol

and remove the practitioner element of treatment by needling. The stress induced symptoms in these animal models are as a result of physical and environmental discomfort to the subjects which results in the physiological changes of the GAS, but do not relate directly to the stresses acting on human subjects. Thus from a clinical perspective there is a difference between the human and the animal in acupuncture techniques and acupoints chosen. These experimental study reports suggested some of the mechanisms explaining the efficacy of acupuncture for stress, and provided a theoretical background, which is helpful in directing acupuncture clinical practice.

Stress produces different physiological and pathological changes and the different stages will affect different internal organs (zang-fu in CM) and result in the unique CM syndromes. All the above experimental studies were based on stressed animal models in the laboratory and focused on the changes at a specific period, rather than all stages of the development of stress. It is necessary to set up reliable stress models according to CM differentiation to explore the effectiveness of CM for stress. Such CM differentiation on animal models has been tested in China. For example, the reports by Wang and Chen (2000), Zhao (1997) and Zhao et al. (1996) reveal that rats under chronic restraint stress manifest liver depression syndrome, deficiency syndrome of both liver and kidney yin, and syndrome of liver depression and spleen deficiency on 15 days, 21 days and 45 day after starting the study. Although the results need further verification, they can have implications for studies on human populations.

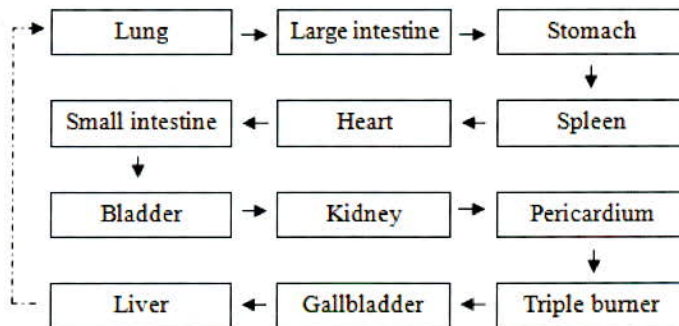
4.4 Traditional Chinese Acupuncture for stress

4.4.1 Introduction to Traditional Chinese Acupuncture

TCA is a minimally invasive technique based on CM. After the patient is examined holistically, by employing both objective and subjective data, a diagnosis is reached. The holistic approach entails an extremely detailed history and asking patients questions about their emotional, physical as well as social well-being. The acupuncturist then assesses the patient's tongue and pulse and makes a CM diagnosis.

According to CM, pathways called meridians and collaterals traverse the body, which are shown in *Figure 4.4.1 The cyclical flow of qi in the twelve meridians*. These pathways carry qi or vital energy from the various organs to the surface of the body and help to regulate yin and yang (see *4.1.1 Yin – yang, qi*). The yin and yang can be thought of in western medicine terms as being like the sympathetic and parasympathetic nervous systems in that they have opposing, yet balancing effects on the human body. The organs in CM are not looked upon anatomically, but rather energetically. Diseases and symptoms are thought to occur when the organs' energy becomes out of balance either due to deficiency or due to excess. The practice of TCA is to insert fine, solid needles into selected body locations (acupoints or acupuncture points) according to CM theory. Classic texts describe 361 points dispersing over the dorsal and ventral aspects of the trunk, limbs, face, head, and neck. These points correspond to the various meridians of the organs and follow their paths over the surface of the body. There are also numerous auricular points that correspond to the various organs, and auricular acupuncture can be included in the treatment of stress and its symptoms depending on the CM diagnosis.

Figure 4.4.1 The cyclical flow of qi in the twelve meridians



As Fruehauf (1995) states, for CM treatment of mental-emotional diseases “the therapeutic focus tends to be on the restoration of uninhibited qi flow, since unbalanced emotions first affect the qi before they influence the physical structure of the body”. What acupuncture does first and foremost is to disinhibit the flow of qi. Acupuncture treatment is aimed at regulating the flow of qi in the meridians and collaterals by dissipating the excess energy and tonifying deficiency, as well as balancing the yin and

yang of the body. Therefore, acupuncture can be a very effective treatment for many kinds of mental-emotional disease, in particular, for promoting relaxation in cases of heightened excitation and restlessness (Flaws and Lake, 2003).

As mentioned in the previous section (see 4.3 *Chinese Medicine understanding of stress*), though “stress” is a new word in CM, its basic theory has a close connection with the CM theory, and its symptoms’ treatment has been a part of TCA throughout its history. The literature review of TCA for stress showed that the literature focuses on particular aspects of stress, e.g. syndrome patterns, symptoms of stress. So far there is no book or article that systematically covers stress and its treatment in CM.

Stress and its symptoms are more individual and non-specific compared with other diseases which have more specific symptoms in the early stage of the illness development. Therefore the researcher wrote the following sections through reviewing articles not just on stress but also related mental and emotional disease, combined with his clinical experience, in order to summarise the general principles of TCA treatment for stress. Much of the material concerning the patterns and treatment derives from following sources: Gao (2005), Pan (2005), Yue et al. (2005), Flaws and Lake (2003), Schnyer and Allen (2001), Yang (1989), Cheng (1987), Li (1985) and Deng (1984).

4.4.2 Aetiology and pathogenesis of stress in Chinese Medicine

According to the previous three sections analyses and discussion and combining the results of research in theory and clinical practice, the causes of stress fall into two main groups:

1. The difference between individuals: the internal stress factors.

The differences between individuals, e.g. personality, education, personal experiences and the current bodily condition could result in mental disorders. When the body’s general condition is not in balance, it is easily subject to stress and manifests changes of emotions. *The Plain Questions* (《素问·调经论》, Su Wen) (Shandong College of CM & Hebei Medical College, 1982) states “excess blood

leads to anger, deficient blood leads to fear.” *The Spiritual Pivot* (《灵枢·本神》, Ling Shu) (Nanjing College of CM, 1986) says “the deficiency of the liver-qi causes fear, excess causes anger.....the deficiency of the heart causes sadness, excess causes keeping on laughing.”

2. Various environmental stressors: the external stress factors.

Anyone’s emotions can be affected by social changes, life style, working conditions, interpersonal relationships, and climate and weather. *The Spiritual Pivot* (《灵枢·口问》, Ling Shu) (Nanjing College of CM, 1986) says “great amaze and greatly sudden fright lead to qi and blood separating, yin and yang tumbling down, meridians blocked.” This indicates that the cause of stress depends on the quality and strength of the stressor and the time that it lasts. Emotions also are related to the weather and climates. *The Plain Questions* (《素问·生气通天论》, Su Wen) (Shandong College of CM & Hebei Medical College, 1982) states that “clear and sunny day makes people feel explicit and fresh; humid weather makes people feel anxious; cloudy and rainy weather makes people feel tired and depressed.” This shows that the natural environment can affect people’s emotions.

The principal pathogenesis of stress in CM is the liver failing to govern the free flow of qi. When this disorder of the liver’s function lasts longer and becomes more severe, it could affect other organs, for instance, the gallbladder (insufficiency with timidity), the spleen (failing to transport and transform), and the heart (failing to get nourishment). The liver and its functions are introduced and discussed in 4.1.4 *The liver*.

According to the theory of disease development, every illness starts with qi disorder (*The Plain Questions* (《素问·举痛论》, Su Wen), Shandong College of CM & Hebei Medical College, 1982). At the early stage, the illness could manifest as excess of qi or qi stagnation (Huang, 2003). Fruehauf (1995) states that “unbalanced emotions first affect the qi before they influence the physical structure of the body”. Because of the liver’s governing the free flow of qi and regulating the mood and emotion, especially for stress which is one kind of emotional and psychological problem, liver qi could be

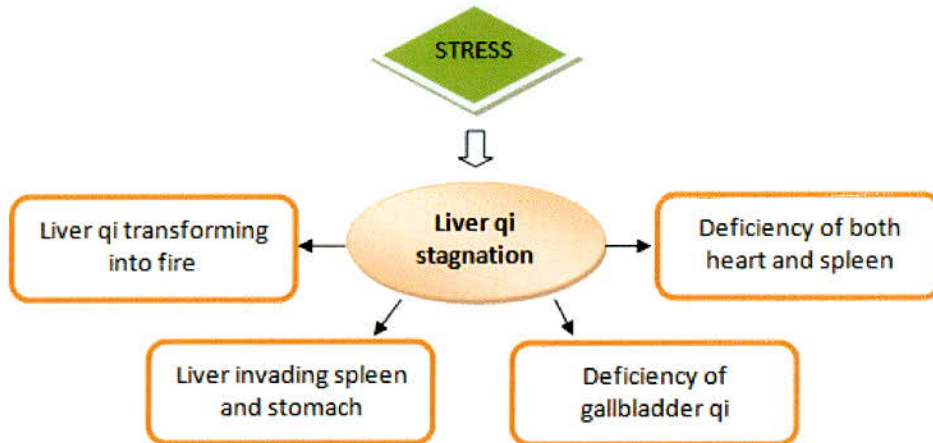
affected first. If liver qi stagnation is severe or enduring over a prolonged period of time, it may transform into heat and eventually into fire, further could affect other zang and fu organs.

The gallbladder is attached to the liver, and they are externally and internally related through the meridians. Clinically the liver and the gallbladder cannot completely be separated. *The Plain Questions* (《素问·灵兰秘典论》, Su Wen) (Shandong College of CM & Hebei Medical College, 1982) records that “the gallbladder seems to be an upright officer who is in charge of making a decision”. This means that bravery and timidity are related to the gallbladder. The gallbladder’s function is closely related to the liver’s function of maintaining the free flow of qi and regulating the mood. Therefore liver qi stagnation could affect gallbladder qi’s function.

Because of the five element relationship of the liver and spleen, and the liver and heart via control cycle, overactivity in the liver may cause or further exacerbate a predisposition to spleen vacuity. If the spleen becomes empty and weak, it will not only be incapable of transforming and transporting body fluids, but will also fail to generate sufficient blood and qi. This may lead to heart qi and heart blood vacuity, rendering the heart unable to store the spirit.

The pathogenesis of stress in CM is summarised in *Figure 4.4.2*. That also leads to the pattern identification of CM for stress in the clinical practice, which is discussed in *4.4.3 Pattern identification of Chinese Medicine for stress*.

Figure 4.4.2 The pathogenesis of stress in CM



In addition, if stress is not treated and becomes more severe and enduring over a prolonged period of time, all those changes in the body could result in the imbalance of yin and yang with consequential health problems. An analysis of the pathogenesis of that particular illness pattern is needed, as well as considering stress.

4.4.3 Pattern identification of Chinese Medicine for stress

According to CM theory (see 4.1.4 *The liver*, 4.4.1 *Introduction to Traditional Chinese Acupuncture* and 4.4.2 *Aetiology and pathogenesis of stress in Chinese Medicine*), the literature review (see 4.3.2 *Chinese Medicine pathogenesis and diagnosis in stress*) and the researcher's clinical experience, five common pattern types of CM for stress are described and outlined below. The establishment of these patterns is due to stress as a main complaint without other illness(es) has been combined. Information concerning symptoms specific to stress has been adapted from personal clinical observation and integrated with the material from the following sources: Gao (2005), Pan (2005), Yue et al. (2005), Flaws and Lake (2003), Schnyer and Allen (2001), Yang (1989), Cheng (1987), Li (1985) and Deng (1984).

4.4.3.1 Liver qi stagnation

Main manifestation:

Mental depression, moodiness, irritability, an intense feeling of frustration;
Snapping easily, tendency to sigh;
Distension, oppression and pain around the chest, lateral body, costal region, breast and abdomen;
Dysmenorrhea, irregular menstruation;
A light red tongue; a wiry pulse.

Analysis: In cases of emotional injury, the liver qi stagnates and the liver fails to be harmonious and flourishing, so depression and moodiness appear. The qi becomes stagnant along the pathway of the liver meridian, which traverses the lower abdomen and stomach, and spreads across the chest and sides of the ribs. One may see abdominal and chest oppression, pain along the ribs. If the qi stagnation causes blood stasis, dysfunction of Penetrating Vessel and Conception Vessels could lead to irregular menstruation and dysmenorrhea.

4.4.3.2 Liver qi transforming into fire

Main manifestation:

Easy anger, irascibility, impetuosity, mental restlessness, aggression, violent outbursts of anger;
Chest and rib oppression, agitation, heart palpitation;
Headache, dizziness, red eyes, red facial complexion, bitter and dry mouth, tinnitus;
Insomnia, excessive dreams;
Early or excessive menstruation;
Constipation and yellow urine;
A red tongue with a thin yellow coating; a wiry and rapid pulse.

Analysis: Extreme or long-term stagnation of liver qi will eventually transform into fire. Because fire is yang in nature, it tends to counter-flow or move upwards, following the meridians and negatively affecting the function of organs (stomach,

heart, and lung) and tissues (head, eyes, ears, and mouth) located above the body. In addition to symptoms of qi stagnation, there are symptoms of heat and fire. The fire can force the blood to move recklessly outside its pathways. Therefore early or excessive menstruation could appear. The extreme heat consumes the fluid in the body, which leads to constipation and yellow urine. As the spirit resides in the heart, upward fire may disturb the heart spirit, causing it to become restless, with insomnia, and excessive dreams.

4.4.3.3 Liver invading spleen and stomach

Main manifestation:

Persistent anxiety and preoccupation, mental depression, vexation, moodiness, irritability, and sighing;

Abdominal or epigastric oppression, breast and / or rib-side distension and pain;

Poor appetite, possible painful diarrhoea, possible alternating constipation and diarrhoea;

Belching, burping, nausea, and vomiting;

A pale, fat tongue; a wiry pulse.

Analysis: This pattern is due to liver qi stagnation. Because of the five elements relationship of the liver and spleen via the control cycle, the liver qi stagnation typically inhibits the spleen qi's mechanism. In addition to the symptoms of liver qi stagnation, there are symptoms of dysfunction of the spleen and stomach. If the liver qi affects the spleen, there is a loss of appetite, abdominal distension, and diarrhoea. When the stomach is attacked, there may be epigastric oppression, belching and burping, possibly nausea and vomiting.

4.4.3.4 Gallbladder qi deficiency

Main manifestation:

Difficulty making decisions, lack of courage and sense of direction in life, easily startled, susceptibility to fright and fear, and fear of staying alone;

Tiredness, dizziness, and rib-side distension and pain;

Easily awake, insomnia;

A pale tongue; a thread and weak pulse.

Analysis: Liver qi stagnation, possibly liver qi counter-flow, plus sudden great fright which specifically damages the gallbladder affect the gallbladder qi's normal movement and its function of making a decision. It is also due to dampness and phlegm resulting from liver qi invading the spleen and spleen vacuity. Gallbladder insufficiency with timidity is very common symptom when someone suffers from huge pressure. It is often combined with symptoms from deficiency of the heart and a disturbed spirit, such as sleeping problems.

4.4.3.5 Deficiency of both heart and spleen

Main manifestation:

Confusion, lack of concentration, poor memory, decreased motivation, diminished interest or pleasure, excessive guilt, obsessive thinking or phobias, propensity to be startled;

Fatigue, weakness, slow thinking and speaking, slow movement, excessive desire to sleep;

Palpitations, restlessness, suspiciousness, difficulty to fall asleep, easy to wake up with excessive dreams during sleep;

Poor appetite, abdominal distension, loose stools, pale face, faint voice;

A pale tongue with a thin whitish coating; a thready and weak pulse.

Analysis: The heart governs blood circulation, and the spleen is the source of qi and blood. Over-work and prolonged stress, over-thinking and too much worry over a long period of time can cause the deficiency of the heart blood and spleen qi. As explained above, liver depression may also give rise to or exacerbate the spleen deficiency. The spleen is usually the first organ to be diseased after liver qi is stagnated. If the spleen becomes vacuous and weak, it will not engender and transform the qi and blood properly, leading to deficiency of both heart blood and spleen qi. If the heart blood is too vacuous to nourish and quiet the spirit, the spirit

may become hyperactive and restless, or it may be unable to engage the world and respond to the environment. A deficiency of both the heart and spleen can cause the lack of nourishment of the body. The whole body, either physical or psychological, presents fatigue and weakness.

The above five pattern types of CM for stress can commonly be seen in clinical practice, especially for patients whose main complaint is stress without other illnesses. Certainly it is common clinically to encounter a complex combination of patterns which includes the above five or others which are not mentioned here. For instance, when patients have more complaints, especially if they have other illnesses, the pattern of stress may follow that of the main complaint. When presented with such complicated patterns, the practitioner should identify the main ones and then modify the treatment for that pattern with additions and subtractions taken from the other, complicating patterns and disease mechanisms. But though a patient may have a serious illness, his stress pattern in CM still relates to the above five basic pattern types. In short, the particular complex pattern combination will determine the treatment principles and the individually tailored treatment plan.

4.4.4 Treatment

As discussed above, the root of stress is liver qi stagnation. At first, TCA treatment for stress should harmonise the liver qi and relieve the liver depression. Additional acupuncture points are used according to any other specific patterns diagnosed.

When stress is a main complaint which is being consulted for, TCA treatment should follow the general principles of the treatment plus those pertaining to any special symptoms which the patient has, e.g. insomnia, tiredness, moodiness. This is because the stress symptoms are very individual. Though the patterns of stress can be diagnosed, some special symptoms should also be considered.

Stress could appear combined with other illnesses and their specific symptoms. Though the treatment should concentrate on the particular illness, at the same time stress must

be considered, as it could affect the result of treatment. All chronic, enduring disease is complicated by liver qi stagnation due to liver depression. Even if the original cause of the disease was not unfulfilled desires, everyone who is chronically ill has unfulfilled desires. At the very least one wants to be healthy and free from illness. So the treatment should combine the non-specific stress treatment with specific illness treatment (Huang, 2003).

The TCA treatment protocol is produced and outlined as follows, which is the researcher's personal clinical experience combined the material from the sources: Flaws and Lake (2003), Schnyer and Allen (2001), Yang (1989), Cheng (1987), Li (1985) and Deng (1984).

4.4.4.1 Treatment principle

Soothing liver qi and relieving liver depression, and relaxing mind and body, combined with some specific treatments for the specific patterns, such as clearing liver fire, fortifying and moving the spleen and stomach, warming the gallbladder, and nourishing heart blood and strengthening spleen qi.

4.4.4.2 Prescription

The standard of acupoints prescription for the treatment of stress consists of:

DU20	DU24	EX-HN3	
LI4	PC6		
ST36	GB34	SP6	LR3

All these acupoints' names are shown in *Table 4.4.4.2*.

Table 4.4.4.2 The acupoints' names in the standard of prescription for the treatment of stress*

	Point name	Full name	Chinese characters	Pinyin name
Head	DU20**	Governor Vessel 20	百会	Baihui
	DU24**	Governor Vessel 24	神庭	Shenting
	EX-HN3**	Extra Point on Head and Neck 3	印堂	Yintang
Arm and hand	LI4	Large Intestine 4	合谷	Hegu
	PC6	Pericardium 6	内关	Neiguan
Leg and foot	ST36	Stomach 36	足三里	Zusanli
	GB34	Gallbladder 34	阳陵泉	Yanglingquan
	SP6	Spleen 6	三阴交	Sanyinjiao
	LR3	Liver 3	太冲	Taichong

*: Source from *Standard Acupuncture Nomenclature*.2nd ed (WHO Regional Office for the Western Pacific, 1993); the order of the acupoints in the table follows the 12 regular meridians' circulative order.

** : Source from *The National Standard of the People's Republic of China-Location of Points* (State Bureau of Technical Supervision of the People's Republic of China, 1991)

4.4.4.3 Supplementary acupoints

In addition to the main points above, the following points can be selected according to the other 4 different patterns.

- Liver qi transforming into fire: LR2 (行间, Xingjian), HT5 (通里, Tongli), PC5 (间使, Jianshi), LI11 (曲池, Quchi).
- Liver invading spleen and stomach: ST25 (天枢, Tianshu), RN12 (中脘, Zhongwan), RN6 (气海, Qihai), SP4 (公孙, Gongsun)
- Gallbladder qi deficiency: GB40 (丘墟, Qiuxu), ST40 (丰隆, Fenglong), PC7 (大陵, Daling), RN12.
- Deficiency of both heart and spleen: HT7 (神门, Shenmen), RN4 (关元, Guanyuan), PC7, SP3 (太白, Taibai).

4.4.4.4 Rationale for the use of acupoints

1. Standard prescription

DU20 awakens the brain, strengthens the brain as a sea of marrow, and stimulates the free flow of the qi all over the body. It opens the orifices, clears the mind, stabilizes

the will and purifies the spirit. DU20 also expels liver wind, spreads liver qi, restores collapsed yang. Besides all those, DU20 can regulate the qi of the heart, clear heat, and stop spasm.

DU24 is located in the front of the top of the head. Governor Vessel goes into the brain and its branch connects the kidney and crosses the heart. Acupuncture on DU24 can soothe the qi of Governor Vessel and tranquilize the mind, and regulate the qi of the kidney and nourish the sea of marrow. Research has found that emotional expressions have a close connection with the hypothalamus and limbic system. The body surface projections of those central nervous systems locate around Governor Vessel on the head (Yang et al., 2003).

EX-HN3, as the reflex point of the pituitary gland, regulates the blood, calms the spirit and promotes relaxation. By doing so, it controls hormonal secretions and the chemical composition of the blood (Jia et al., 2004).

LI4 is the source point of the large intestine meridian of Hand-Yangming. It can dispel wind and clear heat, open the blockage and regulate the qi, and unblock meridians and relieve pain.

LR3 is the source point and stream point of the liver meridian of Foot-Jueyin. It can be used to course the liver and relieve depression, calm the liver and restrain hyperactivity of yang, regulate blood and activate the collaterals, and improve the lower energizer.

LI4 and LR3 are called Si Guan points (四关穴), also called Four Gates points. It was first proposed in *The Great Compendium of Acupuncture and Moxibustion* (《针灸大成》) by Yang Jizhou in 1601, Ming Dynasty. The combination of LI4 and LR3 can stimulate, regulate qi and activate blood, unblock the meridians and induce resuscitation, calm the liver and extinguish wind, calm fright and tranquilize the mind, dispel wind and relieve pain (Wang and Hong, 2000). Maciocia (2006) states

that LR3's function is to move stagnant liver qi. Combining LR3 with LI4 achieves a balance of yin and yang, alongside a balance of arm and leg meridians. When moving qi, a combination of arm and leg points boosts the qi-moving effect of the points. Therefore, LR3 is seen in both the context of its function and the qi dynamics of the channel system. The molecular biological research shows that Si Guan points can regulate the psychological-neuroendocrine-immunity system (Meng et al., 2003). Wang and Xu (2003) reported that using penetration needling on Si Guan points for stress was very effective in their clinical practice.

PC6 is the connecting point of pericardium meridian of Hand-Jueyin and one of confluent points of the eight extraordinary meridians. It is used to regulate qi and remove blockage, open and clear the heart collaterals, and soothe the liver and harmonise the middle burner. Flaws (2003) prefers the combination of LR3 and PC6 instead of SP4 and PC6 to rectify and regulate Chong qi in Penetrating Vessel to treat emotional disorders.

ST36 is the sea point of stomach meridian of Foot-Yangming. Its function is to ascend and descend the functional activities of qi, regulate the stomach and invigorate the spleen. Li et al. (2000)'s research showed that electro acupuncture on ST36 could reduce the cortisol concentration and strengthen the immunologic function by increasing the activities of T and B lymphocytes in the spleen.

GB34 is the sea point of gallbladder meridian of Foot-Shaoyang as well as one of eight influential points – the tendon influential point. Its function is to soothe the liver and promote gallbladder qi, relax muscle tension and relieve spasm. As the gallbladder is attached to the liver, GB34 can enhance the function of soothing the liver and relieve liver qi stagnation combined with other points in that group. Qiao (1999)'s clinical experience showed that GB34 is a useful point for stress.

SP6 is a crossing point of three foot yin meridians (liver, spleen, and kidney). SP6 nourishes the yin of the entire body, and regulates the blood. Acupuncture on SP6 can

soothe the liver and invigorate the spleen, harmonise and tonify the liver and kidney, calm fright and tranquilise the mind. Wu et al. (2007, 2006)'s research indicated that SP6 can balance the autonomic nervous system and endocrine system.

This group of acupoints used in the treatment of stress and its symptoms is the summary of the researcher's twenty years of clinical experience combined with the experience of other doctors of Chinese medicine in China from whom he learned and his literature review. As stress affects whole body and has individually non-specific symptoms, the acupoints in the main prescription are selected from different meridians to soothe liver qi and relieve liver depression, and relax mind and body, rather than only choosing points on the liver meridian.

2. Supplementary acupoints

Liver qi transforming into fire: LR2, the ying-spring point of the liver meridian, can resolve liver depression and clear liver fire. Because fire is yang in nature and tends to counterflow or move upwards to affect the function of heart, HT5 and PC5 together are used to clear and calm the heart, and tranquilise the mind. LI1 is helpful to relieve the symptoms of heat and fire which follow the meridians up to head.

Liver invading spleen and stomach: ST25, the alarm point of the large intestine, is located at the border of the upper and lower abdomen and is good for ascending and descending of qi. RN12 is the alarm point of the stomach and the fu-organ influential point and is on upper abdomen. RN6 is on the lower abdomen and enriches qi's function. The combination of the three points fortifies and moves the spleen and stomach, and relieves the local symptoms. SP4 and PC6 are a pair of confluent points of eight extraordinary meridians and are used to enhance the above function according to the principle of selecting of the combination of local and distal points.

Gallbladder qi deficiency: GB40, the source point of the gallbladder meridian, strengthens body resistance to eliminate or suppress pathogenic factors and regulates the gallbladder's disorder – timidity. Gallbladder qi disorder can easily result in

phlegm producing in the body. ST40, the connecting point of the stomach meridian, is used to promote the circulation of qi and resolve phlegm. When pathogenic qi invades the heart, the pericardium is always the first to be attacked. PC7, the stream point as well as source point of the pericardium meridian, is used to nourish heart and tranquilise the mind. RN12 is helpful to relieve stomach symptoms.

Deficiency of both heart and spleen: HT7, the stream point and source point of the heart meridian, nourishes the heart, and refreshes and calms the spirit combined with PC7. RN4, the alarm point of the small intestine (which is attached the heart) and the crossing point of the Conception Vessel and the three foot yin meridians, can enrich the qi and blood of heart and spleen and relieve the local symptoms of the spleen. SP3 is the stream point and source point of the spleen meridian and the combination of SP3 and RN4 is used to improve the function of the spleen in producing qi and blood.

Some back-shu points are often used in some patterns, for example, BL15 (心俞, Xinshu) and BL20 (脾俞, Pishu) for deficiency of both of heart and spleen. In the researcher's clinical practice, the patient experiencing stress often chooses a supine position, and also stays in one position during the treatment. So back-shu points were not selected in this study.

4.4.4.5 Methods

The process of treatment for stress follows the general process of TCA clinical practice. After general consultation according to Chinese Medicine including observation, hearing and smelling, interrogation, and palpation, the patient is asked to lie down on their back or their abdomen, which depends on the patient's condition and the treatment principle. For example, when a patient has a bad back pain and his treatment focuses on his back pain, a prone position will be chosen (see *8.1 TCA group*). One position is usually chosen for one treatment session. Bilateral points are selected on the twelve meridians. The angles of inserting needles depend on the location of the acupoints, e.g. the needles are inserted obliquely or horizontally on the points on the head, other parts of body perpendicularly. The needles are retained 20

minutes. During that period, the needles are manipulated twice. Acupuncture techniques should be gentle and shallow with light manual or electrical stimulation. That is because most people who suffer from stress are more sensitive. A treatment session usually lasts 45 minutes.

In summary, it was decided that a protocol of specific acupuncture points should be used as the basis for TCA treatment for chronic stress in order to soothe liver qi, relieve liver depression, and relax mind and body. Additional points would be added for any other specific patterns or symptoms identified during treatment sessions, as would be the case in clinical practice. This protocol including aetiology, pathogenesis, pattern identification, and treatment for stress was the combination of the researcher's personal clinical experiences and his literature review, and will be further improved by future practice.

Chapter 5 A Systematic Review of the Use of Traditional Chinese Acupuncture in the Treatment and Management of Stress

This chapter consists of a systematic literature review of clinical trials on the use of acupuncture for managing stress. Some of the key laboratory studies on animals are included in *4.3.3 Research into Chinese Medicine for stress*.

5.1 Search Methods

5.1.1 Databases

All medical, nursing, complementary therapy, health, social, psychological and behavioural sciences databases available on Ovid Online were searched. These included EBM Reviews, AMED, British Nursing Index, CINAHL, EMBASE, Ovid MEDLINE and PsycINFO. The search was carried out from their respective inception to the first week of April in 2008.

In addition, the search was performed on a database which is called China National Knowledge Infrastructure (CNKI). The CNKI is the key national project of China. Its purpose is knowledge sharing throughout China and the world. From its beginning in June, 1996, the global research of CNKI full-text databases has grown substantially. The CNKI covers research carried out in China and is used in universities, public libraries, research institutions, enterprises, and hospitals in more than twenty countries. This data source provides access to Chinese scientific literature in Chinese. The databases in the CNKI used in this project were:

- Chinese Journal Full-text Database,
- Chinese Journal Full-text Database (Century Journals),
- Chinese Book Full-text Database,
- Chinese Important Conference Paper Full-text Database,
- Chinese Doctoral Dissertations Full-text Database,
- Chinese Outstanding Master's Theses Full-text Database,
- Journal Full-text Database in China Hospital Knowledge Database (CHKD),

- Newspaper Full-text Database in CHKD,
- Conference Paper Full-text Database in CHKD,
- Doctoral Dissertations and Master's Theses Full-text Database.

The time of search was from its inception to the first week of April 2008.

Efforts were made to identify unpublished and ongoing research and conference abstracts using relevant internet websites.

5.1.2 Search terms

On Ovid Online, the search terms used were “acupuncture” or “Traditional Chinese Medicine” or “complementary medicine” or “alternative therapy” or “complementary alternative medicine”, and “stress” or “chronic stress” or “mental stress” or “emotional stress” or “psychological stress”.

On the CNKI, the search terms used were “针刺” (acupuncture) or “针灸” (acupuncture-moxibustion), and “应激” (stress) or “紧张” (distressed or nervous).

As it was mentioned in 4.3 *Chinese Medicine understanding of stress*, “应激 (ying ji)” (stress) is a relatively new word in China and may not be used specifically in some articles. The researcher therefore employed other words, such as “紧张 (jin zhang)” (distressed or nervous) and “焦虑 (jiao lü)” (anxiety), which have similar meanings to “应激 (ying ji)”. In Chinese, “焦虑 (jiao lü)” is another word which is commonly used to express and explain the feelings experienced by those under stress. Also in clinical practice in China, patients rarely consult doctors with the complaint of “应激 (ying ji)” (stress). They often say “焦虑 (jiao lü)” (anxiety) or “紧张 (jin zhang)” (distressed or nervous) instead of “应激 (ying ji)” (stress). This may explain why there were no further clinical research reports concerning stress in China.

In English, “stress” and “anxiety” are two words. Each of them has a clear and different meaning when used in clinical practice. As the research topic is concerned

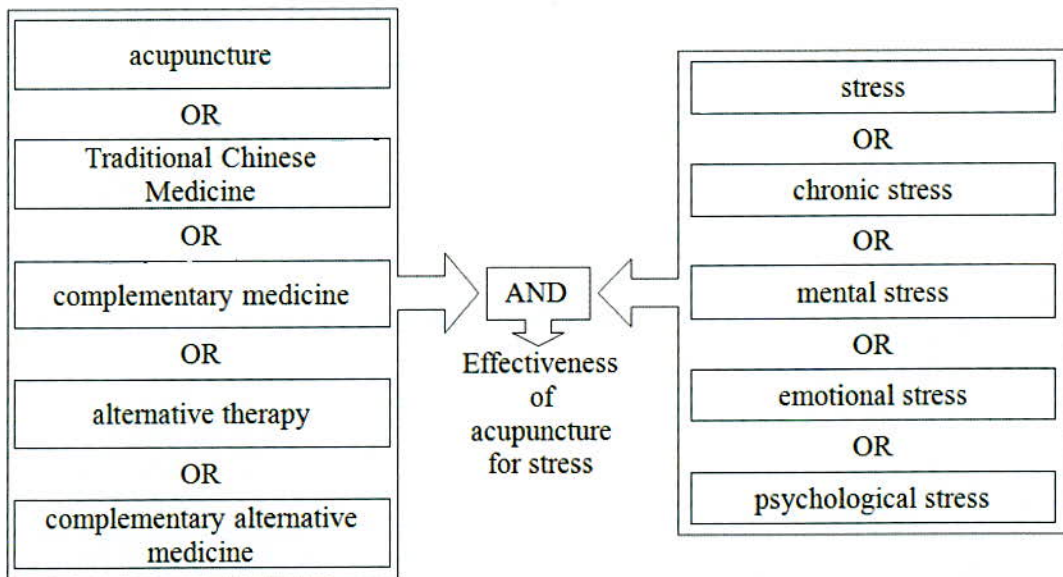
with acupuncture for stress, “anxiety” was not used as a search item in the literature search on Ovid Online.

Chinese Medicine (CM) includes TCA and belongs to the mainstream medicine in China. There is a huge amount of experimental research, clinical studies and reports on CM and TCA. For example, 394,604 articles were identified on the CNKI in the search of “中医 or 针刺 or 针灸 and 应激” (CM or acupuncture or acupuncture-moxibustion and stress), and 394,743 articles were identified in the search of “中医 or 针刺 or 针灸 and 紧张” (CM or acupuncture or acupuncture-moxibustion and distressed (nervous)). Therefore in this systematic review the search terms on the CNKI did not include “中医” (CM) to decrease the number of articles.

5.1.3 Search strategies

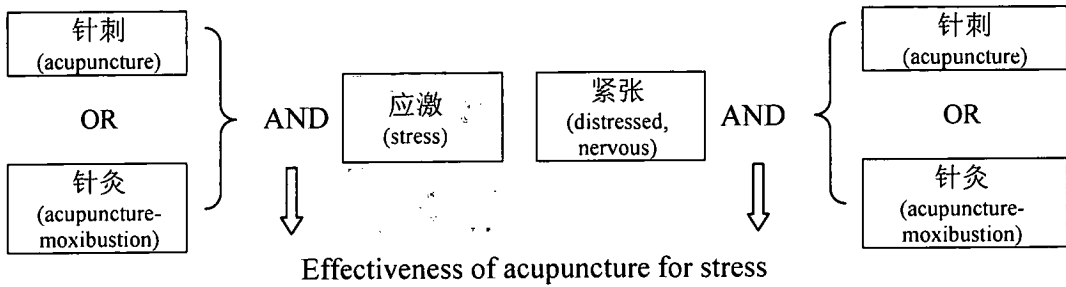
The Ovid Online search strategy is detailed in *Figure 5.1.3-1*.

Figure 5.1.3-1 Literature search strategy on Ovid Online



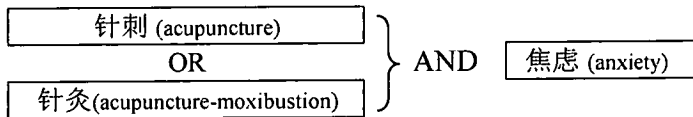
As the design of the databases on the CNKI is different from that on Ovid Online, a different search strategy was used on the CNKI and is given in *Figure 5.1.3-2*.

Figure 5.1.3-2 Literature search strategy on the CNKI



The alternative search strategy in the CNKI databases is shown in *Figure 5.1.3-3*.

Figure 5.1.3-3 Alternative literature search strategy on the CNKI



5.1.4 Filtering

The inclusion of articles was based on the abstract’s title, contents and indexing term. The full text articles were retrieved if they met the inclusion criteria. All abstracts were in English or Chinese. “Potential” research papers were noted for retrieval and given a preliminary “study type” classification as systematic reviews, randomized controlled trials (RCTs), uncontrolled studies, case reports, qualitative research and surveys. The research into specific illnesses induced by stress, and animal and basic laboratory-based studies were not included in the review. Note, studies were not included if their abstract provided insufficient details and their full text could not be retrieved. No language restrictions were imposed during the filtering stages of the search.

5.1.5 Inclusion criteria

The types of study selected on Ovid Online included RCTs, controlled trials (CTs), and uncontrolled trials (UCTs). UCTs were included in order to provide further information concerning the effectiveness of acupuncture for symptoms of stress and the interventions used. Given that few RCTs were identified in the search. Only RCTs were included on the CNKI in both searches with the main search strategy and the alternative search strategy to reduce the amount of research articles.

Attempts were also made to locate relevant systematic reviews. Case studies and clinical reports were not included.

“Stress” was the key search term. The research covered emotional stress, mental health, psychological problems, and sports medicine. Stress may also include: chronic psychological stress which due to work or everyday life; or may have been caused by negatively perceiving life events; or induced by a special problem, such as an illness; or situational stress could result from situational stressors, e.g. stress test, competition, exercise, operation etc. Articles included in the review had to centre on stress. If the conditions or illnesses were induced by stress, the articles were excluded. For example, the study carried out by Jambrik et al. (2004) to investigate the effectiveness of traditional acupuncture for the endothelial dysfunction induced by mental stress was not included. The reports on Post Traumatic Stress Disorder (PTSD) were not included as it is a severe and ongoing emotional reaction to an extreme psychological trauma (Satcher et al., 1999).

In China, there is a clear diagnosis for “焦虑 (jiao lü)” (anxiety) including generalized anxiety disorder (GAD). In the west, stress is a different concept to either anxiety or GAD. In China people with “应激 (ying ji)” (stress) in clinical practice include those with “焦虑 (jiao lü)” (anxiety). Reports on GAD were included in the search on the CNKI but they had to be RCTs.

Articles were selected when they mentioned that the symptoms were caused by psychological stress. For example, Wang and Kain’s research (2001) used auricular acupuncture for anxiety. Subjects consisted of staff members from a hospital operating room – an operation can generate a considerable amount of stress. Therefore such papers concerning situational anxiety were included.

Articles on acupuncture included whole body acupuncture, electro-acupuncture or auricular acupuncture. If the result of the research is about the effectiveness of the

combination of acupuncture and another therapy, it was not included in the review. For example, a study of acupuncture and moxibustion used to reduce stress (Toyama et al., 1982), and a research into the effectiveness of combined electro-auricular-acupuncture and enflurane anaesthesia for patients undergoing abdominal or vaginal surgery (Stellpflug et al., 1979). The trial was included if the independent and specific result of acupuncture was shown though that trial was about the combination of acupuncture and another therapy, e.g. Liu et al. (1998). Acupressure (Fassoulaki et al., 2003) and transcutaneous electric stimulation (Schwartz, 1998) were not included.

Outcome measures used in the included studies had to be valid and clearly described. The article was not included if its outcome measure only used an overall subjective assessment of effectiveness based on symptoms and identified by the researcher, practitioner or doctor, which could be biased.

5.1.6 Data collection and analysis

The data extracted included: study design, the participants, the intervention and any comparison or control intervention, details of acupuncture, outcome measures, results, and conclusion. The quality of the trials, and the design and contents of the studies are assessed and discussed in *5.2 Results* and *5.3 Discussion*.

5.2 Results

5.2.1 Search history

A total of 1496 articles on Ovid Online and 1650 articles on the CKNI were identified. The majority of the articles were laboratory experiments on animals, or addressed stress related to an ongoing medical, physical or psychological condition (other than stress which was the focus of this project and met the inclusion criteria (see *5.1.5 Inclusion criteria*)), or were not clinical trials of effectiveness, or were not detailed abstracts, or those studies where the full text could not be retrieved (e.g. Bennett (1997), Ericolani et al. (1997), Bagirov (1991), and Galoic-Krleza (1991)). There were 15 articles identified on Ovid Online and 2 articles on the CKNI which were included.

The details of the results of search history in both databases with the main search strategy are shown in *Table 5.2.1-1*.

Table 5.2.1-1 Search history

	Ovid Online	CNKI	
Total identified articles	1496	“针刺”or“针灸”and“应激” (acupuncture or acupuncture-moxibustion and stress)	“针刺”or“针灸”and“紧张” (acupuncture or acupuncture-moxibustion and distressed (nervous))
		603	1047
Included articles	17	2	

As only 2 articles were found in the search on the CKNI with the main search strategy, the alternative search strategy was carried out. The result of the search history with the alternative search strategy is given in *Table 5.2.1-2*.

Table 5.2.1-2 Alternative search history

	CNKI
Total identified articles	“针刺”or“针灸”and“焦虑” (acupuncture or acupuncture-moxibustion and anxiety)
	349
Exclude articles	9
Included articles	3

The full text versions of 12 potential trials of acupuncture in “焦虑 (jiao lü)” (anxiety) were retrieved for further analysis resulting in the exclusion of another 9 studies. The reasons for excluding the studies were as follows:

- 5 studies did not have control groups (Lu, 2004; Guo and Nie, 2002; Hai et al., 2002; Jia and Zhao, 2002; Qiao, 2001);
- 2 trials only had improvement rates subjectively assessed by doctors (Lian & Lei, 2001; Liu et al., 1998);
- an article (Wang et al., 2003) reproduced in 2 different journals;
- one study combined with breathing technique and intradermal needle therapy (Fu, 2006).

In total, three articles were identified in the alternative search on the CNKI.

5.2.2 Data for the search

The studies varied greatly in terms of treatment modality, study sample and trial methodology. The key data for each trial is summarized in *Table 5.2.2-1, 2, & 3.*

Table 5.2.2-1 Clinical trials of acupuncture for chronic stress

Study	Design	Stressor	Treatment*	Control	Outcome measures	Results	Conclusion
Chan et al. (2002)	UCT 17 healthy staff in hospice	Work	Acup. weekly for 4 wks; HT7	No control	EPDS	The greatest fall in the EPDS scores was observed within the first 2 treatments. At the end of study, there was an average reduction of 44% in the EPDS scores	Further research is needed
Sandberg et al. (2002)	RCT 30 post-menopausal women 12 weekly with follow-ups at 3 and 6 months	Meno-pause	EA BL15, BL23, BL32, SP6, SP9, LR3, HT3, PC6, DU20	SNI	General psychological well-being mood and experience of climacteric symptoms	Mood scale improved only in EA group, mood was sign. better. No sign. difference on climacteric symptoms or well-being existed between the gps	EA is no better than SNI for the amelioration of general psychological distress and experience of climacteric symptoms. EA might had additional effects on mood
Wang & Kam (2001)	RCT 55 staff in operation room Acup. once.	Work stress	AA 1) shenmen (n=22); 2) relaxation point (superior lateral wall of the triangular fossa) (n=15).	3) Sham acup. at acupoint on the middle ear (n=18)	STAI, the life experiences survey, BP, HR, electrodermal activity	People in relaxation point group sign. less anxious than those in shenmen and sham groups at the 30mins and 24-hours intervals, and remained less anxious than patients in shenmen group 48 hrs after treatment began.	While treatment did not produce any sign. physiological changes, subjects who received acup. did experience a profound change in their behavioural anxiety levels.
Garvey et al. (1997)	RCT 12 subjects self-reported stress	Every day life	TCA 4 weekly	Sham; non-acup.	GHQ, the diastolic and systolic blood pressure	The difference with GHQ between the treatment and sham group was not statistically sign. The improvement of blood pressure for the treatment gp is greater than for the sham gp.	The most sign. change in stress indicator was in terms of just three of the measures undertaken.
Romoli and Giommi (1993)	CT N=70 Acupoints examined by a metal-tip spring probe.	Everyday life	AA 4 weekly (50 patients with possible psychosomatic disorders of the cardiovascular, respiratory and digestive systems)	Same AA given to 20 symptom-less volunteers	MMPI test, Paykel's scale for stressful life events, SRT	Similar trend of response to acup. in both groups, significantly more pronounced in the stress group for the reduction of the SRT score and the number of EA points.	The outer ear was sensitized by stress response in certain recurrent areas, especially of the cavum conchae. The area with the highest relative density of ear acupoints was the Sanjiao area

*: unknown the acupoints used if there is no acupoints given in the table.

Abbreviations: AA=auricular acupuncture, acup.=acupuncture, BADI=Bennett's affective dissonance inventory, EPDS=Edinburgh Postnatal Depression Scale, GHQ= The General Health Questionnaire, gp=group, MMPI=Minnesota Multiphasic Personality Inventory, RCT=randomized control trial, sign.=significantly, SNI=superficially inserted needles, SRT= Symptom Rating Test, STAI=state-trait anxiety inventory scale, TCA=Traditional Chinese Acupuncture, UCT=uncontrolled trial, wk=week.

Table 5.2.2-2 Clinical trials of acupuncture for situational stress

Study	Design	Stressor	Treatment	Control	Outcome measures	Results	Conclusion
Ogata et al. (2005)	CT Unknown recruitment and sampling 25 healthy volunteers	Mental arithmetic	EA after the test; 1)EA at ST36, SP6 (n=11); 2)EA at LI4, PC4 (n=14).	Non-acup.	Rate of sweating on the palm or the sole	5 Hz on ST36 causes paSR, Fsw and paSR.Fsw reduced, whereas on LI4 pISR and Fsw reduced, but pISR.Fsw was not altered; 100 Hz on ST36 paSR and paSR.Fsw reduced, but Fsw unchanged whereas on LI4 neither pISR, Fsw nor pISR.Fsw altered.	Acup. at 5 Hz and as 100 Hz may reduce mental stress-induced sweating through different mechanisms.
Li et al. (2004)	RCT 17 healthy adults	bicycle exercise test	EA at PC 5 & 6 or LI 4 & 7 30 min before exercise (n=12)	EA at GB 37 & 39 30 min before exercise (n=5)	SBP, DBP, MBP, HR, RPP, and ECG	EA led to an increase in maximal workload, and reduced peak SBP, MBP and RPP. responses to exercise; EA did not alter DBP or HR responses. Control did not alter the hemodynamic responses.	EA at specific acupoints improves exercise capacity and reduces the hemodynamic responses in approximately 70% of normal subjects.
Middlekuff et al. (2004)	UCT 38 healthy humans	Handgrip exercise; Cold presser test	Acup. after the test; PC6, LR3, LI4.	No control	BP, HR	Acup. did not attenuate the increase in BP or HR	Acup. does not attenuate the BP or HR responses during handgrip exercise or the cold presser test in normal healthy humans
Wang et al. (2004)	RCT 67 pairs mothers / children Intervention : 30 mins before surgery	Children about to undergo surgery	AA at relaxation, tranquilizer point, and master cerebral point (n=34)	AA at sham points (shoulder, wrist, and extraneous) (n=33)	STAI Physiological measures (mother); MYPAS (child)	Acup.: lower maternal anxiety (p<0.01), lower children anxiety (p<0.05). BP & HT: NS	Children of mothers who underwent acup. benefitted from the reduction of maternal anxiety during the induction of anesthesia.
Xu et al. (2004)	RCT 60 stressed armed policemen	Anti-terrorism manoeuvre	Gp.1 n=30 daily 2 weeks. PC6, ST36	Non-acup. Gp.2 30 stressed policemen Gp.3 30 unstressed policemen	SDS, SAS	Scores of SDS and SAS in gp.1 were lower than other 2 gps (p<0.01).	Acup. can improve the psychological state.
Zhao et al. (2004) (Chinese)	RCT 80 officers and soldiers in the army	exercise	Acup. at xiongtong point and jiantong point. Once per day after exercise for 2 weeks. (n=40)	No-acup. (n=40)	POMS, RT, CFF, GLU, LDH, CPK, hemoglobin, blood lactic acid.	All outcome measures improved sign. post acup. control gp outcomes worse than baseline.	Acup. can reflectively induce the central nerves to transform towards stress state, plays the role of regulating and improving fatigue of the organism.
Akimoto et al. (2003)	RCT 21 female soccer players	Competitions	Acup. before and during the competition; LI4, ST36, ST6, LU6. (n=9)	Non-acup. (n=12)	Salivary SigA, salivary cortisol, rating of physical well-being, profile of mood states (POMS)	The decrease of SigA and increase of cortisol were inhibited by acupuncture; Acup. improved subjective rating of muscle tension and fatigue; the POMS score was modulated by acupuncture.	Acup. is effective for physical and mental well-being of athletes.
Middlekuff et al. (2002)	RCT 15 chronic heart failure patients into 2 of 3 groups	Acute mental stress test before and during acup. and control	Acup. (n=10) LI4(R), LR3(R), PC6 (L).	Non-acupoint acup. (n=10); no-needle acup. (n=10)	MSNA, BP, HR	Acup. eliminated the increase of MSNA induced by mental stress, did not attenuate the change in BP and HR	Acute acup. attenuates sympathoexcitation during mental stress in advanced heart failure patients

Middlekuff et al. (2001)	Single-blind, CT with 3 parallel arms. 19 healthy volunteers	Colour Word Test or Mental Arithmetic	Acup. after the test; LI4 (R), LR3 (R), SP6 (L)	Non-acupoint acup.; no-needle acup.	MSNA, BP, HR	Acupuncture had no effect on resting MSNA, BP or HR. Acupuncture and needling nonacupoints blunted the similar increase in mean arterial pressure during mental stress	Acupuncture does not modulate baseline MSNA or MSNA responses to mental stress in normal humans. Acupuncture and needling nonacupoints have a similar effect on BP
Wang et al. (2001)	RCT 90 elective ambulatory surgery patients	operation	1. AA at TCA points (kidney, heart, Shenmen) (n=31) 2. AA at 3 relaxation points as above (n=32)	3. AA at three points unrelated to anxiety (finger, shoulder, extraneous points) (n=27)	STAI	Relaxation group less anxious than control (P<0.05). TCM group NS	AA decreases preoperative anxiety in patients undergoing elective ambulatory procedures.
Stellon & Palmer (1999)	CT, non-randomised 206 outpatients undergoing OGD	Gastro-intestinal endoscopy	Acup. prior to and then throughout the endoscopic procedure; LI4, PC6, ST9, DU23, DU24.	With intravenous diazepam; no any treatment	Direct observation by the attending nurse, self-report questionnaire	Respiratory complications were least in acupuncture group and there was some evidence of benefit from acupuncture relieving emotional distress	Acup. as an alternative to diazepam sedation for diagnostic gastrointestinal endoscopy
Apchel (1996)	CT 24 aqualung swimmers	exercise	3 gps: calm, relatively calm and anxious (n=8 / gp.) 2 groups of points alternated every other day in 1 week. LI4, ST36, DU20, PC6, HT7, DU20.		Self-appraise questionnaire, Spielberger-Khanin's scale, SVM, CFLF, LSR, static tremor, RMO, HR, BP, epimephrine, norepinephrine in the urine.	The effect was higher in the calm group and lower in the anxious group. In subjects placed under extreme conditions, the antistressor effect of acup. was stronger when their in initial state was anxious.	The antistressor effect of acupuncture strongly depended on the initial functional state of the subject. Acupuncture can be differentially prescribed as a means of correction of stress
Uskok et al. (1995)	RCT 40 patients, undergoing gynaecological surgery	operation	PC6, auricular Shenmen, Jarricot's anti-anxiety points (n=20) 30mins before operation	Diazepam 10mg (n=20)	SATI prolactinemia, cortisololemia and hemodynamic parameters	Acup. more effective (P<0.001)	Both hemodynamic and neurohormonal trends "showed their validity", but acup. was more effective in relieving anxiety
Zhang et al. (1991) (Chinese)	UCT N=43 12 boxers; 31 University students.	Competition; Exercise stress test.	Acup. PC6, ST36. After competition or exercise.	No control. Pre & post study.	Echocardiography	HR, SV, SV LVE, LV mV _{o2} , COI, ESV sign. improved pre & post acup.	Acup. at PC6 can accelerate the recovery of heart from stress.

Abbreviations: AA=auricular acupuncture, acup.=acupuncture, BP=blood pressure, CFLF=flicker fusion frequency, CFLF=the critical frequency of light flashes, COI=Conflict of Interest, CPK=creatine phosphokinase, CT=control trial, DBP=diastolic, EA=electro-acupuncture, ESV=end-systolic volume, Fsw=rate of sweat expulsion, GLU=glutamic acid, gp=group, HR=heart rate, L=left, LDH=lactic dehydrogenase, LSR=the latency of a simple sensorimotor reaction, LVE=left ventricular enlargement, MBP=mean blood pressures, MSNA= muscle sympathetic nerve activity, MYPAS = Modified Yale Preoperative Anxiety Scale, NS=nonsignificant, OGD=oesophago-gastro-duodenoscopy, paSR= palmar sweat rate, plSR=plantar swear rate, POMS= Profile of Mood States, R=right, RCT=randomized control trial, RMO=reaction on moving object, RPP=the rate-pressure product, RT=simple response time, SAS=self-rating anxiety scale, SBP=Brachial systolic, sign.=significantly, SDS=self-rating depression scales, STAI=state-trait anxiety inventory scale, SV=stroke volume, SVM=the capacity of short-term visual memory, UCT=uncontrolled trial.

Table 5.2.2-3 Clinical trials of acupuncture for “焦虑 (jiao lü)” (anxiety) in the CNKI

Study	Design *	Treatment	Control	Outcome measures	Results	Conclusion
Liu et al. (2007)	RCT N=86	6 daily acup. per wk for 6wks. EX-HN1, PC6, HT7, SP6, dingshen.	Group A: western medicine (n=29); Group C: combined acup. and western medicine (n=28)	HAMA, SAS, CGI, TESS	Therapeutic effect between 3 groups NS, but the efficacy index was higher in acup. gps and gp C than group A ($P < 0.01$). The differences of TESS between 3 groups in different time ($P < 0.01$), and the scores were lowest in acup. gp and lower in gp C.	Acupuncture has a significant effect for anxiety with fewer side effects.
Wang et al. (2005)	RCT N=65	Once per day for 30 sessions. EX-HN3, DU20, PC6, HT7, RN17, SP6	Western medicine (n=30)	Improvement rate: (clinical symptoms, SAS)	Both gps pre & post treatment $p < 0.01$. Acup. gp 34.3% recovered, 94.3% generally improved; control gp 26.7% recovered, generally improved 83.3% (NS).	Acupuncture has the same effects as the western medicine.
Wang et al. (2003)	RCT N=62	EA daily on weekdays, for 6wks. EX-HN3, DU20, GB5, GB20	Take trazodone 100mg-150mg/d (n=32)	HAMA, SAS, SDS	Effective rate: EA 66%, trazodone 59% ($p > 0.05$)	EA was more effective and quicker than trazodone without side effects.

*: Stressor was not mentioned in all articles. All subjects were the patients in the hospital.
Abbreviations: acup.=acupuncture, CGI=Clinical Global Impression Improvement Ratings, d=day, EA=electro-acupuncture, gp=group, HAMA=Hamilton Anxiety Scale, m=month, NS=nonsignificant, SAS=self-rating anxiety scale, SDS=Self-Rating Depression Scale, TESS=Treatment Emergent Symptom Scale, wk=week, yr=year,

All 22 trials were quantitative in nature. There were no qualitative studies. No systematic review relating to acupuncture for reducing stress levels in adults was found. The results are given in *Table 5.2.2-4*.

Table 5.2.2-4: Results of literature search

	Stress		“焦虑” (anxiety) in the CNKI	Total
	Chronic stress	Situational stress		
RCT	3	8	3	14
CT	1	4	0	5
UCT	1	2	0	3
Total	5	14	3	22
EA	1	2	1	4
Manual body acupuncture	2	10	2	14
AA	2	2	0	4
Total	5	14	3	22

In total, there were 14 RCTs, 5 CTs, and 3 UCTs. One trial which had a control group failed to indicate the recruitment and sampling (Ogata et al., 2005).

Of the 22 trials, 5 studies investigated chronic stress, 14 situational stress, and 3 were identified from the search in acupuncture for “焦虑 (jiao lü)” (anxiety) on the CNKI.

Of the 5 studies concerned with chronic stress, 2 articles reported stress induced as a result of stressful work in a hospital (Chan et al., 2002; Wong & Kain, 2001); 1 research study investigated stress associated with everyday life (Garvey et al. 1997); and 2 studies explored chronic stress induced by specific problems, e.g. menopause (Sandberg et al., 2002) and cardiovascular (Romoli et al., 1993),

For the 14 articles concerned with situational stress, 4 used stress tests, e.g. mental arithmetic (Ogata et al., 2005; Middlekauff et al., 2001), handgrip exercise and cold presser test (Middlekauff et al., 2004), mental stress test (Middlekauff et al., 2002), and colour word test (Middlekauff et al., 2001). The stressors in the other articles were as follows: operations for endoscopy (Wang et al., 2004 & 2001; Stellon & Palmerl, 1999; Uskok et al., 1995); exercises or manoeuvre (Li et al., 2004; Xu et al., 2004; Zhao et al., 2004; Apchel, 1996); and competition (Akimoto et al., 2003; Zhang et al., 1991).

Various acupuncture methods were employed in these studies: 14 studies used manual body acupuncture, 4 used electro-acupuncture, and 4 used auricular acupuncture.

There were variations in the number of acupuncture sessions given, session duration and type of acupuncture intervention and acupoints used.

The number of sessions of acupuncture given ranged from 1 to 36 sessions (see *Table 5.2.2-5 Sessions of the trials*). Of the 14 trials of situational stress, 12 trials investigated the immediate effectiveness after 1 session of acupuncture, 1 trial for 4 sessions, and 1 for 14 sessions. In the reports for chronic stress, there was 1 study into the immediate effectiveness after 1 session of acupuncture (Wang & Kain, 2001), 3 trials for 4 sessions, and 1 article for 12 sessions (Sandberg et al., 2002). For “焦虑 (jiao lü)”

(anxiety) on the CNKI, there were 2 articles, which both gave a total 30 treatment sessions per subject (Wang et al., 2005; Wang et al., 2003). One study provided 36 treatment sessions per subject with the schedule of 6 daily acupuncture treatments per week for 6 weeks, which was the longest intervention for all trials (Liu et al., 2007).

Table 5.2.2-5 Sessions of the trials

	1 session	4 sessions	12 sessions	14 sessions	30 sessions	36 sessions
Chronic stress	1	3	1			
Situational stress	12	1		1		
“焦虑” (anxiety) in the CNKI					2	1

Studies were heterogeneous in that the frequency of the intervention varied depending on the study design (i.e. experimental or clinical) and the treatment period (i.e. a single treatment, daily or weekly). The trials on the CNKI were more likely to provide daily treatment in the case of “焦虑 (jiao lü)” (anxiety) studies.

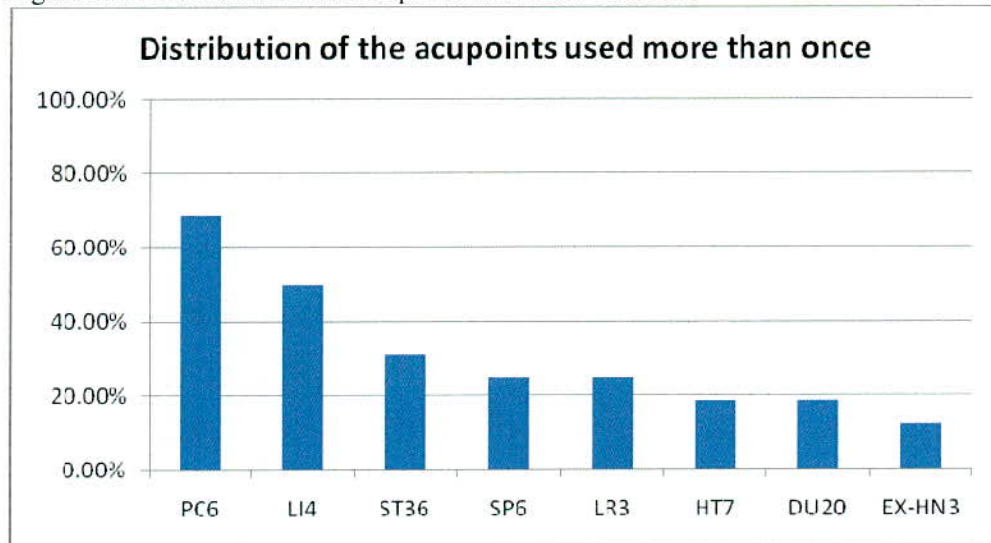
In the 18 articles where whole body acupuncture was used as the intervention, one study used an individual traditional acupuncture prescription (Garvey et al., 1997) but did not mention the individual identification of patterns and acupoints selected, and 1 study used non-traditional acupoints (Zhao et al., 2004) according to the balance acupuncture theory. This is a new form of acupuncture treatment used by this particular research group and not common in clinical practice.

Totally 16 trials used traditional acupoints which were clarified in the articles. *Figure 5.2.2* shows the distribution of the acupoints used more than once in those 16 trials.

PC6 was used in 11 studies, 68.75% of 16 articles which used traditional acupoints; LI4 was used 8 times (50.00%); ST36 was 5 times; SP6 and LR3 were used 4 times; HT7 and DU20 were used 3 times, and EX-HN3 was used twice. Apart from those acupoints, LU6 (孔最, Kongzui), LU7 (列缺, Lieque), LI7 (温溜, Wenliu), ST6 (颊车,

Jiache), ST9 (人迎, Renying), SP9 (阴陵泉, Yinlingquan), HT3 (少海, Shaohai), PC4 (邻门, Ximen), PC5, GB5 (悬颅, Xuanlu), GB20 (风池, Fengchi), RN17, RN23 (廉泉, Lianquan), RN24 (承浆, Chengjiang) was used only once. RN23, RN24 and ST9 were used during the procedure for diagnostic upper gastrointestinal endoscopy as local acupoints (Stellon et al., 1999).

Figure 5.2.2 Distribution of the acupoints used more than once*



*: the order of the acupoints follows the 12 regular meridians' circulative order.

In all 18 articles of body acupuncture, only one study used a single acupoint -- HT7 (Chan et al., 2002). All other studies used more than one point.

For 4 studies of auricular acupuncture for stress, 3 reports were from the same researchers, Wang and his colleagues. They investigated the different effects of auricular acupuncture for stress in different subjects comparing relaxation points, traditional auricular acupoints and sham points (Wang & Kain, 2001), relaxation points and sham points (Wang et al., 2004), relaxation points and traditional points using a TCA prescription (Wang et al., 2001). The results demonstrated that the relaxation points used were more effective in relieving anxiety and participants remained less anxious longer. One study (Romoli et al., 1993) revealed that the same auricular acupuncture points had a significantly more pronounced trend for the reduction of the

Symptom Rating Test Score in the group of participants with stress symptoms compared to the participants who had no symptoms.

5.3 Discussion

This is the first comprehensive review that has specifically investigated the use of acupuncture for stress. Twenty two studies of acupuncture for stress were identified, 14 RCTs, 5 CTs, and 3 UCTs; 5 of chronic stress, 14 of situational stress, and 3 of “焦虑 (jiao lü)” (anxiety) from the CNKI.

There were further reports of stress induced by an experimental condition, e.g. stress test, competition, or exercise. This is an artificially induced situation which was more easily controlled in the laboratory but may not reflect what happens in either clinical practice or in situations where subjects are unclear chronic stress.

The studies included in the review were highly diverse in terms of methodology, treatment modalities and other characteristics. Broadly they fell into 2 categories: firstly to investigate whether acupuncture can affect stress levels and secondly to reveal how it works. In order to investigate those 2 aims, different studies used different outcome measures, which included psychological, biochemical, and physiological outcome measures. There were 4 reports which combined psychometric and physiological measures (Zhao et al., 2004; Wang et al., 2004; Wang & Kain, 2001; Garvey et al., 1997), and 2 combined psychometric and biochemical measures (Akimoto et al., 2003; Uskok et al., 1995). Those studies suggest that the combination of different types of outcome measures was helpful to comprehensively investigate the results of acupuncture for stress. The psychometric measure could investigate the changes of participant's symptoms and collect subjective information, while biochemical and physiological measures could provide objective data and at the same time could reveal the mechanism of acupuncture used to treat stress.

Cortisol has been used as a measure of stress in research (see 3.2.4 *The diurnal profile of salivary cortisol concentration*). There were 2 articles retrieved which used cortisol

as a measurement. These studies investigated the difference in cortisol concentration before and after acupuncture. For example, Akimomo et al. (2003)'s research showed an increase of salivary cortisol inhibited by acupuncture. In Uskok et al. (1995)'s report, the trend of using serum cortisol "showed its validity" which suggested that it was a useful outcome measure. So far there is no research into acupuncture on diurnal salivary cortisol profile in stressed people.

Stress can affect all of the body's systems and results in different individual symptoms. The complexity of stress therefore makes research difficult. In 22 identified studies, only one trial used individualised TCA treatment (Garvey et al., 1997), but it failed to mention the individual identification of patterns and acupoints selected. All other studies used either one single acupoint or the same group of acupoints for every participant, which were not changed during the study period. Seventeen trials related to acupuncture for the situational stress. They chose specific symptoms of stress or limited the research to exploring a specific condition. For example, Ogata et al. (2005)'s research showed that acupuncture could reduce mental stress-induced sweating, and Wang et al. (2004 & 2001) and Akimomo et al. (2003) found that acupuncture was helpful in relieving anxiety induced by stress. If the same conditions were used for all participants and the same stressors or / and focusing on a specific symptom of stress, this may reduce the effects of individual differences. However, individuals will react differently to stress. It may be inappropriate to ignore the individual differences in the research into stress. Research into using acupuncture for stress must consider individual identification of patterns according to CM theory and individual treatment should be carried out. Analysis of such research can provide information to guide clinical practice.

Although research on the effect of stress on animals was not the specific focus of this project, studies on animal models yield more encouraging results (see *4.3.3 Research into Chinese Medicine for stress*), most only researched into one acupoint, and trial methodology was totally different. Animal models in laboratory experiments are more easily controlled and can be standardised, and especially are good for the study of

stress which could be affected by many reasons. It also is useful to explore the genetic effects for stress, as human study groups are not genetically identical as the way animal models are, so the genetic polymorphisms natural in any population make interpretation of data so much harder. Animal tests are restricted by budget, laboratory equipment, policy, and animal rights. Animal research may not be generalisable to human. Thus some human studies have not given the same results as animal models. For example, Middlekauff et al. (2001, 2002 & 2004) found that acupuncture did not affect blood pressure (BP), heart rate (HR) and muscle sympathetic nerve activity (MSNA), which was opposite to the result of the animal model test (Li et al., 2001).

Generally most trials retrieved from the literature demonstrated a positive effect on the reduction of parameter associated with increased stress. It is difficult to interpret the findings of the studies because their heterogeneity, i.e. the range of interventions, different acupuncture techniques employed, and the acupoints used.

There were 5 studies which compared acupuncture and western medicine. Uskok et al. (1995) found that acupuncture before the operation was more significantly effective in relieving anxiety than Diazepam. Liu et al. (2007), Wang et al. (2005) and Stellon & Palmerl (1999)'s research showed that acupuncture had the same effects as the western medicine, but did not have side effects. Furthermore, Wang et al. (2003) revealed that acupuncture produced a quicker response than drugs.

In addition, some research showed that the effect of acupuncture seemed similar to sham acupuncture, i.e. needling non-acupoints (Middlekauff et al., 2001) or superficially inserting needles (Sandberg et al., 2002). It is difficult to draw meaningful conclusions using needling non-acupoints or superficially inserting needles as a control, since it is similar to sham transcutaneous electrical nerve stimulation (TENS) which is not an actual therapy, and can easily be distinguished from genuine acupuncture. Ter Riet et al. (1990, cited by White et al., 1999) described the use of sham TENS as a control for acupuncture as a "fatal mistake" in scientific terms. "Sham intervention" is discussed further in *10.1.1.1 Attention group*.

This search was carried out from the respective inception to the first week of April in 2008. Of 22 relevant papers, there have been 18 papers since 1997. It demonstrated that research into acupuncture on stress has become more popular during the last decade. This may be connected with widespread application for the use of acupuncture to reduce levels of stress in clinical practice.

There were only 2 articles identified on acupuncture for stress in human subjects which were found on the CKNI (Zhao et al., 2004; Zhang et al., 1991). Both investigated stress in specific situations (competition or exercise) rather than chronic stress. It is estimated that 80% of all illnesses are stress induced (Friedman et al., 2003). In clinical acupuncture practice many presenting illnesses are possibly stress induced, such as irritable bowel syndrome (IBS), stomach disorders, pain and menstrual problems. Cultural background may influence the individual's perception of stress, which has been discussed in *4.3 Chinese Medicine understanding of stress* and also see *5.1.2 Search terms*. In China, acupuncture clinical research concentrates on the different illnesses induced by stress and symptoms related to stress, and does not look at stress as a condition itself. Also there are a lot of animal laboratory experiments carried out to investigate the effectiveness of acupuncture for stress. Because TCA belongs to mainstream medicine in China, the government invests in the TCA research projects, and animal tests are more easily carried out than western countries.

The 3 studies of acupuncture for “焦虑 (jiao lü)” (anxiety) were carried out in the hospitals in China. The participants in the study were included because they had a clear diagnosis by the Chinese Classification of Mental Disorders - second revised edition (CCMD2-R) or Diagnostic and Statistical Manual of Mental Disorders - 4th Edition (DSM-IV). All control groups for the 3 studies took western medicines. This meant that the participants' symptoms were more serious than general chronic stress symptoms, and were given 30 or 36 treatment sessions, which are much longer than any of the other studies identified in this review.

The research identified that in China, acupuncture for “焦虑 (jiao lü)” (anxiety) was often combined with another therapy, e.g. psychotherapy (Cui, 1999; Liang, 1996), Chinese traditional medicine (Li et al., 2007; Zhang et al., 2006), auricular-plaster therapy (Zhang, 2000), the treatment with channel acupuncture plus oxygen (Guo and Jia, 2005), meditation (Li and W, 2007), moxibustion (Gao and Zou, 2006), systematic desensitization (Liu et al., 1998), western medicine (Zhou and Yang, 2003), and music (Zhang et al., 2002).

The Chinese studies identified showed that the treatment in China is quite different from the UK. For example, acupuncture and other therapies are offered by the hospitals in China. In China most acupuncturists are qualified medical doctors who can prescribe medications including western and traditional Chinese medicine. Longitudinal research with a larger number of patients or / and in combination with other treatments is more easily carried out. In the UK, integrated practice is limited, as is research. The findings from Chinese studies provide some new ideas for future research and clinical practice in western countries.

5.4 Conclusion

In conclusion, the studies in this review into acupuncture for stress were heterogeneous, and there is currently insufficient evidence from clinical research on acupuncture for the treatment of stress, especially for chronic stress, for firm conclusions to be drawn. However, there are promising results in the management of stress experimentally induced and some positive findings reported for chronic stress and “焦虑 (jiao lü)” (anxiety), which indicates that further large, well-controlled studies are required to demonstrate true effects.

The quality of future trials could be improved by utilizing the proposed standardised reporting of acupuncture studies, e.g. following Standards for Reporting Interventions in Controlled Trials of Acupuncture (STRICTA) (MacPherson et al., 2001). There are many reasons which could affect stress levels and the manifestation of its symptoms. In order to fully assess the effectiveness of acupuncture for stress, it is essential to identify

an appropriate method to measure stress. It is also important to control and limit the non-treatment effects. Considering the acupuncture treatment itself, future research should explore and clarify the treatment principles, methods of treatment, selection of acupoints for stress and its symptoms. According to CM theory, the identification of patterns could be included in research designs. This could be used to investigate whether individualised Chinese traditional treatment can enhance the effectiveness of acupuncture for treatment of stress and its related symptoms.

Chapter 6 Study Design and Methods

This chapter provides details of the study design and methods including: the study aim and hypotheses, outcome measures, recruitment of participants, study procedures and data analyses.

6.1 Introduction to the study design

6.1.1 The aim of the study

The aim of the study was to investigate whether Traditional Chinese Acupuncture (TCA) was effective in improving stress levels for adults experiencing symptoms of chronic stress. This was an exploratory study which included: a pilot randomised controlled trial (RCT), case study reports and focus groups. The aim of the pilot was to inform the design of a future RCT and contribute to the evidence base.

6.1.2 The hypotheses of the study

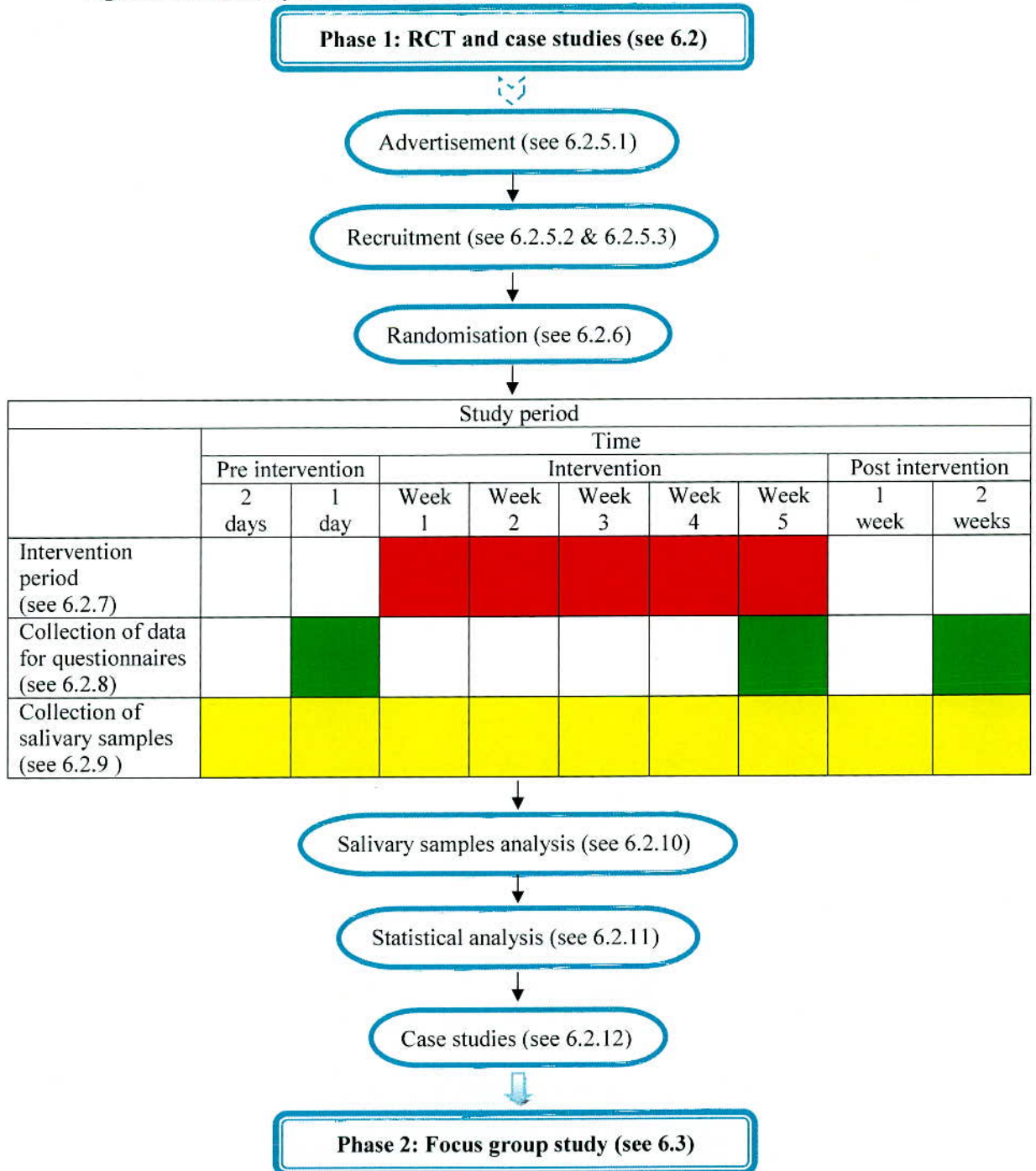
The hypotheses of this study were that:

1. TCA would demonstrate the improvement of perceived stress and its symptoms after 5 sessions of treatment.
2. TCA would help to normalise the diurnal salivary cortisol profile of adults experiencing chronic stress.
3. TCA would provide improved outcomes compared with controls.

6.1.3 Summary outline of the methods

The methods used in the study are given in *Figure 6.1.3*. This figure illustrates the study's time frame and clarifies the study design. Phase 1 consisted of the RCT and individual case studies; phase 2 consisted of a focus group study. The case study reports and focus groups study were based on the participants recruited to the RCT.

Figure 6.1.3 Summary outline of the methods



6.1.4 Rationale for the study design

A three armed pilot RCT was employed to explore the feasibility of using TCA to reduce stress. Case study reports were used to explore individual differences before, during and after the intervention period. The focus groups study gathered qualitative information on the participants' experience of the intervention and collected information concerning the acceptability of the research process.

6.1.4.1 The randomised controlled trial (RCT)

This study focused on the use of TCA for the reduction of stress and its symptoms and the individual's perception of stress. TCA is a package of care which includes the Chinese Medicine's diagnostic procedure and not just the process of penetrating needling (Verhoef et al., 2004). Non-specific or potential placebo effects may operate in acupuncture therapy and have been identified in various studies (Elden et al., 2005; Linde et al., 2005; Pariente et al., 2005; Usichenko et al., 2005; White et al., 2004; Millman 1977). Given the need to control for nonspecific / placebo effects, a three armed study was employed consisting of: a TCA group, an attention group, and a control group. The attention group received the non-specific effects of relaxation, time out and practitioner attention (also received by the TCA group), but not the TCA specific treatment (see 6.2.7.2 *Attention group*). The control group had no intervention, therefore their outcomes were likely only to have been influenced by the Hawthorne effect. The Hawthorne effect (Landsberger, 1958) describes the frequently observed changes in non-intervention control groups. The participants in the control group were aware that they were involved in a research study and as a result, they may have changed their behaviour or life style, which may subsequently have affected outcomes.

This study design allowed a more in-depth investigation of the total package of the TCA intervention, with a comparison of TCA to attention indicating the role of the specific TCA effects, a comparison of attention to control indicating the role of the non-specific effects, and a comparison of TCA to control indicating the effects of the total TCA package.

There were three main study periods for each group (pre intervention, during the 5 week intervention period, and 2 weeks post intervention). The pre intervention measurements provided baseline data. The 2 weeks post intervention period provided an opportunity to see if any effects of TCA were sustained.

Decisions determining the number of treatments and frequency required for successful outcome are problematic (Birch, 2004; Lewith et al., 2002). In China neurasthenia, a condition which has symptoms similar to that of stress is treated once every other day (Qiu and Chen, 1992). One course generally lasts 10 sessions. After 1 course of treatment, the treatment stops for 1 week to see if the symptoms are resolved. If not, another course of treatment would be provided. In the UK, acupuncture treatment is not covered by the NHS and is expensive for most people. People in the UK cannot afford to take acupuncture for this kind of problem as frequently as in China. According to the researcher's clinical experience and understanding, most private acupuncture treatment in the UK is taken once a week. In order to ensure the research study reflected practice in the UK, and also because of the limited time and budget, a weekly intervention over a 5 week period was decided.

6.1.4.2 The case study reports

Case study approaches have been used in different disciplines, e.g. social science, medicine, and criminology. These models give far more emphasis to the "objective" observer, studying "the case" (Stark and Torrance, 2005). Yin (1994) believes there are three types of case studies – exploratory case studies, descriptive case studies, and explanatory case studies. The strength of using a case study is that it can take an example of an activity – "an instance in action" – and "use multiple methods and data sources to explore it and interrogate it" (Walker, 1993). Thus it can achieve a "rich description" of the situation and explore it from the participants' perspective (Geertz, 1973).

The use of case reports have been an important part of medicine in both the West and the East (Ferrigno et al., 2006). In Chinese medicine, case studies or case reports have been retained as a long and continuous tradition ever since *the Yellow Emperor's Canon of Internal Medicine* («黄帝内经», Huang Di Nei Jing or Nei Ching) which was written 2000 years ago. Throughout the history of Chinese medicine, many of the books have included case studies or case reports. This was partly because that these books were written before the use of western medicine and development of RCT methodology. Another main reason is that Chinese medicine theory is different from western medicine theory and it is difficult to apply western medical methodology to Chinese medicine practice and research. As Farquhar (1987) noted, in China, practitioners continue to learn from the documented clinical experiences of notable physicians and the “oral transmission” of clinical experience and insight. How case studies and practitioner engagement in therapeutic interventions are described and accounted for, offers insights into Chinese medical ways of knowing and transmitting knowledge. Within the domain of Chinese medicine, the role of case studies is critical in developing theory, improving practice and disseminating knowledge.

This project was a small pilot study, and it would be difficult to carry out statistical analyses for the limited data and draw a conclusion from such a small sample size. It was therefore helpful and necessary to use a case study approach to look at the differences between the individuals in the 3 groups. Furthermore, the cases studies in this project included medical records which facilitated both the practice and the research process, at the same time explored objective and subjective responses of the participants and the researcher. Objective responses were measured using both qualitative and quantitative methods. Subjective response included the comments from the participants and the researcher.

6.1.4.3 The focus groups study

Focus groups were used to sample the range of participants' opinions through feedback and comments on the methods and process of the research project. For the intervention, the use of combined quantitative and qualitative methods offers a broad

insight into the effects of the treatment on both specific symptoms and the experience of having treatment.

As the clinical trial lasted over a long time period and participants attended the study at different times, focus groups were undertaken when most participants in the TCA and attention groups had recently finished the clinical trial to ensure that they were able to recall their experiences.

Data from the focus groups were subjected to content analysis. Themes and categories were identified which had emerged during the sessions and analysed (Robinson, 1999).

6.2 Study Phase 1: RCT and case studies

The RCT commenced in September 2005 and lasted approximately 39 weeks. This included the free treatment given to the participants allocated to the attention group and control group. The clinical study finished at the end of July 2006 (excluding the break for Christmas and the New Year). See *Appendix 8 Clinical timetable*.

6.2.1 Questionnaires and outcome measures

Three questionnaires were used in this study – Recent Life Events Questionnaire (RLE), the Perceived Stress Scale - 14 (PSS-14) and Measure Yourself Medical Outcome Profile (MYMOP) (see *Appendix 7 Questionnaires*). The primary outcome measures for the study were the PSS-14, the MYMOP and the diurnal profile of salivary cortisol concentration. For details of these methods see *3.2 Rationale for using measures of stress in this study*.

6.2.2 Settings

The TCA treatment and attention interventions took place at all campuses at Thames Valley University (TVU). The focus groups for the TCA and attention groups were held at the Centre for Complementary Healthcare and Integrated Medicine at TVU.

6.2.3 Inclusion / exclusion criteria

The participants recruited to the study needed to meet the following inclusion and exclusion criteria. The rationale for establishing inclusion and exclusion criteria is explained and discussed in *10.1.3 Criteria and screening questionnaires*.

Inclusion criteria:

1. be over 18 years old;
2. have greater scores of the PSS-14 than the population mean (>20);
3. be able to understand the information sheet, consent form, and any instructions about the study;
4. read and sign the informed consent form after the nature of the study had been fully explained;
5. be able to attend for treatment at the specified clinical times;
6. be able to complete the successive 5 weekly sessions of TCA or attention;
7. be able to comply with providing the salivary samples at the specified times and recording the exact time;

Exclusion criteria:

1. had serious or life-threatening medical conditions, for example, cancer, diabetes, polio, tuberculosis, epilepsy, HIV/AIDS or clinical psychoses;
2. were taking medication for psychological disorders or stress related symptoms;
3. were needle phobic;
4. were currently using any complementary therapies for stress;
5. had experienced a severe life event in last month (screened by the RLE);
6. were pregnant;
7. were planning to change the pattern of taking the contraceptive pill during 8 weeks of the study.

6.2.4 Ethics approval

Ethics approval for the research was sought and granted by the Research Review Committee of Thames Valley University in August 2005.

6.2.5 Recruitment

6.2.5.1 Initial approach

Advertising for study participants commenced in August 2005. Advertisements were put on the university intranet, broadcast mail, notice boards in every university building in Ealing and an organic food shop called “As Nature Intended” in Ealing. (See *Appendix 1 Advertisements for participants recruitment*). In the advertisement, the word “relaxation” was used instead of “attention only” to avoid the participants’ psychological bias.

When the researcher received replies to the advertisement, he emailed out the general information sheet to introduce the study and inform potential participants about the requirements of the study (see *Appendix 2 Research information for participants*). The people who thought they were eligible for the study were invited to contact the researcher who then arranged an interview.

All responses to the advertisements are shown in *Appendix 3 Response records*.

6.2.5.2 Interview

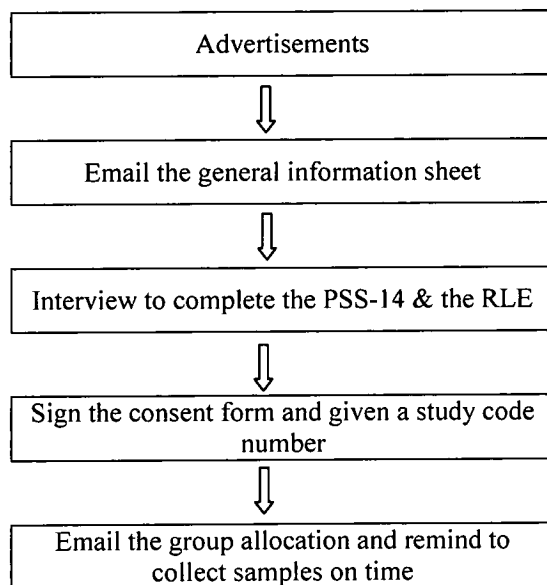
During the interview, the respondents were asked to complete both the PSS-14 and the RLE to make sure they satisfied the criteria. If the criteria were met, the person was asked to sign the consent form (see *Appendix 4 Consent form*) and was given a study code number to maintain their anonymity in the study. This code number was allocated sequentially. It replaced the participant’s name and appeared on all forms and questionnaires, so that participants’ details were kept confidential. No names were attached to written or machine readable schedules.

The participants were not told the result of randomisation and group allocation during the interview. They were informed that they would be offered 5 weeks of free TCA treatment after completing the full study if they were randomised to the control group.

The researcher was only aware of randomisation result of group allocation once he knew the participant's study code number. In order to avoid the researcher's bias and participants' preference for group allocation, the researcher only emailed participants the result of group allocation after the recruitment interview.

The participants in the attention group were not informed about the opportunity to have 5 weeks of free TCA treatment until they finished the whole study and provided all samples. *Figure 6.2.5* shows the recruitment process.

Figure 6.2.5 Recruitment process



6.2.5.3 Study participation

The study packs were prepared and contained the following:

- A re-sealable plastic bag with the study code number and the date of sampling, which was only used once.

- Four saliva sampling tubes which are called “salivettes” (Schwartz et al., 1998; Kirschbaum et al., 1992) provided by Sarstedt Ltd in Leicester, the UK. The researcher used a permanent marker on the salivettes to mark the participants’ study code numbers, dates and serial numbers identifying when they should collect their samples.
- A self seal single use freezer bag.
- The instructions for collecting saliva with the salivette (from Sarstedt Ltd) which informs how to use the salivette (see *Appendix 6.1*).
- The introduction and time-record sheet (see *Appendix 6.2*) on which was written the exact date when the participant had to provide samples (See *Figure 6.2.9-1 The dates of taking salivary cortisol samples* and *Figure 6.2.9-2 The time points of taking salivary cortisol samples per day*).

The contents of the study pack are given in *Table 6.2.5.3*.

Table 6.2.3.5 Contents of the study pack

Item	Number
re-sealable plastic bag	1
salivette	4
the self seal ice-cube bag	1
instructions for collecting saliva	1
the introduction and time-record sheet	1

At the recruitment interview, if the people met the criteria and were recruited in the study, they were given detailed verbal explanations of the procedure to follow during the study and were then given 2 study packs for the first 2 days’ samples which provided the baseline data for the study.

At the beginning of the study, the clinical sites were based in the health centre at St. Mary’s Road campus, TVU and Westel House, TVU. Ealing recruitment was slow and therefore, to widen the opportunities for other staff to take part, an additional clinical location was set up in the health unit in Slough campus, TVU in January 2006.

Because this study was carried out for successive 8 weeks, according to the time table, the recruitment interviews had to stop 8 weeks before the Christmas and the 2006 New Year break. They started again in January 2006.

Further information on the participants allocated to each of the 3 groups is given in *7.1 Screening of respondents recruited into the study* and *7.2 Demographic characteristics*.

After completing the study and providing the necessary salivary samples, the participants in the attention and control groups were offered 5 sessions of free acupuncture treatment.

6.2.6 Randomisation

Block randomisation was used to randomise 18 participants into the three groups – the TCA group, attention group and control group. The randomisation was carried out by an administrator in the Centre for Complementary Healthcare & Integrated Medicine at TVU on 30th April 2005 (see *Appendix 5 The result of the block randomisation*).

The participants received the results of the randomisation and their allocation through email after the recruitment interview and having received the study code number.

6.2.7 Intervention period

The intervention period lasted 5 weeks. The arrangement of the participants in each of the 3 groups is given in *Table 6.2.7-1* and *Figure 6.1.3 Summary outline of the methods*.

Table 6.2.7-1 Arrangement of the intervention period in each group

TCA group	Week 1	2	3	4	5	↔	Weekly TCA
Attention group	Week 1	2	3	4	5	↔	Weekly attention only
Control group	Week 1	2	3	4	5	↔	Do nothing

6.2.7.1 TCA group

As Table 6.2.7-1 shows, participants in the TCA group received weekly sessions of TCA for a period of 5 weeks. 25*0.25mm and 40*0.25mm Classic Plus sterile acupuncture needles were used, which were supplied by Harmony Medical. Acupuncture treatment was individualised, with diagnosis and treatment principles selected according to Chinese medicine theory (See *Chapter 4 Traditional Chinese Acupuncture (TCA) in the Treatment and Management of Stress*). The timing for the treatment procedure over the study period is given in Table 6.2.7-2.

Table 6.2.7-2 The timing for the procedures for the intervention in the TCA and attention group over the study period

	TCA Group		Attention Group	
	Time	Action	Time	Action
Week 1	5 minutes	Introduce acupuncture	5 minutes	Introduce relaxation
	10 minutes	General consultation according to CM*, collect samples and give salivettes	10 minutes	General consultation, collect samples and give salivettes
	15 minutes	Insert and take out needles	20 minutes	Lie down on the couch
	20 minutes	Lie down on the couch		
Week 2	10 minutes	General consultation according to CM, collect samples and give salivettes	10 minutes	General consultation, collect samples and give salivettes
	15 minutes	Insert and take out needles	20 minutes	Lie down on the couch
	20 minutes	Lie down on the couch		
Week 3	10 minutes	General consultation according to CM, collect samples and give salivettes	10 minutes	General consultation, collect samples and give salivettes
	15 minutes	Insert and take out needles	20 minutes	Lie down on the couch
	20 minutes	Lie down on the couch		
Week 4	10 minutes	General consultation according to CM, collect samples and give salivettes	10 minutes	General consultation, collect samples and give salivettes
	15 minutes	Insert and take out needles	20 minutes	Lie down on the couch
	20 minutes	Lie down on the couch		
Week 5	10 minutes	General consultation according to CM, collect samples and give salivettes	10 minutes	General consultation, collect samples and give salivettes
	15 minutes	Insert and take out needles	20 minutes	Lie down on the couch
	20 minutes	Lie down on the couch		

*: CM=Chinese Medicine.

After each session of TCA, the participant was given a study pack (see *Table 6.2.3.5 Contents of the study pack*) for the next day sampling.

6.2.7.2 Attention group

For the attention group, participants received weekly sessions of “attention” for a period of 5 consecutive weeks. Participants attended the clinical site once a week. The researcher carried out a general consultation (in a western style of asking how they were and making notes, not to read the tongue, feel the pulse and do other specific consultation according to Chinese medicine theory). The participant lay on the couch for a similar amount of time as the participants in the TCA group. The timing of the intervention is given in *Table 6.2.7-2*. In general, the researcher managed the participants in the attention group in the same manner as the participants in the TCA group (apart from the TCA which also included a Chinese medicine consultation). When completing each attention session, every participant was given a study pack (see *Table 6.2.3.5 Contents of the study pack*) for the collection of the next day’s samples. Participants in the attention only group were under the impression that this was also a form of treatment under investigation.

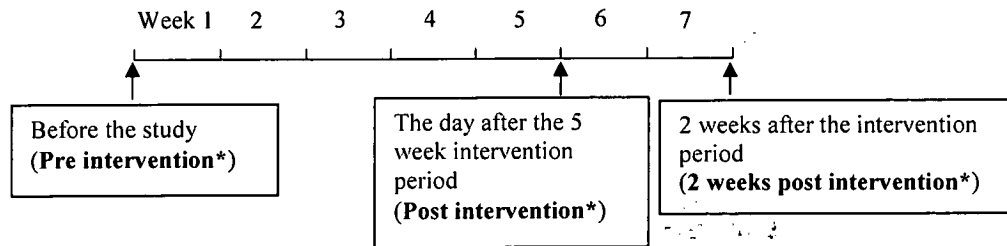
6.2.7.3 Control group

The participants in the control group acted as a waiting list control. They did not attend the clinical site and only provided salivary samples on the same day each week. When participants handed in their samples, a new study pack (see *Table 6.2.3.5 Contents of the study pack*) was provided for the next sampling period.

6.2.8 Collection of data for questionnaires

The RLE, PSS-14 and MYMOP were completed by the 3 groups on the day of commencement of the study which provided the baseline data for the study, the day after the completion of the 5 week intervention period, and 2 weeks after the intervention period (see *Figure 6.2.8*).

Figure 6.2.8 The dates of completing questionnaires



*: Phrases used in the tables and figures in *Chapter 7*.

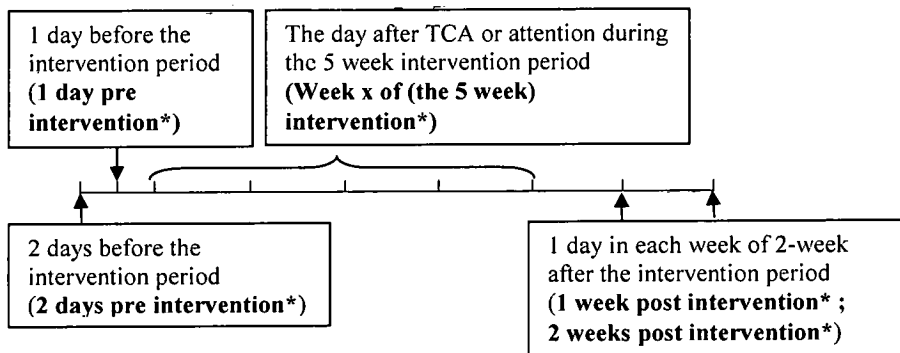
6.2.9 Collection of salivary samples

Salivary samples were collected on 9 separate days over a total period of 8 weeks. The collection days were:

- The two consecutive days prior to commencement of the study;
- The day following each session of acupuncture or attention;
- The same day for each week of the 2 weeks after the intervention period.

They are shown in *Figure 6.2.9-1*.

Figure 6.2.9-1 The days of taking salivary cortisol samples



*: Phrases used in the tables and figures in *Chapter 7*.

For the control group, the samples were taken at the same time points.

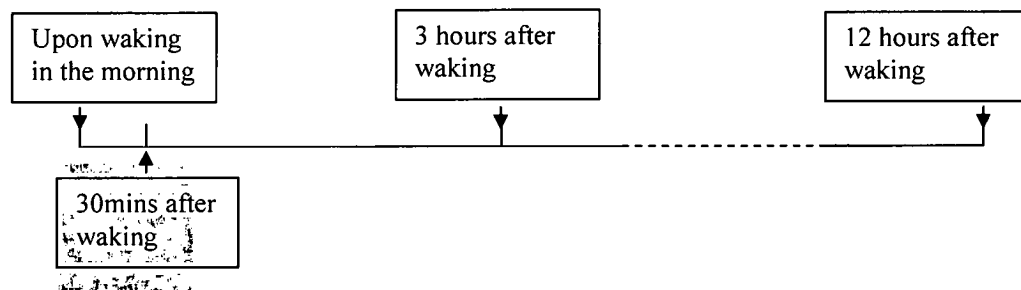
All collecting dates were weekdays rather than weekends.

A salivary cortisol sample was taken at the following 4 points in time on each day for 9 separate days over a total period of 8 weeks. These are also shown in *Figure 6.2.9-2*.

4 points in time one day when a salivary sample was taken were:

- immediately upon waking in the morning;
- 30mins after waking;
- 3hrs after waking;
- 12hrs after waking.

Figure 6.2.9-2 The time points of taking salivary cortisol samples per day



The exact time the sample was taken was recorded on the introduction and time-record sheet (see *Appendix 6.2 Introduction and time-record sheet*).

The researcher stressed the important points in the instruction sheet concerning salivary collection (see *Appendix 6.2*) when he gave the study pack to the participants. Saliva should be collected before they brushed their teeth in the morning. During the day, saliva should be collected no earlier than 30 minutes after eating or drinking.

Salivary samples were collected by participants using the salivettes. These were premarked by the researcher using a permanent marker (see *6.2.5.3 Study participation*). Participants wrote down the exact collection time on an Introduction and Time-record Sheet (see *Appendix 6.2*), kept the salivettes in the freezer and carried them in the provided self seal ice-cube bags and gave them to the researcher. Afterwards all the salivettes were kept in a -80°C freezer in the laboratory until they are analysed.

6.2.10 Salivary samples analysis

An independent biochemist at Imperial College carried out the double blind analysis of the salivary cortisol samples. The salivary cortisol concentration was analysed by using a High Sensitivity Salivary Cortisol Enzyme Immunoassay by Salimetrics LLC (USA). Standard range in assay: 0.003 ug/dL – 3.000ug/dL (0.083nmol/L – 82.77nmol/L) (Salimetrics LLC, 2006) (See *Appendix 10 The method sheet for Expanded Range High Sensitivity Salivary Cortisol Enzyme Immunoassay Kit from Salimetrics*)

6.2.11 Statistical analysis

The data for the PSS-14 and the MYMOP is nonparametric. The significance of differences of the mean scores of the PSS-14 and the MYMOP between pre- and post-intervention period, pre- and 2 weeks after the intervention period, and post- and 2 weeks after the intervention period within groups were assessed by Wilcoxon Signed Ranks Test (Kinnear and Gray, 1999). Mann-Whitney Test was used to compare the change of the PSS-14 and the changes of the MYMOP outcome measures between the 2 of 3 study groups and between the 2 of 3 data collection points. All p-values were two-tailed. The correlation between the change of the PSS-14 and the changes of the MYMOP outcomes before and after the 5 week intervention period was carried out using the Pearson Correlation. All analyses were performed using SPSS 14.0 for Windows.

For the cortisol concentrations which were more normally distributed, the data was transformed to enable parametric analysis. The independent samples t-test was used to compare the morning rises of cortisol concentration over the 5 week intervention period between the 2 of 3 study groups, which was carried out by SPSS 14.0 for Windows. The morning rise of cortisol concentration (delta (Δ) cortisol) was the change of cortisol concentration between immediately upon waking in the morning and 30mins after waking.

The small sample size and large standard deviation calculated for each of the three groups indicated that there was high probability of a type II error occurring (Burns, 2000). That is no significant effect could be detected, even if a trend was observed.

The diurnal profile of salivary cortisol concentration was plotted using the mean scores of the three groups' cortisol concentration on 9 separate days. The time-points were: 2 days and 1 day before the intervention period, week1, week2, week3, week4 and week5 of the 5 week intervention period, 1 week and 2 weeks after the intervention period. The graphs of the data were presented with standard error bars, calculated using the spreadsheet software Excel (Microsoft Office XP Professional). The aim was to identify whether there was any apparent trend in the salivary cortisol concentrations of the participants in the intervention groups compared to those of the participants in the control group. Excel was also used to plot the morning rises of cortisol concentration of each group over the 5 week intervention period. These analyses were carried out to explore whether there were any changes in the diurnal pattern of cortisol concentration during the study.

6.2.12 Case studies

Case studies were conducted on all participants who were involved in the RCT. The information was detailed as follows:

1. Date of starting the study.
2. Reasons for joining the study and case history.
3. Major presenting symptoms.
4. Life events occurring during the intervention period and potential factors that could act as confounders.
5. Intervention. This part reported and monitored what happened to participants and their responses and feedback during the 5 week intervention period.

In the TCA group, the TCA treatment was introduced, including the TCM diagnosis, the TCA therapeutic principles, method, and the summary of acupoints used in the treatment.

6. Results of outcome measures. This part gave the details of the individual results of the PSS, the MYMOP and the diurnal cortisol profile.
7. Participant's comments on their experience of the 5 week intervention period. This part recorded the participants' written feedback in their MYMOP questionnaires.
8. Comments and discussion from the researcher. According to the above details, the researcher evaluated and discussed participants' responses and results, including the relationship between the outcomes and the differences between individual participants.

6.3 Study phase 2: Focus groups

6.3.1 Procedure of focus groups study

After completion of the whole study (after 8 weeks), a letter was sent out by an administrator at the Centre for Complementary Healthcare and Integrated Medicine (CCHIM) at TVU to the participants in acupuncture group and the attention group to invite them to attend focus groups (see *Appendix 12.1 Information sheet for the focus group*). The focus group for the TCA group and the attention group were conducted separately at the CCHIM in Walpole House, TVU in Ealing London and facilitated independently.

Two focus groups discussed the same topic in a manner that was structured around number of key themes (See *Appendix 12.2 Focus group questions and prompts*). Participants' experience of using TCA treatment or attention for stress and how they felt about the research and their expectations of TCA were explored. Despite the structure of the "topic guide", it was natural that within a group there would be digression. As a result, these issues were explored. Sometimes such digressions can generate new areas for discussion. When this happened, the group was encouraged to continue until the issue was exhausted and then steered back to the original list of questions.

Each session lasted 1.5 hours and was audio-tape recorded. To ensure confidentiality, participants were given a number to identify them during the discussion. Notes were

taken during the focus groups by an independent researcher to supplement the tape recorded data. Tapes were independently transcribed and checked against notes taken during the focus groups.

The researcher was not involved in any of the activities of the focus groups study, which allowed participants to speak freely. All the records were kept in a locked filing cabinet and were not passed on to the researcher until he had finished the biochemical and patient-centred outcome scores analysis, thereby avoiding bias.

6.3.2 Analysis

The transcripts were analysed manually by the researcher using thematic content analysis (Robinson, 1999). The analytic framework was provided by the themes given in the topic guide when holding the focus groups (see *Appendix 12.2 Focus group questions and prompts*). Emergent themes were identified through repeated scrutiny of the transcript (see *Appendix 12.3 & 12.4 Transcription of the TCA group and the attention group*).

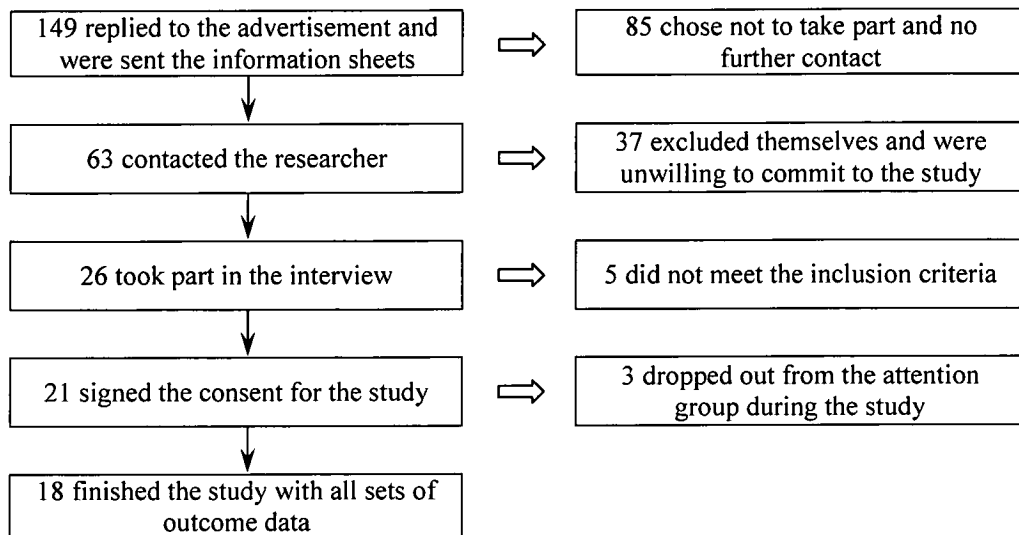
Chapter 7 Phase 1 Results – The Randomised Controlled Trial

This chapter presents the results of the randomised controlled trial (RCT). The outcomes analysed include the Perceived Stress Scale 14 (PSS-14), the Measure Yourself Medical Outcome profile (MYMOP), and the salivary cortisol responses.

7.1 Screening of respondents recruited into the study

In total 149 people replied to the advertisements between August 2005 and 8th March 2006. After reading the general information concerning the study (see *Appendix 2 Research information for participants*) sent by email, eighty five people chose not to take part in the study and had no further contact. Sixty three people contacted the researcher for more details of the research. Thirty seven excluded themselves because they could not commit to the study (see *Appendix 3 Response records*). Twenty six people attended the recruitment interview and were asked to complete the PSS-14 and the RLE. Five were excluded because they did not meet the required score of the PSS-14 (see 3.2.2 *The Perceived Stress Scale – 14 (PSS-14)*), had suffered a recent severe life event, could not meet the time schedule, were taking medication, or were receiving acupuncture or Chinese medicine for a current condition. Twenty one people met the inclusion criteria and were recruited into the study. During the study, three people subsequently dropped out because they found difficulty maintaining the requirements of the study schedule (see *Appendix 3*). All those people who dropped out were from the attention group. The details are given in *Figure 7.1*.

Figure 7.1 Recruitment into the study



The resulting 18 participants with the self-reported high stress levels as identified by the PSS-14 (greater than a score of 20) were randomised into the three groups – TCA group, attention group and control group. None of the participants were involved with night-shift work nor were they compensated for participation in the study. Since all participants were university staff, overall daily activities were comparable.

7.2 Demographic characteristics

In this study there were 3 male participants, one in each group as allocated by randomisation, and 15 female participants. There was a wide range of ages; the youngest was 19 years old (in the control group); the oldest was 58 years old (in the attention group); the mean age of participants in the 3 groups was 42.3 ± 2.7 years old. The mean age of each study group is given in *Table 7.2-1*. They did not reach statistical significance ($p > 0.05$) according to the Independent Samples T-Test. In addition, there were no statistically significant differences in gender, occupation and acupuncture experience between the 3 groups ($p > 0.05$). *Table 7.2-1* summarises the demographic data.

Table 7.2-1 Demographic characteristics of the study groups

		TCA Group	Attention Group	Control Group
Gender	Female	5	5	5
	Male	1	1	1
Age	18 - 19yrs	0	0	1
	20 - 29yrs	0	1	2
	30 - 39yrs	1	1	1
	40 - 49yrs	3	1	1
	50 - 59yrs	2	3	1
	Mean±SE	46.0±3.8	45.3±4.8	35.5±4.9
Occupation	Academic staff	2	2	3
	Administrator	4	4	3
Acupuncture experience	Yes	2	2	3
	No	4	4	3

Participants in the study reported a different history of stress. At the initial interview, some participants reported that they had suffered from stress for a long time, but did not provide an indication of the length of time they had been stressed. Some participants emphasised the period of time prior to the study when their stress levels had been at their worst. But this was not routinely reported. Individual details of the duration of stress for the 3 study groups are given in *Table 7.2-2*.

Table 7.2-2 The individual duration of stress in the 3 groups

TCA Group		Attention Group		Control Group	
ID	History	ID	History	ID	History
3	Long time	2	10 years	1	1 year
6	Long time	4	8 years	5	Long time
7	Long time	8	3 years	9	2 years
10	Long time	12	5 years	11	5 years
14	3 years	15	11 years	13	Long time
17	1 year	16	3 years	18	10 years

7.3 The Recent Life Events Questionnaire (RLE)

Participants reported recent life events and previous life events which continued affecting them during the period of the study. The RLE was completed at 3 time periods: at entry to the study (pre intervention), after 5 weeks of the intervention (post intervention), and 2 weeks after the intervention period (2 weeks post intervention). The RLE measured at entry to the study identified that some participants were still affected by life events which had happened before the 1-month cutoff period of the questionnaire.

Table 7.3 indicates that certain individuals in the groups reported that they were significantly affected by both life events which either occurred during the cutoff period or previous life events (prior to the cutoff period) that were still affecting them. The significance of the individual RLE is discussed in the individual case studies (see *Chapter 8*). In general, the participants in the TCA group experienced slightly more life events during the whole study period than the other 2 groups, but the difference between the TCA and other 2 groups did not reach statistical significance ($p>0.05$).

Table 7.3 Recent life events experienced by the study participants

TCA Group						
	Pre intervention		Post intervention		2 weeks post intervention	
ID	Events happened	Still affecting	Events happened	Still affecting	Events happened	Still affecting
3	0	6	1	1	2	2
6	2	0	0	0	0	0
7	0	3	0	2	1	0
10	1	2	0	0	0	0
14	0	5	0	4	0	4
17	0	3	0	1	1	1
	3	19	1	8	4	7
Total	22		9		11	
	42					
Attention Group						
	Pre intervention		Post intervention		2 weeks post intervention	
ID	Events happened	Still affecting	Events happened	Still affecting	Events happened	Still affecting
2	0	0	1	0	0	0
4	0	6	0	2	1	0
8	0	1	0	2	1	1
12	0	4	2	2	0	1
15	0	2	0	0	0	0
16	0	3	0	0	0	0
	0	16	3	6	2	2
Total	16		9		4	
	29					
Control Group						
	Pre intervention		Post intervention		2 weeks post intervention	
ID	Events happened	Still affecting	Events happened	Still affecting	Events happened	Still affecting
1	1	2	1	1	0	0
5	2	4	0	2	0	1
9	0	0	0	0	0	0
11	2	6	0	0	1	1
13	0	2	0	2	0	3
18	0	2	1	1	0	0
	5	16	2	6	1	5
Total	21		8		6	
	35					

7.4 Chinese medicine diagnosis and treatment in the TCA group

TCA treatment was individualised with diagnosis and treatment principles selected according to TCM theory (see *Chapter 4*).

7.4.1 Chinese medicine diagnosis in the TCA group

In the TCA group, 6 participants received weekly TCA treatment for 5 weeks. The main Chinese medicine diagnoses obtained at the beginning of the study are given in *Table 7.4.1*.

Table 7.4.1 Chinese medicine diagnoses in the TCA group

Participant	Chinese medicine diagnoses
3	Liver qi stagnation and liver invading spleen and stomach
6	Liver qi stagnation
7	Liver qi stagnation and liver invading spleen and stomach
10	Liver qi stagnation and transforming into fire
14	Liver qi stagnation and deficiency of gallbladder qi
17	Liver qi stagnation and blood stasis

Diagnoses were made according to Chinese medicine theory and for all participants. These were related to the liver's functional disorder, which may have affected the spleen/stomach or the gallbladder's function, or transformed into fire or reduced blood stasis. There were 2 subjects who had the same Chinese medicine diagnoses. The diagnosis and treatment details are given in *4.4.2 Pattern identification of Chinese Medicine for stress* and *4.4.3 Treatment*.

During the 5 week TCA treatment period, the main Chinese medicine diagnoses did not change, though there were different complaints and symptoms appeared.

7.4.2 Acupoints used in the TCA group

According to the above diagnosis and the different complaints reported during the different sessions, each participant in the TCA group received the TCA treatment individually. Five participants were treated in the supine position, and one participant in the prone position. The same positions were kept for the 5 sessions. The different

treatment principles for the different participants and different positions determined the acupoints used for the treatment.

A total of 39 acupoints were used for the 6 participants in the TCA group over the 5 week TCA intervention period (30 sessions in total). Of the 39 acupoints, SP6 (三阴交, Sanyinjiao) was used for all (100%) 30 sessions of TCA treatment. DU20 (百会, Baihui) was used 28 times (93.33%); LI4 (合谷, Hegu), ST36 (足三里, Zusanli), PC6 (内关, Neiguan), and EX-HN3 (印堂, Yintang) were used 25 times (83.33%); LR3 (太冲, Taichong) was used 24 times (80.00%); RN4 (关元, Guanyuan) was used 23 times (76.67%); RN6 (气海, Qihai) was used 22 times (73.33%); DU24 (神庭, Shenting) was used 17 times 56.67%; and LI11 (曲池, Quchi) and GB34 (阳陵泉, Yanglingquan) were used 16 times (53.33%). In total there were 12 points that were used more than 50% during the 5 weeks of the TCA treatment. The details are given in *Table 7.4.2* and *Figure 7.4.2*.

There were 7 points which were used between 5 and 15 times. They were GB41 (足临泣, Zulinqi) (12 times), ST25 (天枢, Tianshu) and RN12 (中脘, Zhongwan) (9 times), RN10 (下脘, Xiawan) and DU23 (上星, Shangxing) (8 times), and SP4 (公孙, Gongsun) and SP9 (阴陵泉, Yinlingquan) (7 times), which are shown in *Table 7.4.2*.

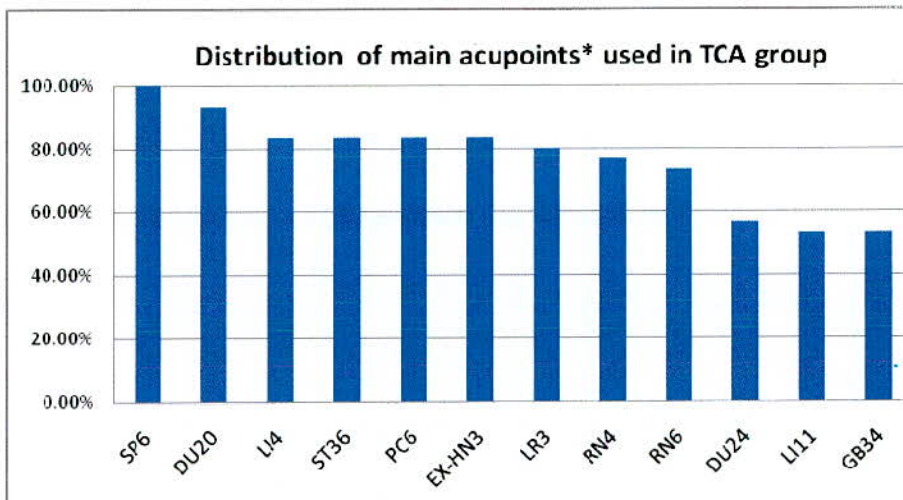
Apart from the above acupoints, there were other 20 acupoints that were used less than 5 times over the TCA treatment period. These were used for a specific symptom or indication, e.g. BL27 (小肠俞, Xiaochangshu) and EX-B7 (腰眼, Yaoyan) were used for 4 times (13.33%) and for one participant who suffered from back pain; LU11 (少商, Shaoshang) was used once for a sore throat. The details are given in *8.1 TCA group (Case studies)*.

Table 7.4.2 Frequency of the main acupoints used in the TCA group over 5 weeks' treatment*

Acupoints	Used times	Used frequency
SP6	30	100.00%
DU20	28	93.33%
LI4	25	83.33%
ST36	25	83.33%
PC6	25	83.33%
EX-HN3	25	83.33%
LR3	24	80.00%
RN4	23	76.67%
RN6	22	73.33%
DU24	17	56.67%
LI11	16	53.33%
GB34	16	53.33%
GB41	12	40.00%
ST25	9	30.00%
RN12	9	30.00%
RN10	8	26.67%
DU23	8	26.67%
SP4	7	23.33%
SP9	7	23.33%

*: The order of the acupoints corresponds to the 12 regular meridians' circulative order.

Figure 7.4.2 Distribution of main acupoints* used in the TCA group**



*: This chart only shows the acupoints which were used at frequency of more than 50.00% in the TCA group during the treatment.

** : The order of the acupoints corresponds to the 12 regular meridians' circulative order.

7.5 The Perceived Stress Scale 14 (PSS-14)

7.5.1 The PSS-14 group data

Table 7.5.1 shows the details of the PSS-14 scores for the 3 groups at the pre intervention baseline, after the 5 week intervention (post intervention), and at the 2 weeks post intervention follow up.

Table 7.5.1 The PSS-14 scores for the 3 study groups

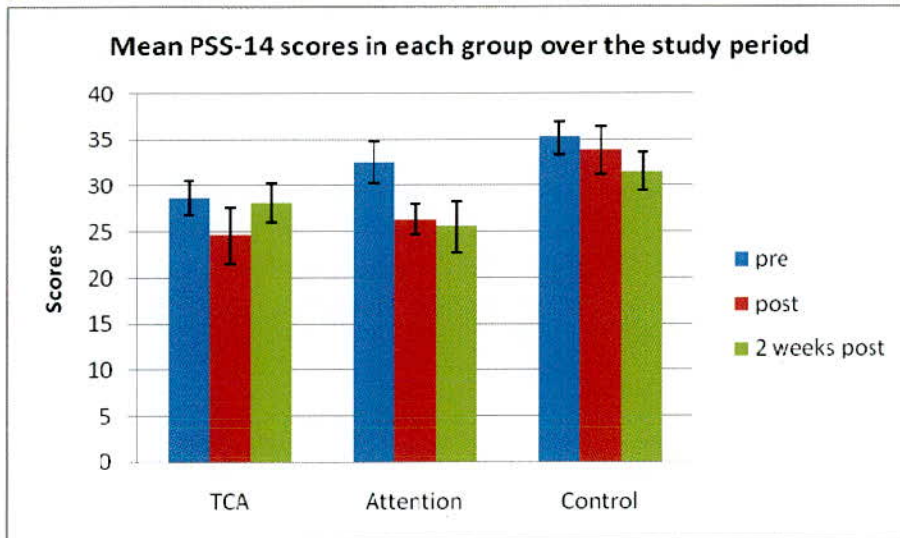
TCA Group			
ID	pre intervention	post intervention	2 weeks post intervention
3	29	31	33
6	33	15*	31
7	30	25	28
10	25	16*	19
14	33	31	31
17	22	30	27
Mean ± SE	28.67 ± 1.80	24.67 ± 3.04	28.17 ± 2.04
Attention Group			
ID	pre intervention	post intervention	2 weeks post intervention
2	29	24	34
4	36	25	25
8	39	32	32
12	29	24	26
15	25	31	20
16	37	22	16
Mean ± SE	32.50 ± 2.28	26.33 ± 1.69	25.50 ± 2.80
Control group			
ID	pre intervention	post intervention	2 weeks post intervention
1	38	34	26
5	31	41	37
9	28	32	30
11	39	23	26
13	38	34	33
18	37	39	37
Mean ± SE	35.17 ± 1.85	33.83 ± 2.57	31.50 ± 2.05

*: The data is less than 20, which is generally accepted as being the mean score of general population.

At base line, the TCA group's PSS-14 mean scores were the lowest of the 3 groups. After the 5 week intervention, the PSS-14 scores decreased in all the 3 groups. However after the 5 week intervention, only in the TCA group, did 2 of the participants' PSS-14 scores drop below 20, which is generally accepted as being the

mean score of general population. Note, this score was used initially to identify participants stress levels and as a criterion to recruit participants in this study (see 3.2.2 *The Perceived Stress Scale – 14 (PSS-14)*). Two weeks after the intervention period, the mean score in the TCA group increased but it was still slightly less than at baseline; whilst the scores in both the attention group and the control group decreased. *Figure 7.5.1* graphically illustrates the PSS-14 mean scores over the 3 time periods for the 3 groups.

Figure 7.5.1 Mean PSS-14 scores over the study period



Data presented as the mean \pm SE

7.5.2 A comparison of the PSS-14 scores within groups, between the data collection points

The Wilcoxon Signed Ranks Test (see 6.2.11 *Statistical analysis*) was used to compare the mean scores of the PSS-14 between the 3 study phases (pre intervention, post 5 week intervention, and 2 weeks post intervention) for each group. The statistical results are given in *Table 7.5.2*. The changes in the PSS-14 over the study period within the groups did not reach significance at the 0.05 level.

Table 7.5.2 The statistical results of the PSS-14 within the 3 groups over the study period

	TCA		Attention		Control	
	z	p	z	p	z	p
Pre & post intervention	1.051	>0.05	1.577	>0.05	0.318	>0.05
Pre & 2 weeks post intervention	0.318	>0.05	1.682	>0.05	0.944	>0.05
Post & 2 weeks post intervention	0.126	>0.05	0.365	>0.05	1.367	>0.05

7.5.3 A comparison of the changes in PSS-14 scores between groups, between the data collection points

The Mann-Whitney Test (see 6.2.11 *Statistical analysis*) was used to compare the changes in PSS-14 scores between the 3 groups and between the data collection points.

The results of statistical analysis are given in *Table 7.5.3*.

Table 7.5.3 The statistical results of the change of PSS-14 scores between the 3 groups over the study period

	TCA and Attention		TCA and Control		Attention and Control	
	z	p-values	z	p-values	z	p-values
Pre & post intervention	0.645	>0.05	0.723	>0.05	1.286	>0.05
Pre & 2 weeks post intervention	1.696	>0.05	0.484	>0.05	0.561	>0.05
Post & 2 weeks post intervention	1.214	>0.05	1.777	>0.05	0.643	>0.05

Table 7.5.3 illustrates that the changes in PSS-14 scores between the data collection points between the groups did not reach significance at the 0.05 level.

7.6 Measure Yourself Medical Outcome Profile (MYMOP)

7.6.1 Symptoms reported in the MYMOP

The MYMOP was completed by participants at 3 time periods: on the day of commencement of the study (pre intervention), the day after the 5 week intervention period (post intervention), and 2 weeks after the intervention period as a follow-up (2 weeks post intervention) (see *Figure 5.2.8*).

A total of 30 different symptoms were mentioned in the first round of MYMOP questionnaires. Details are given in *Table 7.6.1-1*.

Table 7.6.1-1 Symptoms reported in the first MYMOP

TCA Group			Attention Group			Control Group		
ID	Symptom		ID	Symptom		ID	Symptom	
	1	2		1	2		1	2
3	tearful		2	insomnia		1	tired	
6	tiredness	irritability	4	headaches	sleeping pattern	5	skin allergies	asthma
7	stomach upset	muscle tension	8	anxiety leading to chest pain	digestive problems	9	sleeping problems	restlessness
10	insomnia	heavy cold	12	irritation	loss of interest in anything	11	anger	tired
14	anxiety	fearful	15	sweet eating	restlessness	13	anxiety	fearfulness
17	back pain	short temper	16	annoyance	aggression	18	tiredness	low self esteem

Table 7.6.1-1 shows that most of symptoms reported by participants were related to stress, apart from some current acute problems, e.g. heavy cold. Symptoms on the whole were varied: being “tired” or “tiredness” was mentioned 3 times in the control group; the symptoms related to sleeping were reported twice in the attention group, which were “insomnia” and “sleeping pattern”; other symptoms were mentioned once by individuals in each group.

Overall, being “tired” or “tiredness” appeared 4 times; “anxiety”, “fearfulness”, “insomnia”, “irritation” and “restlessness” twice.

Some new symptoms were reported by the participants in the 2 follow-up rounds of MYMOP questionnaires. The details are shown in *Table 7.6.1-2* and *7.6.1-3*.

Table 7.6.1-2 Number of participants reporting new symptoms

	MYMOP follow-up 1	MYMOP follow-up 2
TCA Group	1	1
Attention Group	2	0
Control Group	2	1

Table 7.6.1-3 New symptoms reported

	MYMOP follow-up 1	MYMOP follow-up 2
TCA Group	Dry mouth with stomach upset	Anxiety
Attention Group	Headache with worry; Palpitations	
Control Group	Menstruation; Weight gain	Irregular menstruation

In the TCA group, one participant reported new symptoms in both the MYMOP follow-ups 1 & 2. Two participants in the attention group reported new symptoms in the MYMOP follow-up 1. In the control group, two participants reported new symptoms in the MYMOP follow-up 1, and one participant reported 1 new symptom in the MYMOP follow-up 2.

7.6.2 Activities reported in the MYMOP

Participants were asked to identify one activity which was important to them and it was difficult or they were prevented from doing as a result of their symptoms. All details are given in *Table 7.6.2*.

Table 7.6.2 Activities reported in the MYMOP

TCA Group		Attention Group		Control Group	
ID	Activity	ID	Activity	ID	Activity
3	exercise	2	relaxing	1	studying
6	making time for myself	4	trumpet practice	5	relaxing
7	gym	8	looking after myself	9	job
10	reading	12	control of appetite	11	reading
14	playing with children	15	indecision	13	going for an interview
17	football	16	communicating rationally with my family	18	meeting friends

Table 7.6.2 shows that “reading” and “relaxing” were reported twice within the 3 groups, other items once.

7.6.3 The MYMOP outcome data in the 3 groups

The MYMOP outcomes include 4 components “Profile Score”, “Symptom 1”, “Symptom 2”, “Activity” and “Wellbeing” (see 3.2.3 *The MYMOP*). The data for the mean scores of the MYMOP outcomes during the 3 study periods (pre intervention,

post 5 week intervention, and 2 weeks post intervention) in the 3 groups is given in *Table 7.6.3*.

Table 7.6.3 Mean MYMOP scores for study participants over the 3 time periods

		TCA group mean \pm SE	Attention group mean \pm SE	Control group mean \pm SE
Profile Score	pre intervention	3.71 \pm 0.29	4.54 \pm 0.22	4.42 \pm 0.35
	post intervention	2.00 \pm 0.21	3.25 \pm 0.25	3.96 \pm 0.30
	2 weeks post intervention	2.58 \pm 0.51	2.42 \pm 0.53	3.75 \pm 0.35
Symptom 1	pre intervention	4.17 \pm 0.40	4.67 \pm 0.21	4.50 \pm 0.43
	post intervention	1.50 \pm 0.43	3.17 \pm 0.60	4.33 \pm 0.33
	2 weeks post intervention	2.67 \pm 0.67	2.50 \pm 0.62	3.83 \pm 0.40
Symptom 2	pre intervention	4.00 \pm 0.63	4.80 \pm 0.37	4.60 \pm 0.51
	post intervention	1.80 \pm 0.37	3.40 \pm 0.40	4.20 \pm 0.37
	2 weeks post intervention	1.80 \pm 0.66	1.80 \pm 0.58	3.80 \pm 0.37
Activity	pre intervention	3.40 \pm 0.40	5.00 \pm 0.32	4.40 \pm 0.51
	post intervention	2.20 \pm 0.66	3.80 \pm 0.73	3.60 \pm 0.51
	2 weeks post intervention	2.60 \pm 0.60	2.20 \pm 0.73	4.20 \pm 0.58
Wellbeing	pre intervention	3.33 \pm 0.33	4.00 \pm 0.45	4.50 \pm 0.34
	post intervention	2.50 \pm 0.56	2.83 \pm 0.40	3.67 \pm 0.33
	2 weeks post intervention	2.67 \pm 0.61	2.50 \pm 0.50	3.67 \pm 0.49

Figure 7.6.3-1 Histogram of mean MYMOP scores over the 3 time periods for the TCA group

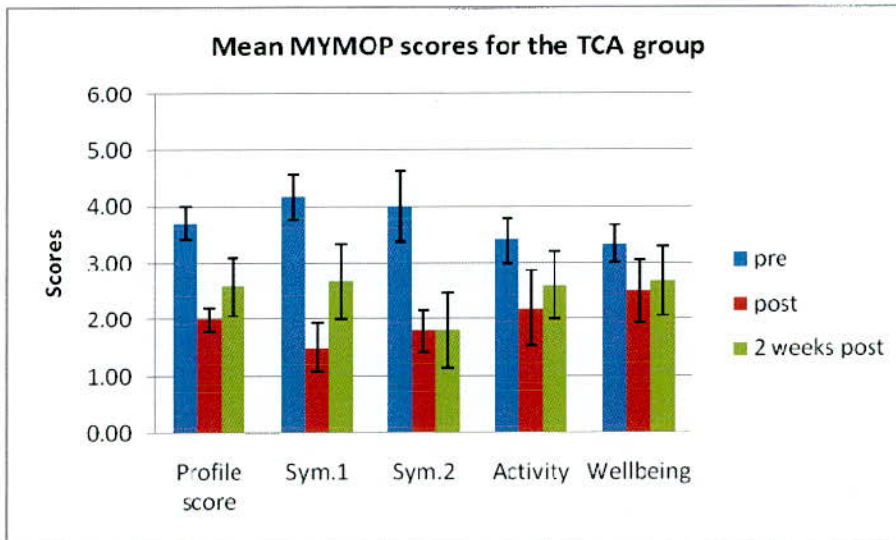


Figure 7.6.3-2 Histogram of mean MYMOP scores over the 3 time periods for the attention group

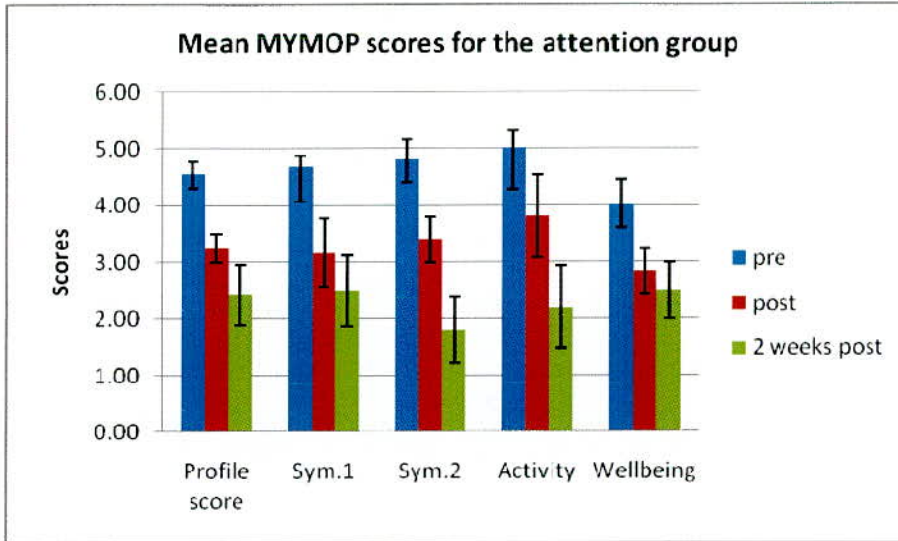
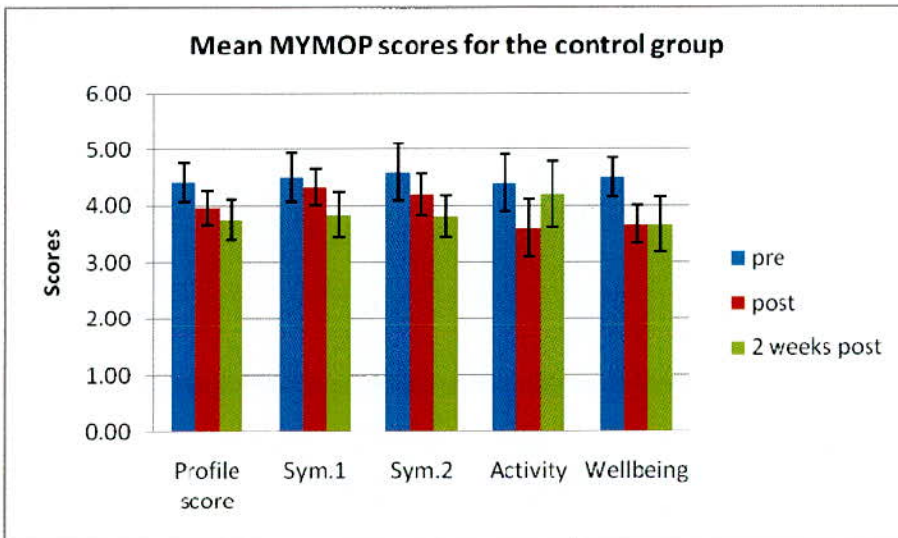


Figure 7.6.3-3 Histogram of mean MYMOP scores over the 3 time periods for the control group



The data in *Table 7.6.3* and *Figures 7.6.3-1,-2,-3* show that all the mean MYMOP scores of the TCA group were the lowest of the 3 groups at both pre and post intervention. This is similar to the results of the PSS-14, which also showed the scores of the TCA group at these 2 time points were the lowest of the 3 groups. Pre

intervention, the mean MYMOP scores of the attention group were the highest of all 3 groups, except for wellbeing which was lower than the control group.

For all 3 groups, after the 5 week intervention period, the mean scores decreased, although this was much less marked in the control group. At two weeks post intervention follow-up, the mean MYMOP scores of the TCA group all increased except for Symptom 2 which remained stable. For the attention group, all the mean MYMOP scores continued to decrease at the 2 weeks post intervention follow-up. The control group showed an increase in the activity score, the mean wellbeing score remained stable and all other mean scores decreased.

7.6.4 A comparison of the mean scores for each MYMOP outcome measure within groups, between the data collection points

The Wilcoxon Signed Ranks Test (see 6.2.11 *Statistical analysis*) was used to compare the mean scores within groups for each MYMOP outcome between the data collection points. *Table 7.6.4-1* shows the results of the statistical analysis, which are illustrated by the charts in *Table 7.6.4-2*.

Table 7.6.4-1 The statistical analysis of the mean MYMOP scores for each group at the 3 data collection points

TCA Group										
	Profile Score		Symptom 1		Symptom 2		Activity		Wellbeing	
	z	p	z	p	z	p	z	p	z	p
Pre & post intervention	2.21	<0.05	2.04	<0.05	2.03	<0.05	1.29	>0.05	1.63	>0.05
Pre & 2 weeks post intervention	1.58	>0.05	1.38	>0.05	1.84	>0.05	1.07	>0.05	1.13	>0.05
Post & 2 weeks post intervention	1.29	>0.05	1.34	>0.05	0.00	>0.05	0.41	>0.05	1.00	>0.05
Attention Group										
	Profile Score		Symptom 1		Symptom 2		Activity		Wellbeing	
	z	p	z	p	z	p	z	p	z	p
Pre & post intervention	2.21	<0.05	1.84	>0.05	2.04	<0.05	1.60	>0.05	1.84	>0.05
Pre & 2 weeks post intervention	2.03	<0.05	1.90	>0.05	2.04	<0.05	1.86	>0.05	2.04	<0.05
Post & 2 weeks post intervention	1.79	>0.05	1.30	>0.05	1.86	>0.05	1.34	>0.05	1.13	>0.05
Control Group										
	Profile Score		Symptom 1		Symptom 2		Activity		Wellbeing	
	z	p	z	p	z	p	z	p	z	p
Pre & post intervention	1.36	>0.05	0.38	>0.05	1.00	>0.05	1.63	>0.05	1.63	>0.05
Pre & 2 weeks post intervention	1.63	>0.05	1.63	>0.05	1.63	>0.05	0.45	>0.05	1.63	>0.05
Post & 2 weeks post intervention	0.74	>0.05	1.73	>0.05	1.41	>0.05	0.82	>0.05	0.00	>0.05

Table 7.6.4-2 Comparison of the difference between the mean MYMOP scores within groups over the study period**

Pre & post intervention	Pre & 2 weeks post intervention	Post & 2 weeks post intervention
Profile Score		
Symptom1		
Symptom2		
Activity		
Wellbeing		

*: $p < 0.05$; **: the data was from Table 7.6.3 the mean scores of the MYMOP over the 3 time periods for the 3 groups.

Table 7.6.4-1 shows that for the TCA group there was a statistically significant improvement in Profile Score, Symptom 1 and Symptom 2 after the 5 weeks of TCA treatment ($p < 0.05$), which is graphically presented in *Table 7.6.4.2*. The attention group had a statistically significant improvement in Profile Score and Symptom 2 ($p < 0.05$). In contrast, comparison of scores in the control group pre and post intervention failed to reach statistical significance ($p > 0.05$). For all 3 groups, the Activity and Wellbeing scores improved post intervention, but did not reach significance ($p > 0.05$).

Between post intervention and the 2 weeks post intervention follow-up, the TCA group showed an overall mean increase in scores whilst the attention group showed further decreases in the mean scores. The control group showed a slight decrease in 3 of the 5 outcomes with one showing a slight increase. None of these changes reached statistical significance ($p > 0.05$).

Over the longer term, by comparing the pre intervention scores with the 2 weeks intervention follow-up, the TCA group showed a decrease in all the scores, but as the result of the slight increases after the end of the treatment the overall improvement did not reach significance ($p > 0.05$). The continuing reduction of the attention group scores showed a significant change in Profile Score, Symptom 2 and Wellbeing over this time period ($p < 0.05$). The small changes for the control group scores did not reach significance ($p > 0.05$).

7.6.5 A comparison of the changes in the MYMOP outcome scores between groups, between the data collection points

The Mann-Whitney Test (see 6.2.11 *Statistical analysis*) was used to compare the changes in the individual components of the MYMOP between the data collection points and between the different groups. The statistical results are given in *Table 7.6.5*.

Table 7.6.5 Comparison of the changes for the MYMOP outcomes between the groups over the 3 data collection points

TCA Group & Attention Group										
	Profile Score		Symptom 1		Symptom 2		Activity		Wellbeing	
	z	p	z	p	z	p	z	p	z	p
Pre & post intervention	0.24	>0.05	1.30	>0.05	0.44	>0.05	0.32	>0.05	0.59	>0.05
Pre & 2 weeks post intervention	1.46	>0.05	0.57	>0.05	0.54	>0.05	1.83	>0.05	1.32	>0.05
Post & 2 weeks post intervention	1.95	>0.05	1.71	>0.05	1.74	>0.05	1.45	>0.05	1.35	>0.05
TCA Group and Control Group										
	Profile Score		Symptom 1		Symptom 2		Activity		Wellbeing	
	z	p	z	p	z	p	z	p	z	p
Pre & post intervention	2.18	<0.05	2.52	<0.05	2.17	<0.05	0.22	>0.05	0.09	>0.05
Pre & 2 weeks post intervention	0.66	>0.05	0.57	>0.05	0.98	>0.05	0.56	>0.05	0.34	>0.05
Post & 2 weeks post intervention	1.48	>0.05	2.16	<0.05	0.67	>0.05	0.11	>0.05	0.10	>0.05
Attention Group and Control Group										
	Profile Score		Symptom 1		Symptom 2		Activity		Wellbeing	
	z	p	z	p	z	p	z	p	z	p
Pre & post intervention	2.10	<0.05	1.48	>0.05	2.08	<0.05	0.55	>0.05	0.51	>0.05
Pre & 2 weeks post intervention	1.29	>0.05	1.55	>0.05	2.24	<0.05	2.17	<0.05	1.09	>0.05
Post & 2 weeks post intervention	0.73	>0.05	0.25	>0.05	1.57	>0.05	1.45	>0.05	0.92	>0.05

Table 7.6.5 shows that there were statistically significant differences for some MYMOP outcomes when comparing the TCA group and the control group, and comparing the attention group and the control group. The comparison between the TCA and control group demonstrated significant differences for Profile Score, Symptom 1 and Symptom 2 when comparing pre and post intervention scores, and for Symptom 1 when comparing post intervention and the 2 weeks post intervention follow-up scores ($p < 0.05$). Significant differences for Profile Score and Symptom 2 were observed between the attention and the control groups when comparing pre and post intervention scores ($p < 0.05$). Symptom 2 and Activity scores were significantly different between the attention and control groups when comparing scores pre intervention and the 2 weeks post intervention follow-up ($p < 0.05$). However, there was no significant differences between the TCA and attention group ($p > 0.05$).

7.7 Correlation between the change in the PSS-14 and the change in the MYMOP scores pre and post intervention for each group

The Pearson Correlation was used to analyse the correlation between the changes in the PSS-14 and changes in the MYMOP outcomes pre and post intervention for each group. *Table 7.7* shows there was no statistically significant correlation between the PSS-14 and the MYMOP results ($p>0.05$).

Table 7.7 Correlation between the change in the PSS-14 and the MYMOP outcomes pre and post intervention

TCA Group												
	PSS-14		Profile Score		Symptom1		Symptom2		Activity		Wellbeing	
	r	p	r	p	r	p	r	p	r	p	r	p
PSS-14			-0.527	>0.05	-0.536	>0.05	-0.366	>0.05	-0.835	>0.05	0.570	>0.05
Attention Group												
	PSS-14		Profile Score		Symptom1		Symptom2		Activity		Wellbeing	
	r	p	r	p	r	p	r	p	r	p	r	p
PSS-14			0.372	>0.05	0.591	>0.05	-0.449	>0.05	-0.367	>0.05	0.670	>0.05
Control Group												
	PSS-14		Profile Score		Symptom1		Symptom2		Activity		Wellbeing	
	r	p	r	p	r	p	r	p	r	p	r	p
PSS-14			-0.147	>0.05	-0.601	>0.05	0.862	>0.05	-0.643	>0.05	0.213	>0.05

7.8 Cortisol response

A total of 648 samples were collected and analysed by an independent biochemist at Imperial College, University of London (see *7.1 Screening of respondents recruited into the study*). The salivary samples for participant No.7 in the TCA group were unreadable and could not be used. The final salivary samples sizes for each group used in the statistical analysis are given in *Table 7.8*.

Table 7.8 Number of participants in each group whose samples were usable

	TCA Group	Attention Group	Control Group
Number of participants whose samples were usable	5	6	6

7.8.1 Mean waking times on the day of sample collection for each group

The salivary samples were collected at 9 different data points (see 6.2.9 *Collection of salivary samples*). The group data on the mean waking time on the day of sample collection over the study period is given in *Table 7.8.1*.

Table 7.8.1 Mean waking time on the day of sample collection

	TCA		Attention		Control	
	Mean time	Mean \pm SE*	Mean time	Mean \pm SE*	Mean time	Mean \pm SE*
2 days pre intervention	6:29	6.49 \pm 0.16	6:42	6.70 \pm 0.41	7:12	7.20 \pm 0.49
2 day pre intervention	6:28	6.47 \pm 0.11	6:45	6.76 \pm 0.35	7:26	7.43 \pm 0.38
Week 1 of 5 week intervention	6:37	6.61 \pm 0.13	6:43	6.72 \pm 0.36	6:57	6.96 \pm 0.46
Week 2 of 5 week intervention	6:30	6.49 \pm 0.15	7:00	7.00 \pm 0.39	7:09	7.15 \pm 0.48
Week 3 of 5 week intervention	6:49	6.82 \pm 0.14	6:50	6.83 \pm 0.40	7:09	7.15 \pm 0.40
Week 4 of 5 week intervention	6:34	6.57 \pm 0.20	6:38	6.63 \pm 0.35	7:09	7.15 \pm 0.40
Week 5 of 5 week intervention	7:11	7.18 \pm 0.57	6:29	6.49 \pm 0.40	7:01	7.01 \pm 0.43
1 week post intervention	7:02	7.04 \pm 0.22	6:38	6.64 \pm 0.27	7:13	7.22 \pm 0.50
2 weeks post intervention	6:39	6.64 \pm 0.22	6:33	6.54 \pm 0.34	7:12	7.20 \pm 0.48

*: In order to carry out the further statistical analysis, the waking times were adjusted to decimal notation.

Table 7.8.1 shows on the whole, the waking time in the control group was later than the TCA and the attention groups. There was a narrower range in standard errors in the TCA group (except for week 5) than the attention and control groups.

The Independent Samples T-Test (see 6.2.11 *Statistical analysis*) was used to compare the differences in the waking time between the groups and between the 9 days of sample collection. No significant difference between the groups and between the days of collection was detected ($p > 0.05$).

7.8.2 The diurnal profiles of mean salivary cortisol concentration for the 3 groups

The diurnal profiles of mean salivary cortisol concentration were constructed for the 3 groups for the 9 data points (2 points pre intervention, 5 points during 5 weeks of the intervention period, and 2 points post intervention). Mean cortisol concentration data for the 9 data collection points over the study period for the 3 groups are given in *Table 7.8.2-1*. Each participant's diurnal cortisol profile was constructed from the 4 salivary cortisol samples taken at the 4 time points during the day (see 6.2.9 *Collection of salivary samples*):

1. immediately upon waking in the morning;
2. 30mins after waking;
3. 3hrs after waking;
4. 12hrs after waking.

Table 7.8.2-1 Mean cortisol concentrations for the 3 groups over time

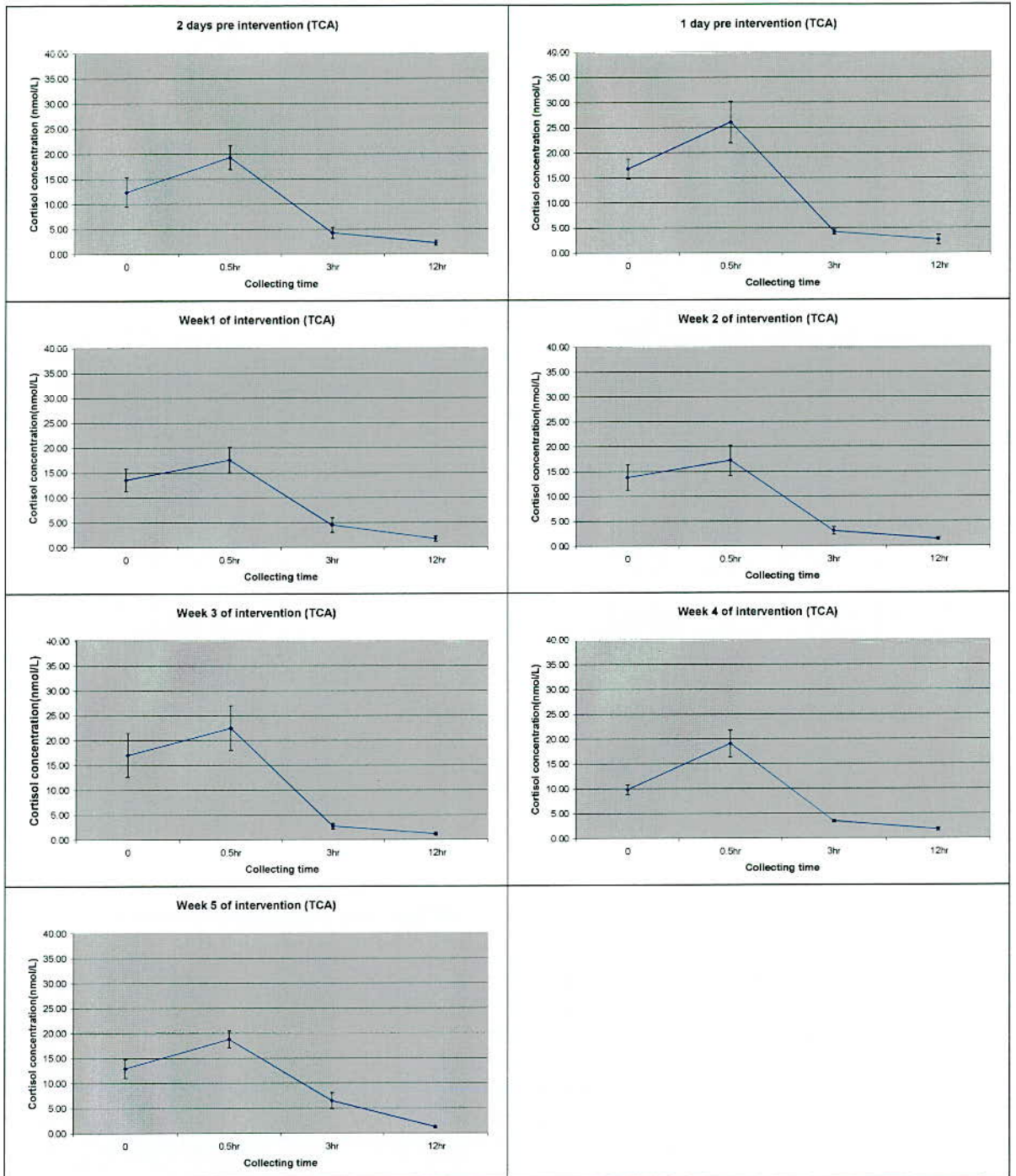
TCA Group			
On waking	30mins after waking	3hrs after waking	12hrs after waking
2 days pre intervention			
12.35±2.92	19.30±2.39	4.19±1.08	2.18±0.51
1 day pre intervention			
16.81±1.97	26.06±4.12	4.16±0.46	2.59±0.95
Week 1 of the 5 week intervention			
13.52±2.24	17.58±2.54	4.47±1.45	1.70±0.56
Week 2 of the 5 week intervention			
13.79±2.55	17.23±3.06	3.05±0.76	1.42±0.24
Week 3 of the 5 week intervention			
17.01±4.41	22.48±4.48	2.69±0.57	1.14±0.32
Week 4 of the 5 week intervention			
9.78±1.00	19.06±2.71	3.43±0.25	1.79±0.30
Week 5 of the 5 week intervention			
12.93±1.93	18.79±1.74	6.44±1.58	1.26±0.25
1 week post intervention			
13.49±3.08	17.68±3.55	5.16±1.57	1.58±0.23
2 weeks post intervention			
20.68±5.76	23.58±3.52	5.72±0.99	1.95±0.14

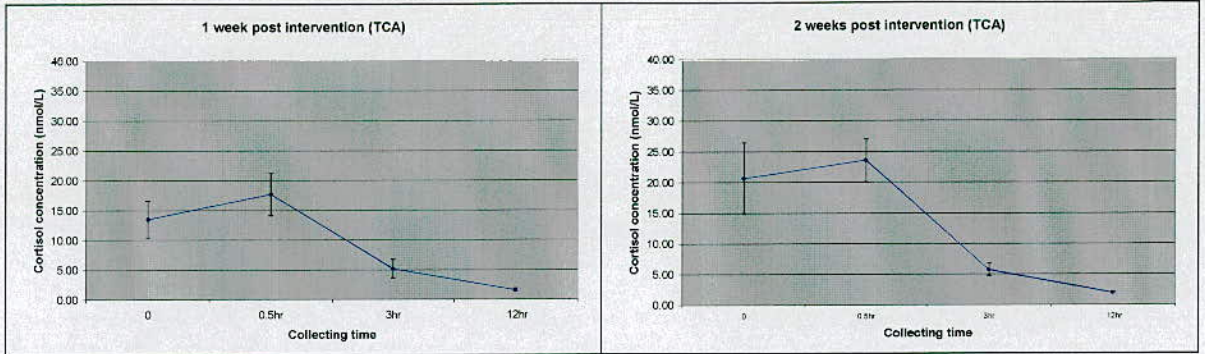
Attention Group			
On waking	30mins after waking	3hrs after waking	12hrs after waking
2 days pre intervention			
21.99±12.42	19.88±10.37	4.71±0.71	2.44±1.00
1 day pre intervention			
22.98±12.55	21.08±8.26	6.40±2.47	1.90±0.80
Week 1 of the 5 week intervention			
19.86±9.97	19.51±7.03	5.24±0.95	1.62±0.38
Week 2 of the 5 week intervention			
9.83±2.46	13.04±3.36	3.18±0.49	1.08±0.26
Week 3 of the 5 week intervention			
12.94±6.86	13.16±4.08	7.44±2.44	1.82±0.33
Week 4 of the 5 week intervention			
11.62±2.79	14.33±2.93	2.83±0.52	1.73±0.46
Week 5 of the 5 week intervention			
7.75±1.53	14.30±3.96	2.36±0.58	1.85±0.44
1 week post intervention			
13.84±6.80	21.15±8.68	6.18±1.27	1.36±0.28
2 weeks post intervention			
11.67±5.00	13.85±6.12	3.30±0.88	1.46±0.69
Control Group			
On waking	30mins after waking	3hrs after waking	12hrs after waking
2 days pre intervention			
7.75±1.02	11.51±2.48	3.96±1.08	2.36±0.95
1 day pre intervention			
7.67±0.67	10.28±1.47	3.78±0.81	2.10±0.19
Week 1 of the 5 week intervention			
8.87±0.90	13.20±2.59	3.72±0.57	1.98±0.61
Week 2 of the 5 week intervention			
7.69±0.88	10.70±2.10	4.66±1.83	1.45±0.36
Week 3 of the 5 week intervention			
7.89±1.24	9.91±1.96	3.86±1.23	1.45±0.53
Week 4 of the 5 week intervention			
8.94±0.86	13.10±1.93	3.05±0.49	1.15±0.20
Week 5 of the 5 week intervention			
10.49±2.52	12.23±3.38	2.79±0.90	1.15±0.08
1 week post intervention			
11.49±1.66	13.21±2.59	4.27±1.37	1.35±0.34
2 weeks post intervention			
9.52±1.15	9.89±2.48	3.38±0.53	1.71±0.66

Data presented as mean ± SE.

Tables 7.8.2-2, 3 & 4 present graphically the average diurnal cortisol profiles for each group. All tables illustrate that the small groups reflected large variations in the cortisol concentration which is known to occur in the normal human population. In the attention group particularly the wide variability in the means was due to the results from a single individual (see 8.2 *Attention group*).

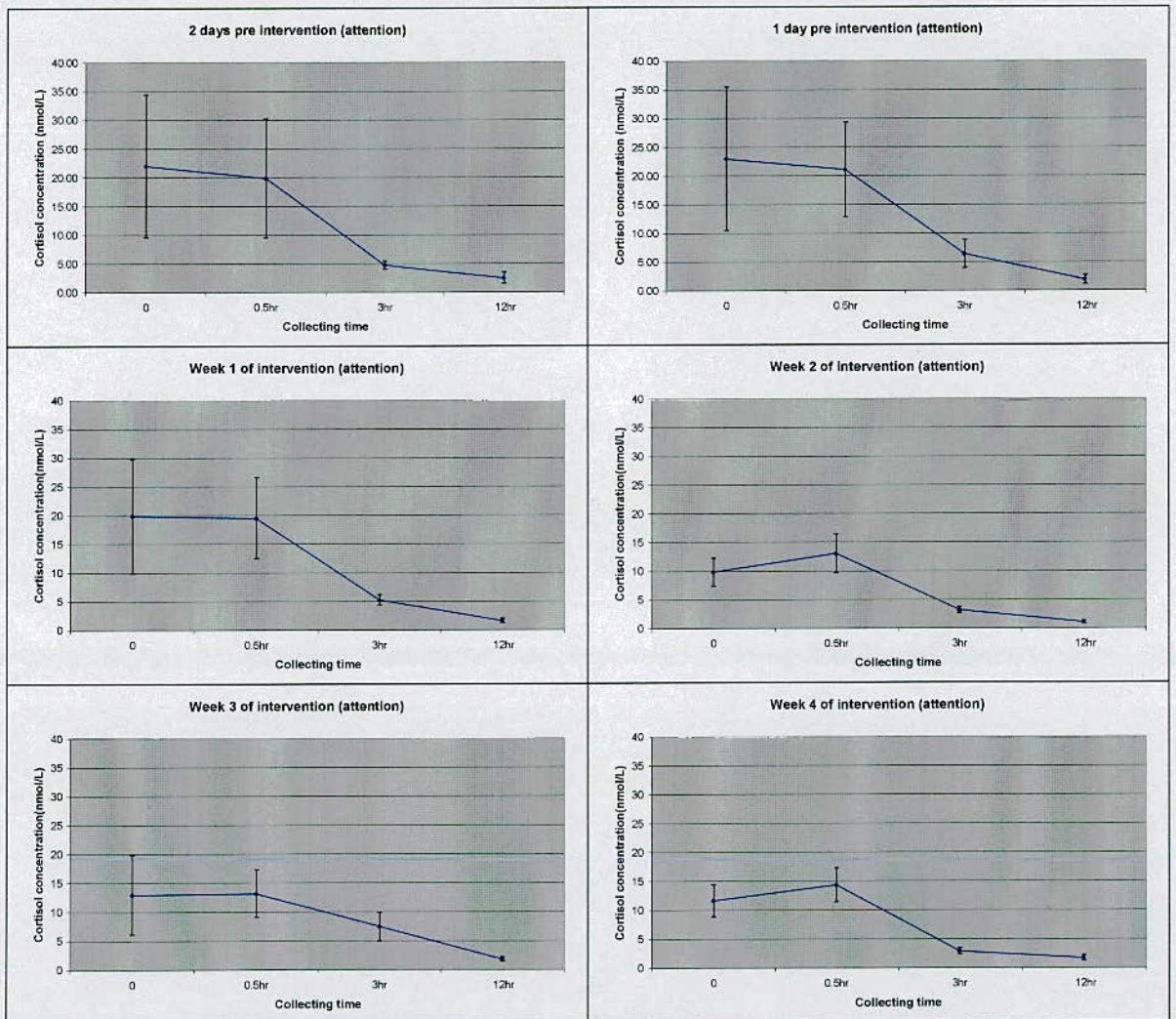
Table 7.8.2-2 TCA group's diurnal profiles of mean salivary cortisol concentration

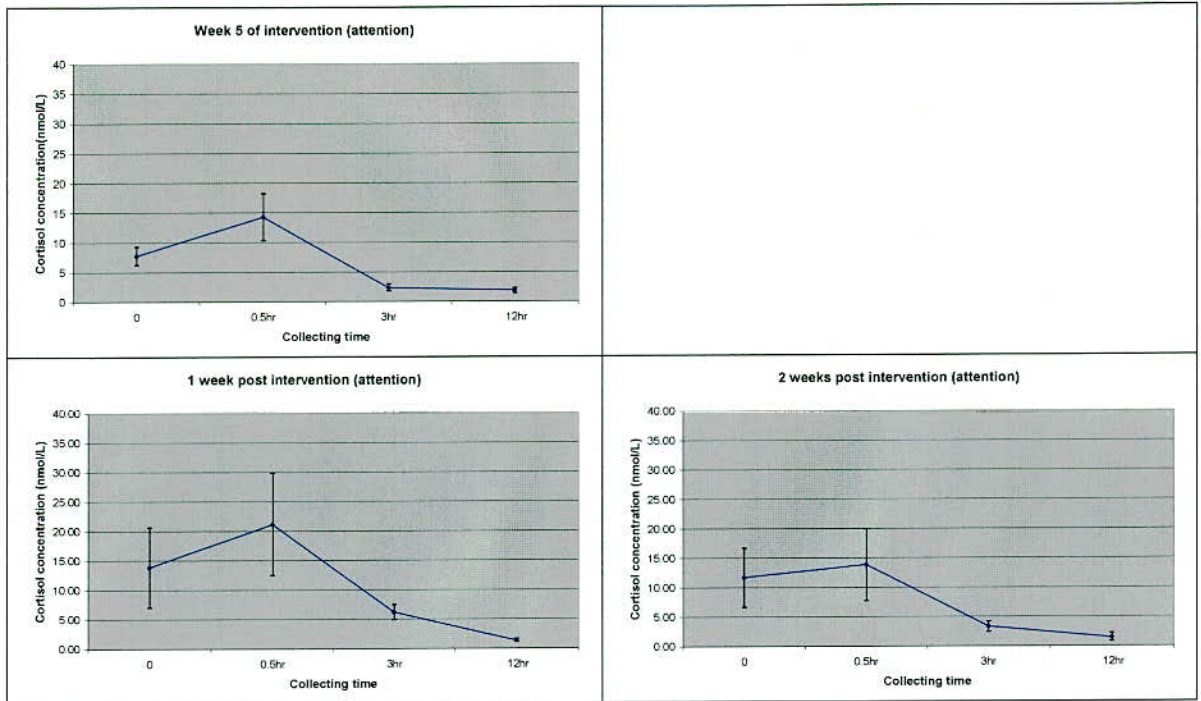




Data presented as mean \pm SE.

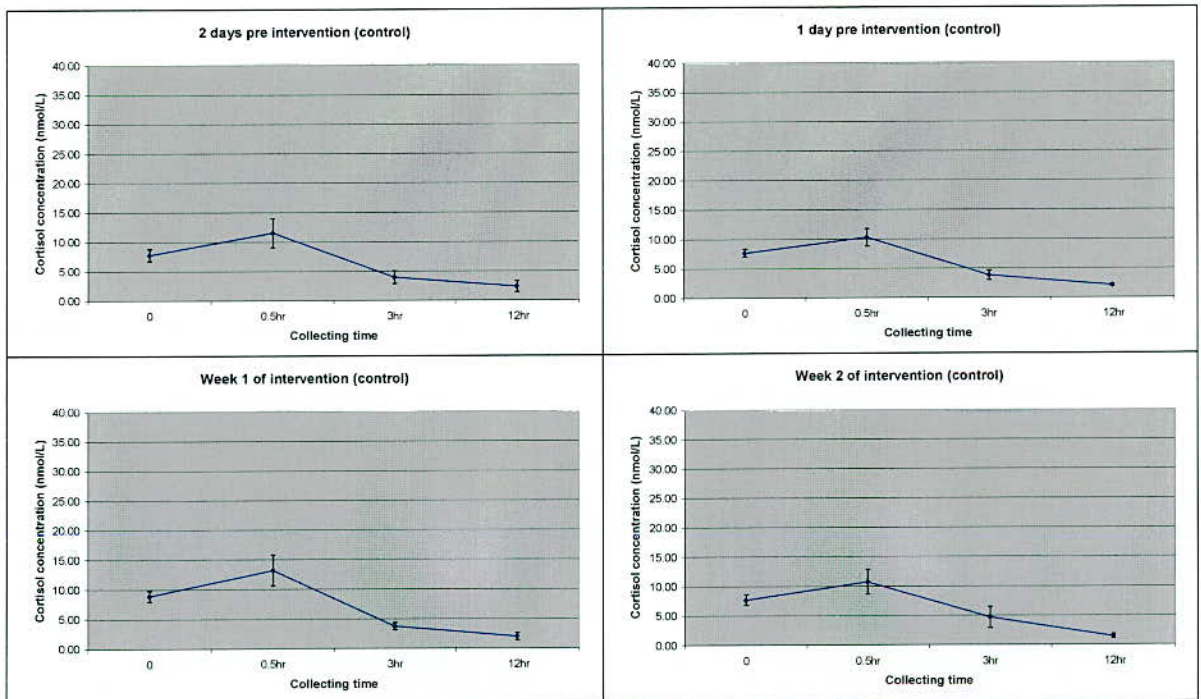
Table 7.8.2-3 Attention group's diurnal profiles of mean salivary cortisol concentration

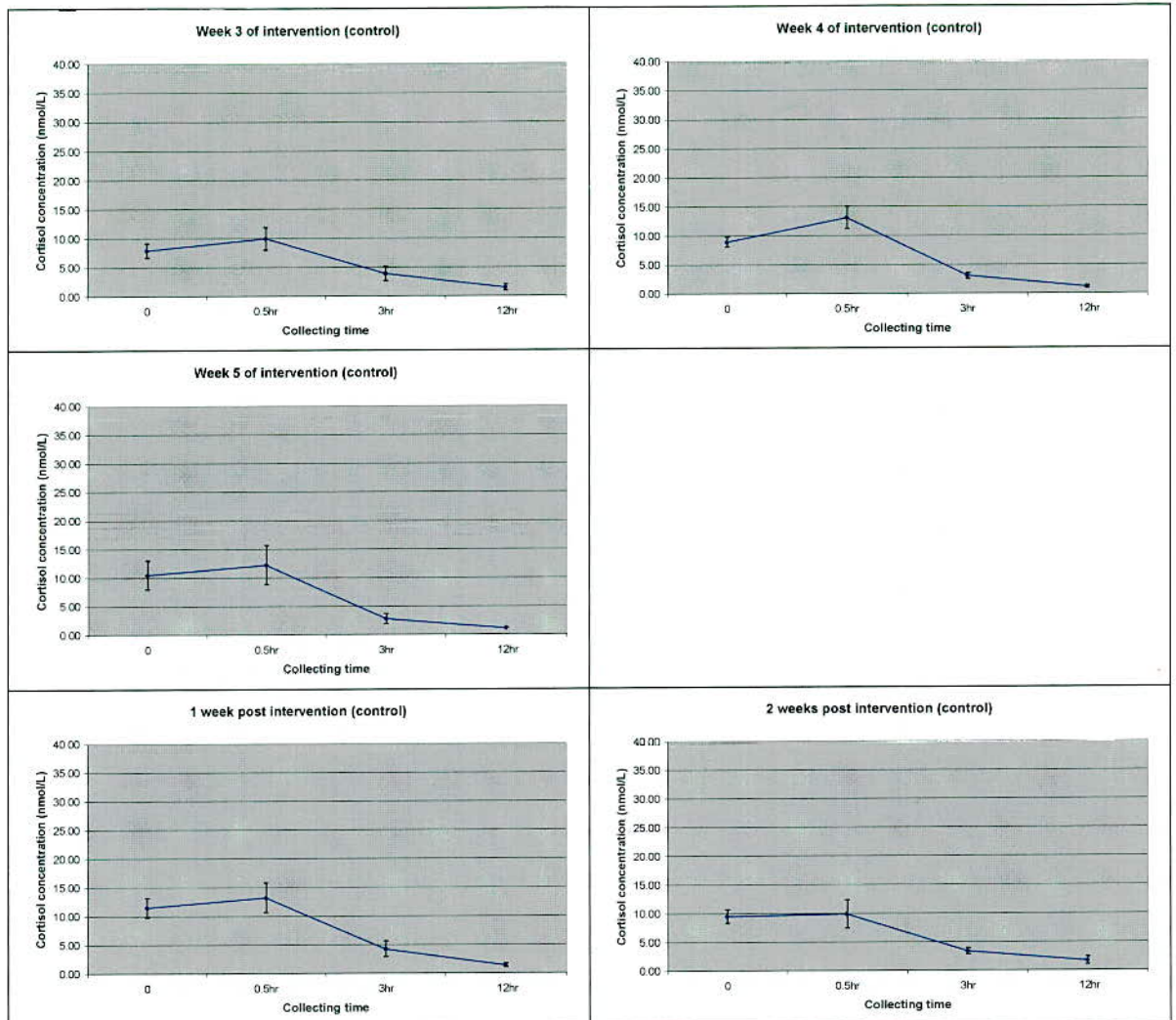




Data presented as mean \pm SE.

Table 7.8.2-4 Control group's diurnal profiles of mean salivary cortisol concentration





Data presented as mean \pm SE.

7.8.3 A comparison of the morning rise of cortisol concentration between the 3 groups

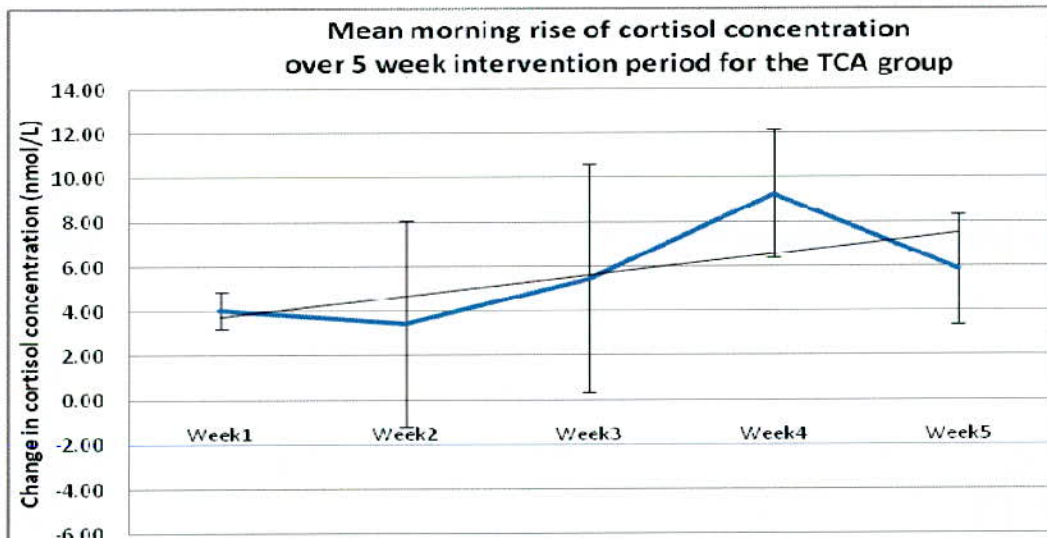
The morning rise in the diurnal cortisol profile is the change of cortisol concentration between the 2 time points, immediately upon waking in the morning and 30mins after waking. The data for the morning rise was analysed in order to further investigate the changes in cortisol concentrations during the 5 week intervention period only. The mean data for the morning rise for each group at each collection point is given in *Table 7.8.3-1*. All the mean data for each group is presented graphically in *Figures 7.8.3-1, 2 & 3*.

Table 7.8.3-1 Data on morning rise of cortisol concentration for the 3 groups

		TCA	Attention	Control
Week1	N	5	6	6
	Mean	4.0620	-0.3500	4.3300
	Std. Deviation	1.87123	8.28743	8.41133
	Std. Error	0.83684	3.38333	3.43391
Week2	N	5	6	6
	Mean	3.4480	3.2100	3.0167
	Std. Deviation	10.31463	7.39779	3.66879
	Std. Error	4.61284	3.02014	1.49778
Week3	N	5	5*	6
	Mean	5.4680	1.2640	2.0167
	Std. Deviation	11.53060	6.92691	2.77749
	Std. Error	5.15664	3.09781	1.13391
Week4	N	5	6	6
	Mean	9.2820	2.7067	4.1550
	Std. Deviation	6.46082	6.23264	4.19886
	Std. Error	2.88937	2.54446	1.71418
Week5	N	5	6	6
	Mean	5.8660	6.5467	1.7350
	Std. Deviation	5.54102	7.24784	4.12916
	Std. Error	2.47802	2.95892	1.68572

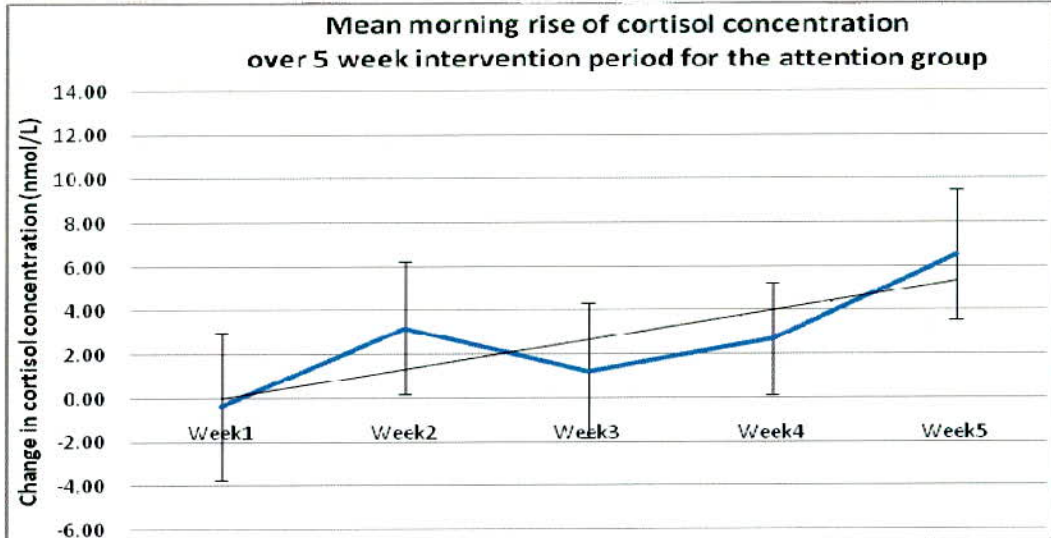
*: the sample for No.8 in the attention group at upon waking in week 3 was empty.

Figure 7.8.3-1 Mean morning rise of cortisol concentration during the 5 week intervention period for the TCA group



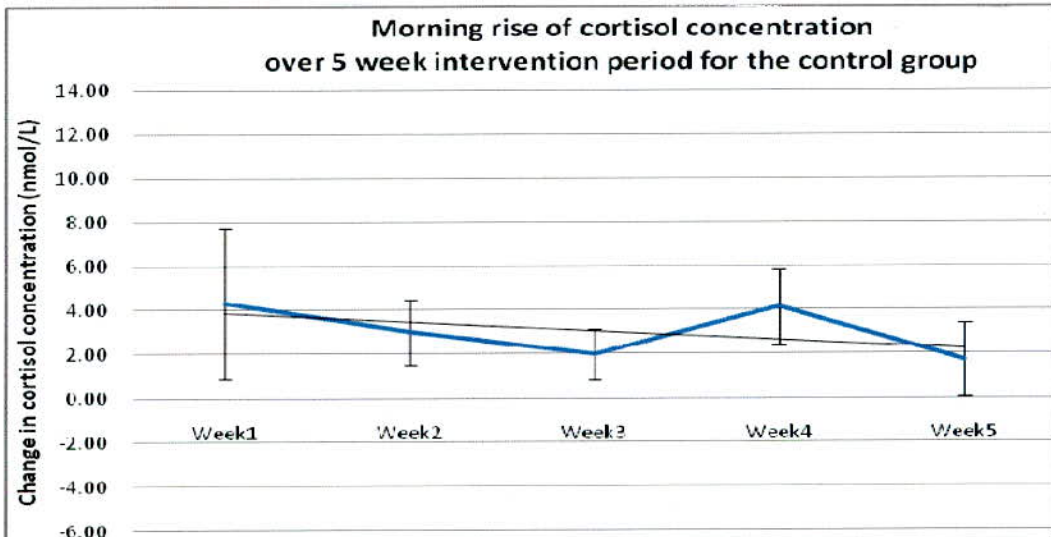
Data presented as the mean \pm SE

Figure 7.8.3-2 Mean morning rise of cortisol concentration during the 5 week intervention period for the attention group



Data presented as the mean \pm SE

Figure 7.8.3-3 Mean morning rise of cortisol concentration over the 5 week intervention period for the control group



Data presented as the mean \pm SE

Table 7.8.3-1 and Figures 7.8.3-1, -2, -3 illustrate that the TCA group had the greatest level of change in week 4 (9.28nmol/L). Generally during the 5 week intervention period, the morning rise in the TCA group was greater than for the other 2 groups (except in week 5 when it was lower than for the attention group). The initial rise in

mean cortisol levels after waking showed an increase during the intervention in the TCA group and the attention group, with both groups showing upward trends. The control group showed an overall decrease in the mean morning rise during the same period.

In week1 of the intervention period, the TCA group and the control group showed a similar mean morning rise, whilst the level for the attention group was much lower than the other 2 groups. Therefore *Figures 7.8.3-1, -2, -3* indicate that the TCA group had a greater increase in the morning rise than the control group during the 5 week intervention period. The attention group also showed an increase in the mean morning rise over the period of the intervention. It is difficult to compare the TCA group and the attention group due to the overall variability of the data as a result of the small sample size.

The Independent Samples T-Test was used to compare the morning rise of cortisol concentration during the 5 week intervention period between the pairs of the study groups. The statistical results in *Table 7.8.3-2* indicate the difference between the groups did not reach statistical significance due to individual variation in this small sample ($p>0.05$).

Table 7.8.3-2 Statistical data comparing the morning rise of cortisol concentration between the groups

	TCA and Attention			TCA and control			Attention and control		
	t	df	p	t	df	p	t	df	p
Week1	1.156	9	>0.05	-0.069	9	>0.05	-0.971	10	>0.05
Week2	0.045	9	>0.05	0.096	9	>0.05	0.057	10	>0.05
Week3	0.699	8*	>0.05	0.716	9	>0.05	-0.246	9*	>0.05
Week4	1.714	9	>0.05	1.590	9	>0.05	-0.472	10	>0.05
Week5	-0.172	9	>0.05	1.419	9	>0.05	1.413	10	>0.05

df: degrees of freedom

*: the sample for No.8 in the attention group at upon waking in week 3 was empty.

7.9 Conclusion

In summary, the results of this pilot study showed that after the 5 week intervention period, the TCA group's MYMOP scores all improved with the Profile Score, Symptom

1 and Symptom 2 reaching statistical significance ($p < 0.05$). The attention group's MYMOP scores all improved, but only the Profile Score and Symptom 2 reached statistical significance ($p < 0.05$). The MYMOP scores for the control group all showed a slight improvement, but none reached statistical significance ($p > 0.05$). Comparison between the 3 groups demonstrated significant improvements on the MYMOP Profile Score and for both reported symptoms for the TCA group compared to the control group ($p < 0.05$), whereas the attention group showed significance only on the MYMOP Profile Score and Symptom 2 when compared to the control group ($p < 0.05$). The PSS-14 scores decreased for all 3 groups. The TCA and attention groups showed larger decreases of the PSS-14 scores than the control group, but the difference between pre- and post-intervention within and between the groups did not reach statistical significance in this small study ($p > 0.05$). There was no statistical correlation between the decrease in the PSS-14 and the MYMOP scores ($p > 0.05$).

The initial rise in individual cortisol levels after waking (the morning rise) showed a mean increase over the intervention period for the TCA group and the attention group only. This trend did not reach statistical significance due to individual variation in this small sample ($p > 0.05$). The control group showed an overall decrease in the mean morning rise during the same period. The diurnal cortisol profiles reflected considerable individual variability.

Chapter 8 Phase1 Results - Individual Case Studies

In this chapter, case studies are presented for each of individuals involved the TCA, attention and control groups. Information for each case is provided as follows:

1. Date of starting the study;
2. Reasons for joining the study and case history;
3. Major presenting symptoms;
4. Life events occurring during intervention period and potential factors that could act as confounders;
5. Intervention;
6. Results of outcome measures;
7. Participant comments on the experience of the 5 week intervention period;
8. Comments and discussion from the researcher.

8.1 TCA group

No. 3 Female, 33 years old.

1. Date of starting the study

5th September 2005

2. Reasons for joining the study and case history

No. 3 had felt very stressed since July 2005 when she separated from her boyfriend.

3. Major presenting symptoms

Tearful (Symptom in the MYMOP), uncomfortable feeling in the lower part of the abdomen, passing a lot of wind, period late for 2 cycles, sad, depressed.

4. Life events occurring during the intervention period

Table TCA 3-1: Recent Life Events

No. 3	Events happened	Still affecting
Pre intervention	0	6
Post intervention	1	1
2 weeks post intervention	2	2

The separation from her boyfriend continued affecting her a lot. Her work was also stressful. In the fifth week of the 5 week TCA intervention she moved her house. During the 2 weeks after the TCA intervention, she had to move her office to a

different geographical location in the university, which made her more stressed and upset as she had to do a lot of things for moving.

5. Intervention

No.3's Chinese Medicine diagnosis was liver qi stagnation and liver invading spleen and stomach. The TCA was for soothing liver qi, and strengthening spleen and mitigating stomach.

The acupoints used in the 5 sessions of TCA treatment were summarised in *Table TCA3-2*.

Table TCA 3-2: Acupoints used in the 5 sessions of TCA treatment

Acupoint	Session 1	Session 2	Session 3	Session 4	Session 5	Total
DU20 (Baihui)	√	√	√	√	√	5
EX-HN3 (Yintang)	√	√	√	√	√	5
DU23 (Shangxing)				√	√	2
DU24 (Shenting)	√	√	√			3
RN10 (Xiawan)		√	√	√	√	4
RN9 (Shuifen)			√	√		2
ST25 (Tianshu)	√	√	√	√	√	5
RN6 (Qihai)	√	√	√	√	√	5
RN4 (Guanyuan)	√	√	√	√		4
ST28 (Shuidao)					√	1
LI11 (Quchi)				√		1
LI10 (Shousanli)		√				1
PC6 (Neiguan)	√	√	√	√	√	5
LI4 (Hegu)	√	√	√	√	√	5
LU11 (Shaoshang)				√		1
ST36 (Zusanli)	√	√	√	√	√	5
GB34 (Yanglingquan)	√		√	√		3
SP9 (Yinlingquan)	√	√	√	√	√	5
ST40 (Fenglong)			√		√	2
SP6 (Sanyinjiao)	√	√	√	√	√	5
LR3 (Taichong)	√	√	√	√	√	5
SP4 (Gongsun)		√	√	√	√	4
GB41 (Zulinqi)					√	1
23	14	16	18	19	17	84

For the first 4 weeks, TCA concentrated on the symptoms from No.3's stress. After 3 weeks' TCA, her wind stopped, and she reported that she did not feel ill and sad, something she had not felt for a long time. After 4 weeks' TCA, her period came on time and was normal. But she was still very irritable because of the stressful

work. In the week 5 of TCA intervention period, she moved house and had a bad cold. So that week's TCA included treatment to manage her cold symptoms.

6. Results of outcome measures

Table TCA 3-3 shows that though No.3's PSS-14 scores increased progressively during the 3 periods of study, the MYMOP scores had declined after the 5 weeks of TCA, however, were not maintained 2 weeks after TCA.

Figure TCA 3 indicates that No.3 had flattened diurnal salivary cortisol profiles with the loss of the morning surge on 2 days before the intervention, in week 2 of the intervention period and 2 weeks after the intervention. The cortisol concentrations at the first 2 collecting points fluctuated during the study period.

Table TCA 3-3: TCA 3's PSS-14 & MYMOP

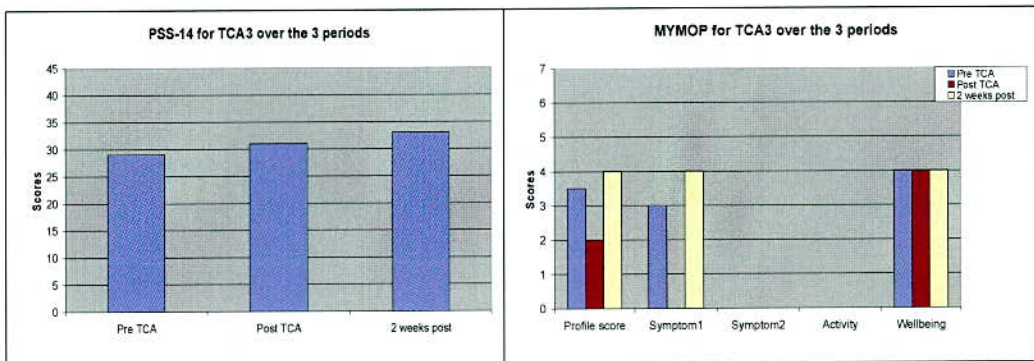
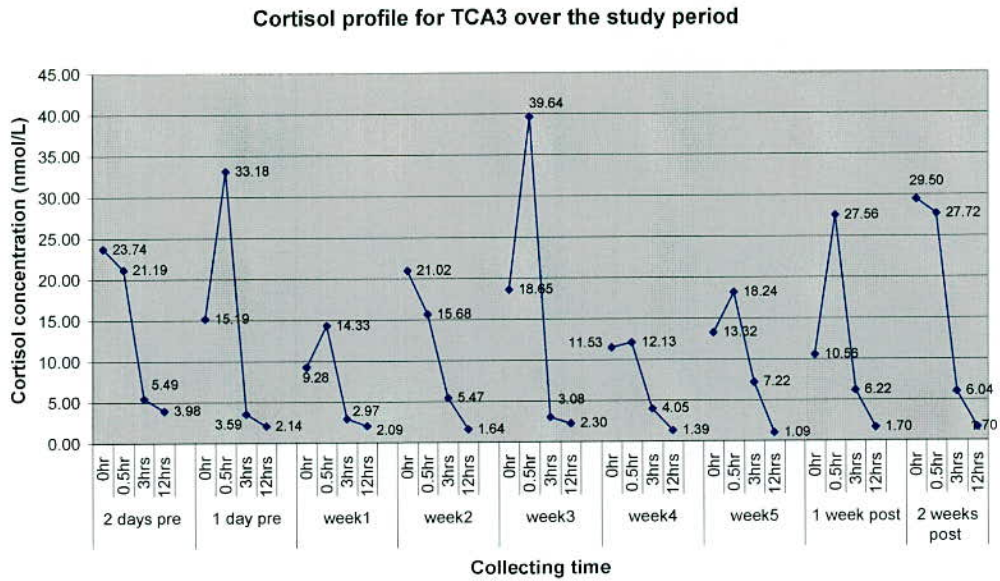


Figure TCA 3: TCA 3’s diurnal profiles of salivary cortisol concentration on 9 collection dates



7. Participant’s comments on the experience of the 5 week intervention period

“Not noticed any particular changes but enjoyed new experience of acupuncture.”

8. Comments and discussion from the researcher

During the study period, there were a lot of things that affected No.3’s stress levels which made her feel she was as stressed as before the study started, as she reported that she did “not notice any particular changes”. In reality after 3 weeks of TCA, some of her symptoms improved, especially after 4 sessions of TCA her period came on time which had been irregular for 2 months.

The cortisol profiles on 2 days before the intervention, in week 2 of the intervention period and 2 weeks after the intervention were stress patterns of cortisol profiles, while in other data collecting points they were normal. Especially at baseline, the cortisol profiles on 2 days and 1 day before the intervention were totally different, which was hard to indicate that those profiles reflected her high self-perceived stress levels. The record of sample collecting time showed that TCA3 took samples between 6:20am to 7:00am. The abnormal cortisol profiles may have been because she did not take the first samples immediately on waking

on those 3 sample collecting dates, or perhaps those times were not her first awaking times in the mornings.

No. 6 Female, 57 years old.

1. Date of starting the study

3rd October 2005

2. Reasons for joining the study and case history

No.6 felt stressed because of her work. She also had worried about her daughter over the last few years. She had sinusitis for many years when it went up and down.

3. Major presenting symptoms

Tiredness (Symptom 1 in the MYMOP), irritability (Symptom 2 in the MYMOP), early waking in the morning, tiredness, sinus headaches.

4. Life events occurring during intervention period

Table TCA6-1: Recent Life Events

No. 6	Events happened	Still affecting
Pre intervention	2	0
Post intervention	0	0
2 weeks post intervention	0	0

As No.6 was a manager, the stress she reported was mainly produced from her work and her everyday life. During the study, she did not experience any specific stressful event.

5. Intervention

No.6's TCM diagnosis was Liver qi stagnation. The principle of TCA focused on clearing liver and regulating qi.

During the 5 weeks of TCA, No.6 suffered from sinus problems on two occasions. Some acupoints especially for her sinuses were chosen. She reported that she had benefited from TCA. TCA treatment encompassed these symptoms, but concentrated on her stress and general condition.

The acupoints used in the 5 sessions of TCA treatment were summarised in *Table TCA6-2*.

Table TCA6-2: Acupoints used in the 5 sessions of TCA treatment

Acupoint	Session 1	Session 2	Session 3	Session 4	Session 5	Total
DU20 (Baihui)	√	√	√	√	√	5
EX-HN3 (Yintang)	√	√	√	√	√	5
DU23 (Shangxing)				√	√	2
DU24 (Shenting)	√	√	√			3
RN12 (Zhongwan)			√			1
RN10 (Xiawan)		√				1
RN6 (Qihai)	√	√	√	√	√	5
RN4 (Guanyuan)	√	√	√	√	√	5
L111 (Quchi)				√	√	2
PC6 (Neiguan)	√	√	√	√	√	5
L14 (Hegu)	√	√	√	√	√	5
ST36 (Zusanli)	√	√	√	√	√	5
GB34 (Yanglingquan)			√			1
SP6 (Sanyinjiao)	√	√	√	√	√	5
LR3 (Taichong)	√	√	√	√	√	5
GB41 (Zulinqi)	√	√		√		3
16	11	12	12	12	11	58

6. Results of outcome measures

After the 5 weeks of TCA, No.6's PSS-14 score decreased from 33 to 15, and the scores of the MYMOP outcomes declined except for "Activity" which increased. Two weeks after TCA, the PSS-14 increased to 29; 3 MYMOP outcomes maintained stable, "Activity" went down, and "Symptom2" went up (see *Table TCA 6-3*).

Figure TCA 6 shows that at baseline, No.6 had a flattened cortisol pattern with the loss of the morning surge on 1 day before the intervention. During and after TCA, there were marked increases in her cortisol concentration on waking which peaked after about 30 minutes.

Table TCA 6-3: TCA 6's PSS-14 & MYMOP

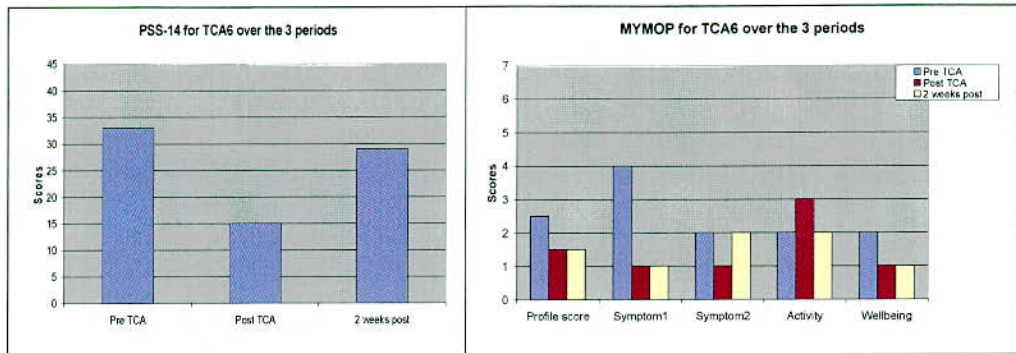
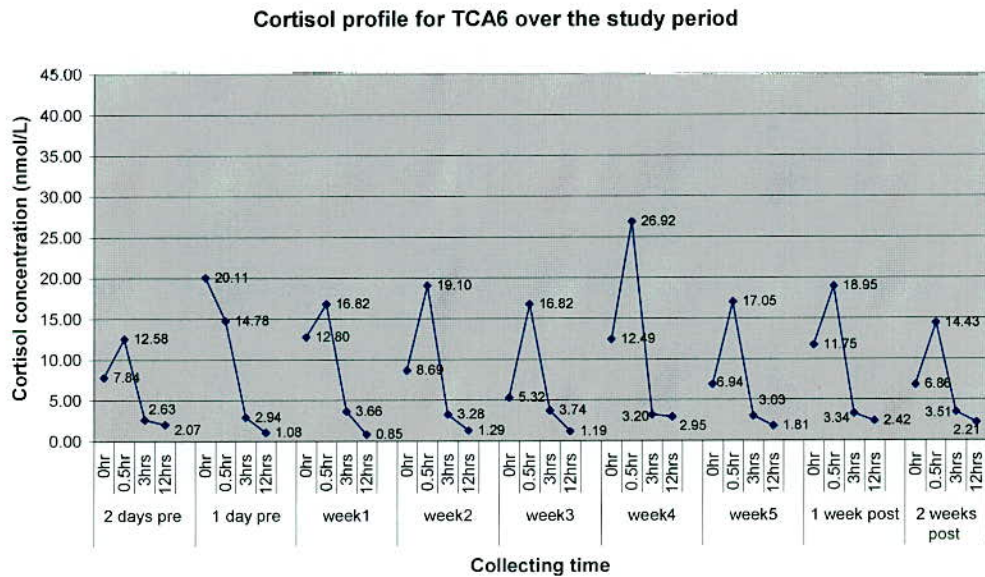


Figure TCA 6: TCA 6's diurnal profiles of salivary cortisol concentration on 9 collection dates



7. Participant's comments on the experience of the 5 week intervention period

“Feeling of lightness immediately after sessions, felt more relaxed”

8. Comments and discussion from the researcher

The flattened cortisol profile on 1 day before the intervention reflected TCA6's high self-reported stress level. During the following study period, No.6's cortisol response showed a normal pattern and maintained stability. This correlated to the improved results of the PSS-14 and the MYMOP after the intervention period. But

the cortisol profiles did not reflect the increased stress level after 2 weeks intervention period which was identified by the PSS-14 (see *Table TCA 6-3*).

No.6 had not experienced any life events during the study period. She suffered stress from everyday life and work. After the 5 weeks of TCA, her response to TCA was positive, as was from her subjective feedback and all outcome measures.

No. 7 Female, 43 years old.

1. Date of starting the study

19th September 2005

2. Reasons for joining the study and case history

No. 7 had felt stressed off and on for many years and she felt it worse in the recent 3 months because of her elder daughter leaving home and new changes in her work.

3. Major presenting symptoms

Stomach upset (Symptom 1 in the MYMOP), muscle tension (Symptom 2 in the MYMOP), premenstrual tension.

4. Life events occurring during intervention period

Table TCA7-1: Recent Life Events

No. 7	Events happened	Still affecting
Pre intervention	0	3
Post intervention	0	2
2 weeks post intervention	1	0

In July 2005 No.7 started her new job. She had to leave home very early morning to travel to work. At the same time, her elder daughter started travelling to the university and needed her help in the morning.

5. Intervention

No.7's TCM diagnosis was liver qi stagnation and liver invading spleen and stomach. The principle of TCA was to clear the liver and regulate qi, and strengthen the spleen and mitigate the stomach. The acupoints used in the 5 sessions of TCA treatment were summarised in *Table TCA 7-2*.

Generally during the 5 weeks of TCA, No.7's condition was stable. On one day in the fourth week, she had a family argument, which made her stomach upset and

she reported “an acidic stomach”. On one day of the TCA treatment days she was not happy due to a work situation and felt more stressed.

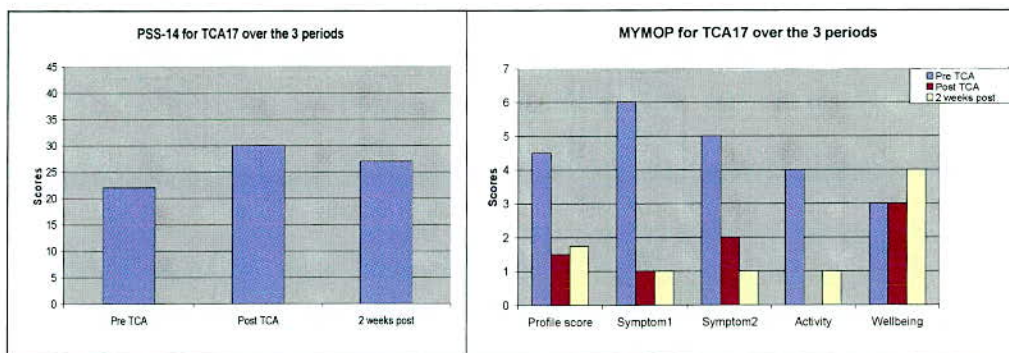
The acupoints used in the 5 sessions of TCA treatment were summarised in *Table TCA 7-2*.

Table TCA 7-2: Acupoints used in the 5 sessions of TCA treatment

Acupoint	Session 1	Session 2	Session 3	Session 4	Session 5	Total
DU20 (Baihui)	√	√	√	√	√	5
EX-HN3 (Yintang)	√	√	√	√	√	5
DU24 (Shenting)	√	√	√	√	√	5
RN12 (Zhongwan)	√	√	√	√	√	5
RN6 (Qihai)	√	√	√	√	√	5
RN4 (Guanyuan)	√	√	√	√	√	5
PC6 (Neiguan)	√	√	√	√	√	5
LI4 (Hegu)	√	√	√	√	√	5
ST36 (Zusanli)	√	√	√	√	√	5
GB34 (Yanglingquan)	√			√	√	3
SP6 (Sanyinjiao)	√	√	√	√	√	5
LR3 (Taichong)	√	√	√	√	√	5
SP4 (Gongsun)			√	√	√	3
KI3 (Taixi)		√				1
14	12	12	12	13	13	62

6. Results of outcome measures

Table TCA 7-3: TCA 7's PSS-14 & MYMOP



No.7's scores of the MYMOP outcomes decreased during the 8 weeks of the study and maintained stability except for “Activity” which did not change after the 5 weeks of TCA, and “Activity” and “Wellbeing” increased in 2 weeks after TCA. No.7's PSS-14 scores increased during the study period.

7. Participant's comments on the experience of the 5 week intervention period

“New job so more anxieties and premenstrual tension”

8. Comments and discussion from the researcher

The data for No.7's cortisol concentration was out of the reading range. The participant had cortisol concentrations over the normal assay range: 0.003ug/dL – 3.000ug/dL (0.083nmol/L – 82.77nmol/L) (Salimetrics LLC, 2006). Her results went up to 900nmol/L in which were unreadable by the machine. This was ten times over the normal human range. The researcher has contacted No.7 to double check. No.7 reported that she did not take medication, e.g. steroids, and did not use a hand-cream with hydrocortisone in it. She was also not experiencing any symptoms to suggest a medical reason for this result. Her cortisol data had to be excluded because it was so abnormal.

The results of the PSS-14 and MYMOP suggested that TCA treated her reported symptoms, seemed not control her stress levels.

No. 10 Female, 57 years old.

1. Date of starting the study

5th October 2005

2. Reasons for joining the study and case history

No.10 felt stressed for a long time because of her work. She had suffered from sinusitis for about 40 years. Her sinus symptoms kept re-occurring. She had a heavy cold for 4 days at the start of the study.

3. Major presenting symptoms

Insomnia (Symptom 1 in the MYMOP), heavy cold (Symptom 2 in the MYMOP), tiredness, lost the sense of smell, nose congestion, thick and yellow nose discharge, night sweats, hot flushes.

4. Life events occurring during intervention period

Table TCA10-1: Recent Life Events

No. 10	Events happened	Still affecting
Pre intervention	1	2
Post intervention	0	0
2 weeks post intervention	0	0

After 5-week TCA, No.10 was much less busy at work due to the timing of the study with respect to the university calendar. The atmosphere in the office was less stressful.

5. Intervention

No.10's TCM diagnosis was liver qi stagnation producing phlegm fire. The principle of TCA was to sooth liver and regulate qi, and clear heat and resolve phlegm. The acupoints used in the 5 sessions of TCA treatment were summarised in *Table TCA10-2*.

Table TCA10-2: Acupoints used in the 5 sessions of TCA treatment

Acupoint	Session 1	Session 2	Session 3	Session 4	Session 5	Total
DU20 (Baihui)	√	√	√	√	√	5
BL7 (Tongtian)	√	√	√	√	√	5
EX-HN3 (Yintang)	√	√	√	√	√	5
DU23 (Shangxing)		√	√	√	√	4
DU24 (Shenting)	√					1
LI20 (Yingxiang)		√				1
RN10 (Xiawan)		√	√			2
RN6 (Qihai)	√	√			√	3
RN4 (Guanyuan)	√	√	√	√	√	5
LI11 (Quchi)	√	√	√	√		4
PC6 (Neiguan)	√	√	√	√	√	5
LI4 (Hegu)	√	√	√	√	√	5
ST36 (Zusanli)	√	√	√	√	√	5
SP9 (Yinlingquan)				√	√	2
ST40 (Fenglong)		√	√			2
SP6 (Sanyinjiao)	√	√	√	√	√	5
LR3 (Taichong)	√	√	√	√	√	5
SP3 (Taibai)			√			1
GB41 (Zulinqi)	√	√	√	√	√	5
KI3 (Taixi)				√	√	2
20	13	16	15	14	14	72

After the first session of TCA, the participant could go to sleep with her mouth closed, though a heavy cold made her sinusitis worse. After the second session, her sense of smell had returned. She had been having this problem for a long time. She reported that she did not feel any stress. The improved sense of smell continued, and she reported “breathing is quieter and easier with the needles around my nose” during the TCA. Also in the last session, she told the researcher: “My husband said I am a lot calmer.”

6. Results of outcome measures

After the 5 weeks of TCA, No.10’s scores of the PSS-14 and MYMOP decreased. The MYMOP maintained stability at 2 weeks after TCA, while the PSS-14 slightly increased at the same period (see *Table TCA 10-3*).

Figure TCA10 shows that TCA10’s diurnal cortisol profiles in week 3 & 5 of the intervention period and 2 weeks after intervention had flattened patterns with the loss of morning surges. At other collecting dates the patterns of diurnal profiles of salivary cortisol concentration were normal and had sharp waking surges in mornings. Her cortisol concentrations were generally quite stable except for 3 profiles without morning rises and the profile in week1 of the intervention which showed that the cortisol concentration at second sample collecting points (30 minutes after awaking) was much lower than other collecting dates at the same collecting time point.

Table TCA10-3: TCA10’s PSS-14 & MYMOP

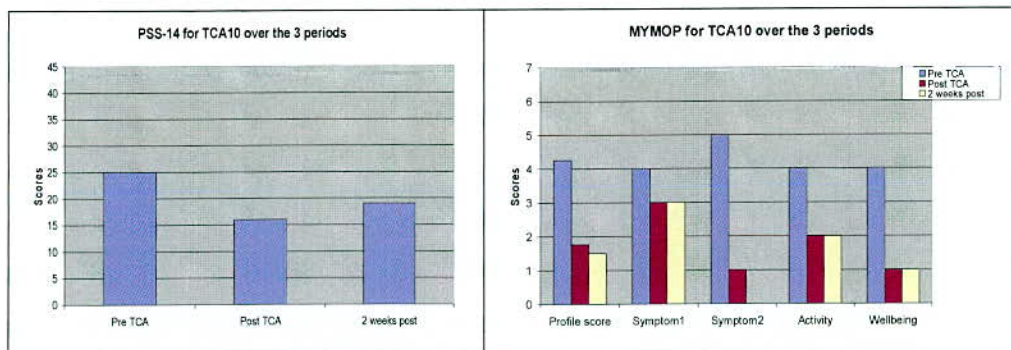
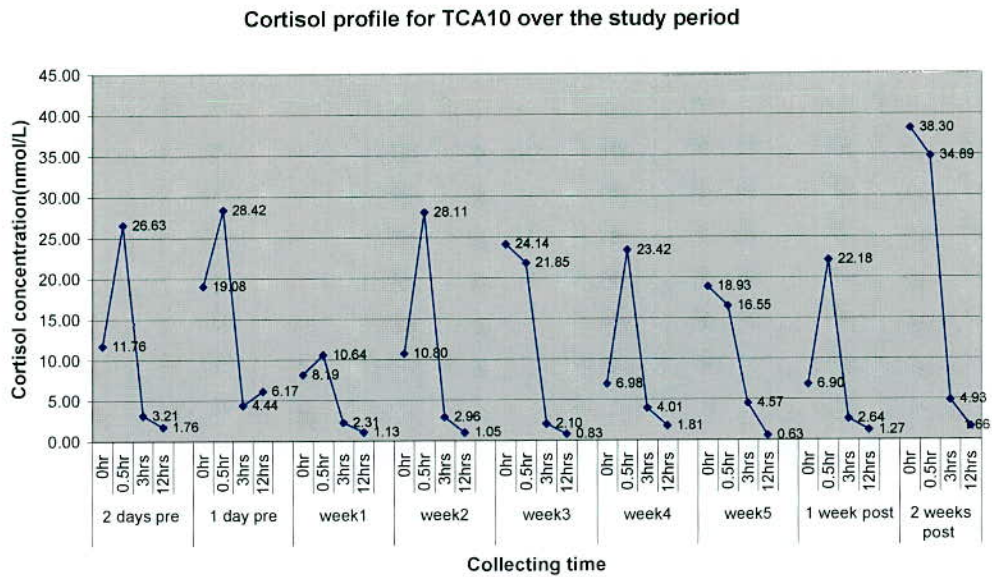


Figure TCA10: TCA10's diurnal profiles of salivary cortisol concentration on 9 collection dates



7. Participant's comments on the experience of the 5 week intervention period

"It is difficult to define the effect of the acupuncture treatment but I would say that I generally feel more positive about things. Members of my family have commented that I seem calmer at home and certainly at work I feel less stressed and have more patience in my dealings with the public.

For about 12 years I have had only an intermittent sense of smell and certainly over the past 4 or 5 years this has been almost non-existent. However, from the second acupuncture treatment my sense of smell has been greatly improved – I would estimate that I can smell about 60% of the time.

I found the sessions relaxing and my colleagues remarked on this when I returned to the office."

8. Comments and discussion from the researcher

The cortisol profile did not reflect the high stress levels she self-perceived as she felt more stress before TCA than after. Generally her cortisol responses were reactive except for week 3 & 5 of the intervention and 2 weeks after when the waking surges in morning disappeared, which might be due to something happened to her which affected her cortisol levels. The researcher did contact No.10 when he

was analysing the data for cortisol profiles. But she could not recount the precise events of these periods in which the results fluctuated because there was a long time between the time when she finished collecting the samples and the time when the researcher analysed the data. The time records for 3 abnormal profiles with a stress pattern showed TCA10 took samples between 6:20am and 6:35am (see 7.8.1 *Mean waking times on the day of sample collection for each group*). The reasons for the abnormal cortisol profiles might be caused by not taking the samples immediately when waking up, or the times when she took samples were not the first time of her awaking. All the abnormal profiles were at the latter part of the study, which might be because the participant did not take her samples on time. That was the first time that No.10 took TCA. She was very sensitive to the treatment and her response to TCA was positive, which was shown by the changes for the PSS-14 and the MYMOP and her subject feedback.

No. 14, Female, 44 years old.

1. Date of starting the study

30th January 2006.

2. Reasons for joining the study and case history

No. 14 felt more stressed since September 2003 as 2 of her 3 children were diagnosed with a life threatening condition.

3. Major presenting symptoms

Anxiety (Symptom 1 in the MYMOP), fearfulness (Symptom 2 in the MYMOP), tiredness and sleeping problems (having a lot of dreams, easily waking and feeling tired in the morning).

4. Life events occurring during intervention period

Table TCA14-1: TCA14's Recent Life Events

No. 14	Events happened	Still affecting
Pre intervention	0	5
Post intervention	0	4
2 weeks post intervention	0	4

No. 14 had a lot of problems with the hospital and her children's school. She had to take her children to the hospital regularly for routine investigations. Every time when she visited the hospital and the school she felt upset and stressed.

During the 5 weeks of TCA, she took one of her children to the hospital once. In 2 weeks after TCA, she had a meeting with her child's school teachers and there was a disagreement.

5. Intervention

No. 14's TCM diagnosis was liver qi stagnation and deficiency of gallbladder qi. The TCA was for soothing liver qi, and enriching and warming the gallbladder. The acupoints used in the 5 sessions of TCA treatment were summarised in *Table TCA14-2*.

Table TCA14-2: Acupoints used in the 5 sessions of TCA treatment

Acupoint	Session 1	Session 2	Session 3	Session 4	Session 5	Total
DU20 (Baihui)	√	√	√	√	√	5
EX-HN3 (Yintang)	√	√	√	√	√	5
DU24 (Shenting)	√	√	√	√	√	5
RN12 (Zhongwan)			√	√	√	3
RN10 (Xiawan)			√			1
ST25 (Tianshu)		√	√	√	√	4
RN6 (Qihai)		√	√	√	√	4
RN4 (Guanyuan)		√	√	√	√	4
LI11 (Quchi)	√	√	√	√	√	5
PC6 (Neiguan)	√	√	√	√	√	5
LI4 (Hegu)	√	√	√	√	√	5
HT7 (Shenmen)			√			1
ST36 (Zusanli)	√	√	√	√	√	5
GB34 (Yanglingquan)	√	√	√	√	√	5
ST40 (Fenglong)			√	√	√	3
SP6 (Sanyinjiao)	√	√	√	√	√	5
LR3 (Taichong)		√	√	√	√	4
GB40 (qiuxu)			√		√	2
LR2 (Xingjian)	√					1
GB41 (Zulinqi)	√	√		√		3
KI6 (Zhaohai)		√		√	√	3
21	11	15	18	17	17	78

During the 5-week TCA, she suffered from an eye infection, a cold and a bad experience in her child’s hospital. The treatments were concentrated on her current symptoms, for example, eye infection and cold. At the same time, the treatment was given for her stress.

6. Results of outcome measures

After the 5 weeks of TCA, No.14’s PSS-14 and MYMOP scales decreased during the treatment period except for “Wellbeing” in the MYMOP which was stable. But the MYMOP scales returned to baseline levels 2 weeks after treatment (see *Table TCA 14-3*).

Figure TCA14 shows that during the study period on 9 sample collecting dates, TCA14’s diurnal profiles of salivary cortisol concentration had waking surges in morning except for 1 week after the intervention when the morning rise was not evident.

Table TCA14-3: TCA14’s PSS-14 & MYMOP

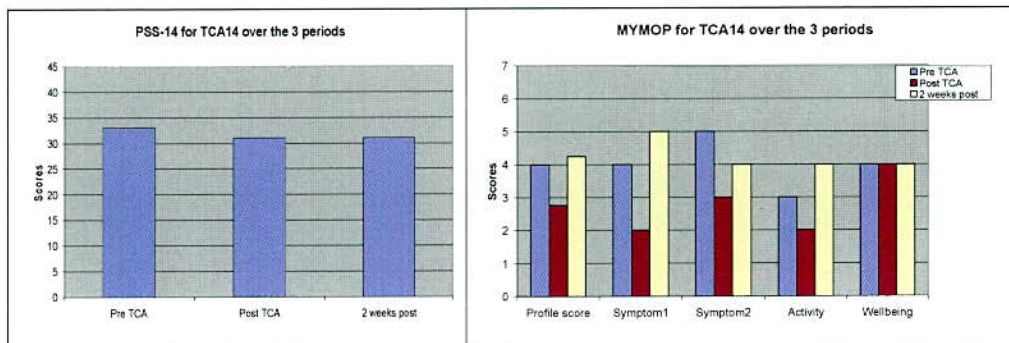
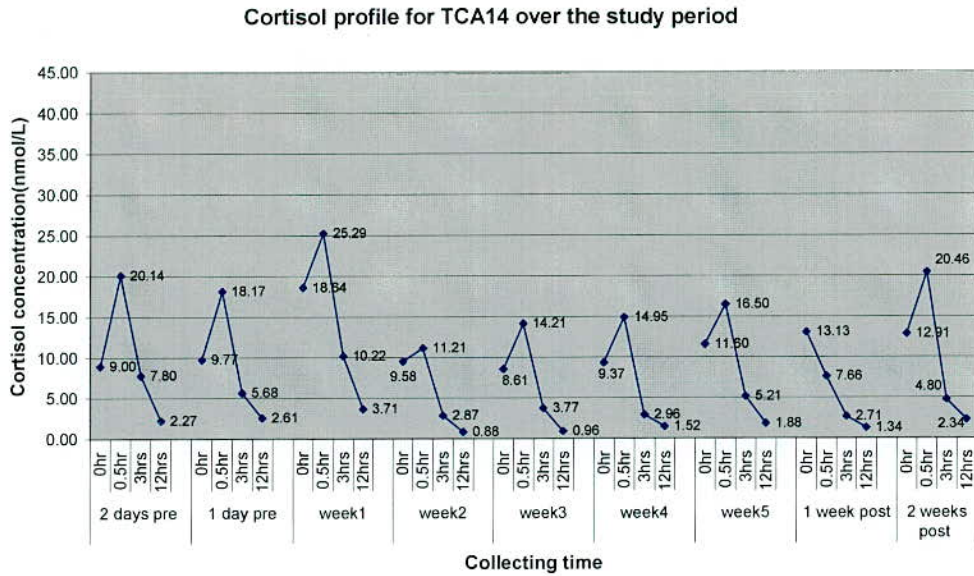


Figure TCA14: TCA14’s diurnal profiles of salivary cortisol concentration on 9 collection dates



7. Participant’s comments on the experience of the 5 week intervention period

No.14 wrote down in her MYMOP follow-up1: “I feel the acupuncture has helped my physical symptoms. My anxiety fluctuates and I am not sure about the affect although I am sleeping better and feel more rested.”

8. Comments and discussion from the researcher

The meeting with school teachers in 2 weeks after TCA affected No.14’s condition a lot, which could explain why the scales in the MYMOP follow-up 2 increased. Within the 5 weeks of TCA treatment, although No.14 suffered a lot of problems which affected her condition and stress level (see *Table TCA14-1*), her diurnal cortisol profiles did not reflect her self-reported high stress levels. The time record for collecting salivary samples showed in 1 week after the intervention. No.14 took the first sample at 7:45am, which was the latest collecting time during the study period. That could indicate that time might not be the first time of her waking or she could take the sample later than immediately waking up, which could explain why in 1 week after TCA the morning rise disappeared.

No. 17 Male, 43 years old

1. Date of starting the study

13th February 2006

2. Reasons for joining the study and case history

No.17 had had lower back pain for 3 months and gradually worse, and he felt more stressed in the last year because of his stressful job and the problems with his friends.

3. Major presenting symptoms

Back pain (Symptom 1 in the MYMOP), short temper (Symptom 2 in the MYMOP), increased worrying, and irritated skin.

4. Life events occurring during intervention period

Table TCA17-1: Recent Life Events

No. 17	Events happened	Still affecting
Pre intervention	0	3
Post intervention	0	1
2 weeks post intervention	1	1

During the 5-week TCA he was in charge of a new system at the university, and in the 2 weeks after TCA he had been offered a new post with a different employer.

On 9th March 2006 in the fourth week of TCA, No.17 started using the steroid cream which was described from his GP for his skin problem.

5. Intervention

No.17's TCM diagnosis was liver qi stagnation and blood stasis. The TCA treatment was for soothing liver and regulating qi, improving the circulation of qi and blood, and alleviating and stopping the pain. The acupoints used in the 5 sessions of TCA treatment were summarised in Table TCA17-2.

Table TCA17-2: Acupoints used in the 5 sessions of TCA treatment

Acupoint	Session 1	Session 2	Session 3	Session 4	Session 5	Total
DU20 (Baihui)			√	√	√	3
LI11 (Quchi)		√	√	√	√	4
GB34 (Yanglingquan)		√	√	√	√	4
SP6 (Sanyinjiao)	√	√	√	√	√	5
GB40 (qiuxu)					√	1
BL40 (Weizhong)	√	√	√	√	√	5
DU4 (Mingmen)	√		√		√	3
BL23 (Shenshu)	√	√	√	√	√	5
BL27 (Xiaochangshu)	√	√	√	√		4
BL24 (Qihaihu)			√		√	2
BL54 (Zhibian)			√	√		2
EX-B7 (Yaoyan)	√		√	√	√	4
EX-B2 (Jiaji)		√		√	√	3
13	6	7	11	10	11	45

At the beginning of the study, as No.17's back pain was worse than other symptoms, his treatment was concentrated on his back pain. At the same time, TCA helped his stress symptoms.

6. Results of outcome measures

No.17's PSS-14 scores decreased after the 5 weeks of TCA, while it slightly increased in the 2 weeks after TCA. The scores of the MYMOP outcomes decreased after the 5 weeks of TCA and in 2 weeks after except for "Wellbeing" in the MYMOP which maintained stability after the 5-week TCA and increased in 2 weeks after (see *Table TCA 17-3*).

In his MYMOP follow up 1 & 2, he wrote down some new symptoms, e.g. depression, negative outlook, unable to cope, dry mouth, upset stomach, and loss of sex drive.

Figure TCA 17 shows that No.17 had 2 cortisol profiles with the loss of the morning rises in week 2 & 3 of the intervention period. Other cortisol profiles had marked morning rises of cortisol concentration. The cortisol concentrations at the third collecting time point (3 hours after waking) in week 5 of the intervention and 1 week and 2 weeks after TCA were higher than the previous collecting dates at the same collecting time points.

Table TCA 17-3: TCA 17's PSS-14 & MYMOP

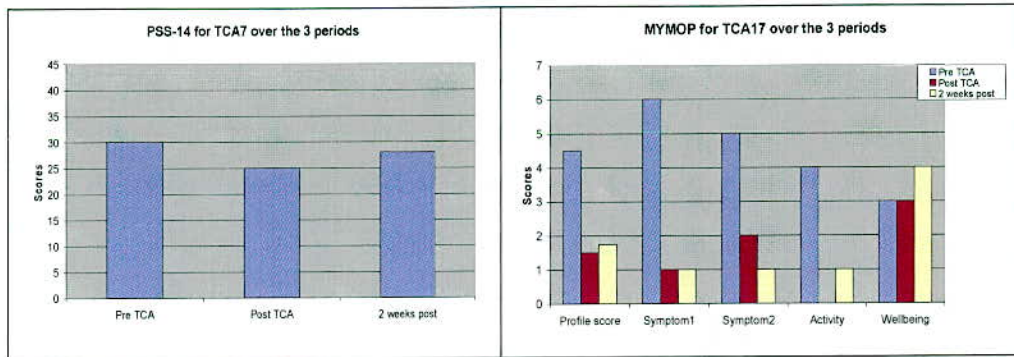
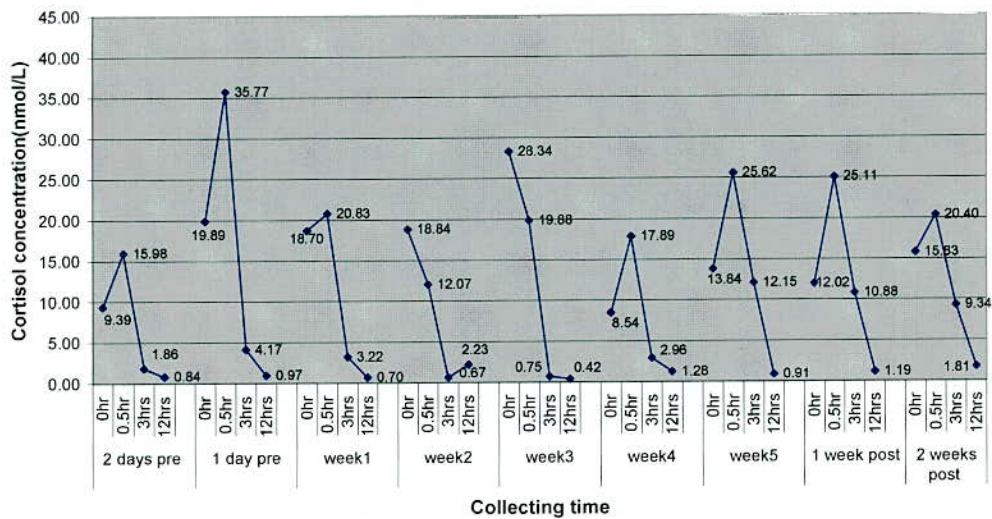


Figure TCA17: TCA17's diurnal profiles of salivary cortisol concentration on 9 collection dates

Cortisol profile for TCA17 over the study period



7. Participant's comments on the experience of the 5 week intervention period

“My back problem does seem to have improved I have noticed at different times in the day.” “Since offered new post I have been feeling down, depressed and anxious about making the right decision. It has affected my sleep, diet and general contentment.”

8. Comments and discussion from the researcher

When No.17 attended the interview for the involvement of the study, he only mentioned his stress rather than his back pain. But at the first time of TCA, he

complained he had a very bad back pain for 3 months which had become worse and worse. There had been no injury or accident. So he was not excluded in this study.

During the 5 weeks of TCA, No.17 suffered from a skin problem which affected his sleep and his general condition, and he had to use the steroid cream from his GP. Also he had a new work in the university and was facing a career change during the 5 weeks of TCA. All these resulted in increased PSS-14 scores. But his diurnal cortisol profile patterns, which had morning rises during the later TCA intervention and after TCA, did not reflect his self-perceived high stress levels. This suggested that TCA may help to manage the stress levels through the HPA. The high cortisol concentrations at the third collecting time point (3hours after waking) in week 5 of the intervention and 1 week and 2 weeks after TCA suggested that No.17 may be eating or drinking before taking his samples and was not following the instructions to wait 30 minutes after eating or drinking. This could have increased the cortisol concentration.

No.17 was the only case where the treatment was concentrated on the back pain rather than stress. In addition, he was the only participant in the study who experienced new stressful event (changing job) which lasted longer and covered the whole study period; the only participant that had to see his GP and took treatment during the 8 weeks' study; and the only participant in the TCA group who reported new symptoms in the MYMOP following 1 & 2 questionnaires (see 7.6.1 *Symptoms reported in the MYMOP*). Because TCA was concentrated on No. 17's back pain, he had to keep lying down on his stomach during the treatment. Acupoints and the position may have affected the results of the treatment for other symptoms.

8.2 Attention group

No. 2 Female, 35 years old.

1. Date of starting the study

5th September 2005

2. Reasons for joining the study and case history

No. 2 had felt stressed for 10 years because of her work and life.

3. Major presenting symptoms

Insomnia (Symptom1 in the MYMOP), forgetful, restlessness.

4. Life events occurring during intervention period

Table Attention 2-1: Recent Life Events

No. 2	Events happened	Still affecting
Pre intervention	0	0
Post intervention	1	0
2 weeks post intervention	0	0

There was nothing affected No. 2 during the 8 weeks of the study.

5. Intervention

No.2 needed the researcher to remind her on one occasion to come the attention session.

For the arrangement of the attention sessions see 6.2.7 *Intervention period*.

6. Results of outcome measures

There were small fluctuations in the scales of the PSS-14 and MYMOP. At the end of the intervention, there was a reduction in the PSS-14 and MYMOP scores, but by the 2 weeks after the attention, all of the scales were higher than previous 2 periods (see *Table Attention2-2*).

Figure Attention 2 shows that No.2’s diurnal salivary cortisol profiles had waking surges in mornings during the study period except for the first (2 days before the intervention) and last (2 weeks after the intervention) samples collecting dates when the cortisol profiles showed no morning rises.

Table Attention 2-2: Attention 2’s PSS-14 & MYMOP

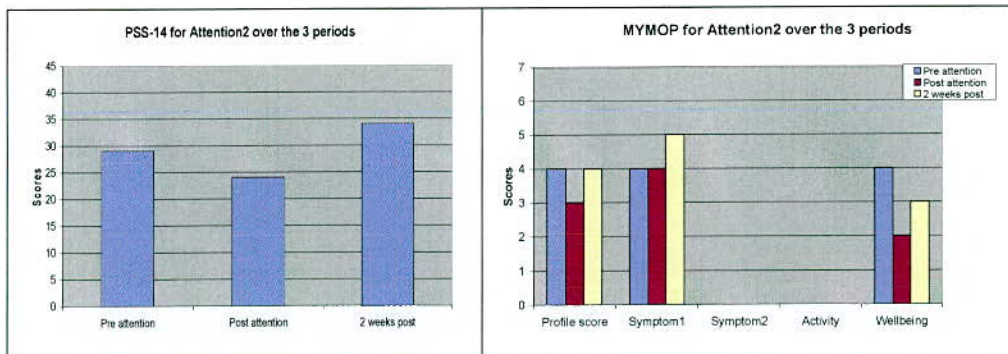
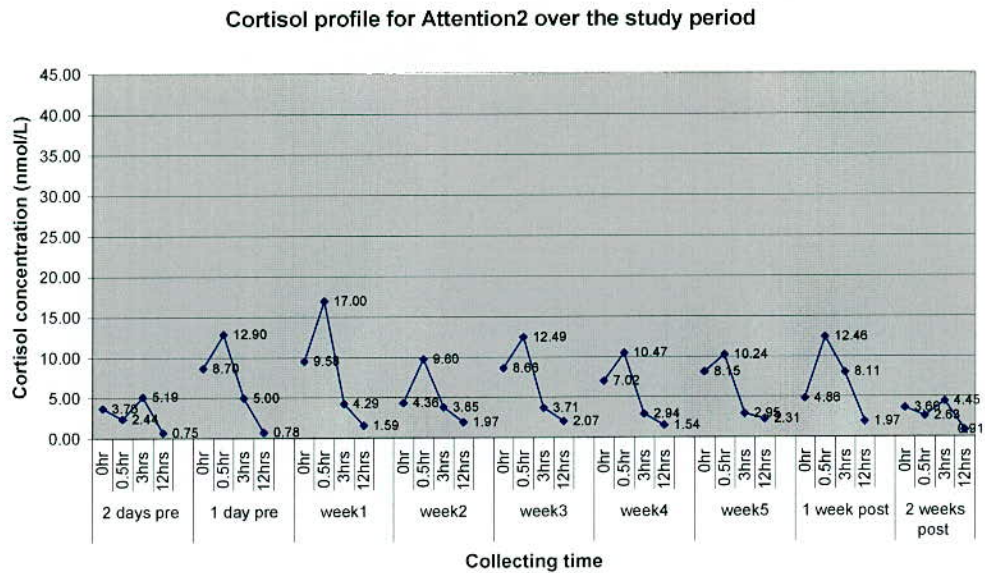


Figure Attention 2: Attention 2’s diurnal profiles of salivary cortisol concentration on 9 collection dates



7. Participant’s comments on the experience of the 5 week intervention period

“I found the relaxation did not make much difference as I found myself thinking of the things I needed to do when I got back to work,”

8. Comments and discussion from the researcher

Generally No.2’s scores of the PSS-14 and MYMOP decreased after the 5 weeks of the attention, but increased in 2 weeks after.

No.2’s cortisol profiles did not reflect her self-reported high stress levels before she started the study. The abnormal patterns of 2 cortisol profiles at the first and the last collecting dates might be caused by her not taking samples on time, though exact times which she recorded in the time-record sheets were similar to other collecting dates (see 7.8.1 Mean waking times on the day of sample collection for each group).

No. 4 Male, 29 years old

1. Date of starting the study

16 January 2006

2. Reasons for joining the study and case history

No.4 had felt stressed for 8 years and felt worse for 2 years because of his work, study and financial circumstances.

3. Major presenting symptoms

Headaches (Symptom 1 in the MYMOP), sleeping pattern (Symptom 2 in the MYMOP).

4. Life events occurring during intervention period

Table Attention 4-1: Attention4's Recent Life Events

No. 4	Events happened	Still affecting
Pre intervention	0	6
Post intervention	0	2
2 weeks post intervention	1	0

After the 5 weeks of the attention, No. 4 still had 2 things affecting him. But he did not think that they were as bad as before. In the third week, No.4 had a cold and took paracetamol for 4 days. That cold left cough until he finished the 5 weeks of the attention.

Two weeks post intervention, No.4 was "dating a fantastic woman" which he wrote down on the follow-up 2 Recent Life Events Questionnaire.

5. Intervention

No.4 needed the researcher to remind him twice to come to the attention sessions. For the arrangement of the attention sessions see 6.2.7 *Intervention period*.

6. Results of outcome measures

The scores of the PSS-14 and MYMOP decreased after 5 weeks' attention except for "Activity" which was the same as baseline. The reduction was maintained stability in 2 weeks after the intervention period.

Figure Attention 4 shows the diurnal cortisol profiles had morning waking rises except for 2 days before the intervention and week 4 of the intervention. The cortisol concentrations at the fourth collecting point on 2 days before the intervention and the third collecting points in week 1 & 3 of the intervention, and 1 week after the intervention were higher than other profiles on other collection dates.

Table Attention 4-2: Attention 4's PSS-14 & MYMOP

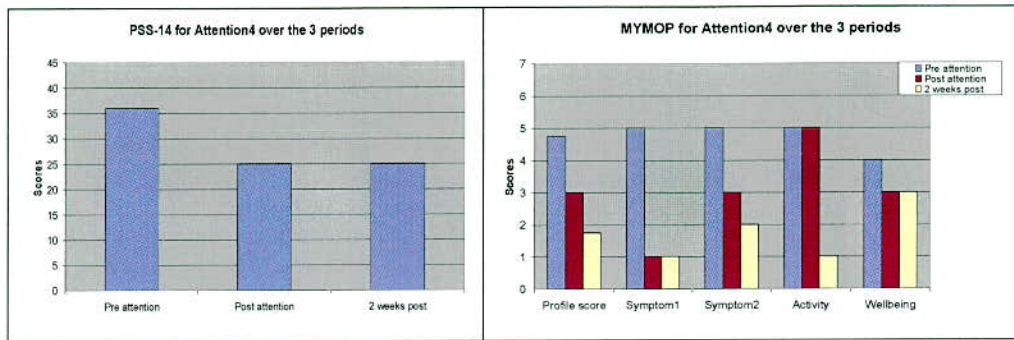
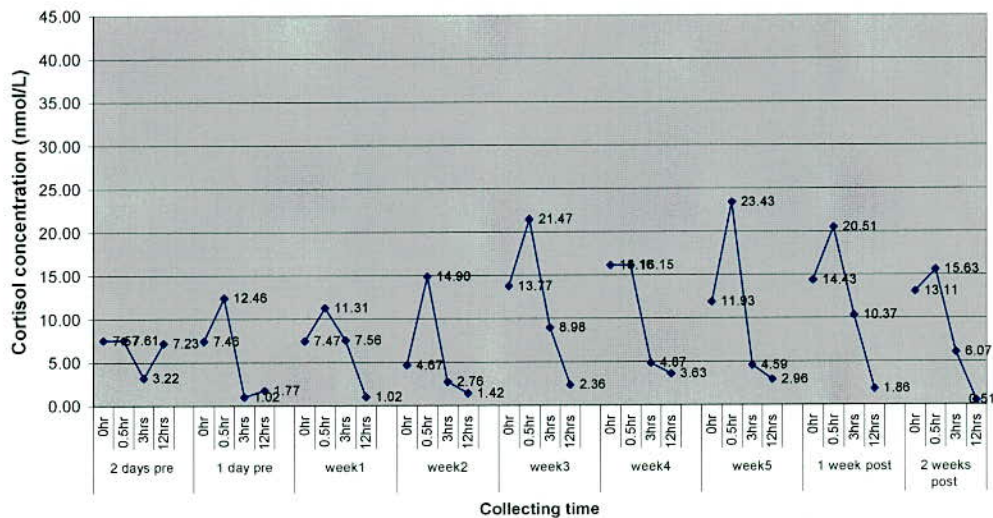


Figure Attention 4: Attention 4's diurnal profiles of salivary cortisol concentration on 9 collection dates

Cortisol profile for Attention4 over the study period



7. Participant's comments on the experience of the 5 week intervention period

“The effects of the relaxation therapy have been short-lived, i.e. 1 hour after the session I have felt as before, but have still been beneficial to me.”

8. Comments and discussion from the researcher

Although No.4 did not think the effects of the attention for a longer time, the PSS-14 and MYMOP scores declined after the 5 weeks of the attention intervention as well as after 2 weeks post intervention. His positive result of the PSS and MYMOP

may have been due to a non-specific effect as he might believe that “relaxation” intervention was helpful for stress.

No.4’s cortisol profile did not reflect his perceived high stress level before the intervention period. The disappeared morning rises in the profiles of 2 days before intervention and week 3 of the intervention could be caused by not taking the first samples immediately when waking up. The time record for collecting samples showed that in 1 week after the intervention No.4 took the third sample at 2 hours after waking instead of 3 hours after waking. This can explain the higher cortisol concentration at that time point. The higher cortisol concentrations at the fourth collecting point on 2 days before the intervention and the third collecting points in week 1 & 3 of the intervention suggested that No.4 may have eaten or drunk before providing the salivary samples which could have increased the cortisol concentrations.

No. 8 Female, 42 years old

1. Date of starting the study

3rd October 2005

2. Reasons for joining the study and case history

No. 8 had felt stressed since November 2002 when her daughter was born. She had felt much more stressed over the last year.

3. Major presenting symptoms

Anxiety leading to chest pain (Symptom 1 in the MYMOP), stomach ache (Symptom 2 in the MYMOP), difficulty in falling asleep, waking up easily, and worrying.

4. Life events occurring during intervention period

Table Attention 8-1: Recent Life Events

No. 8	Events happened	Still affecting
Pre intervention	0	1
Post intervention	0	2
2 weeks post intervention	1	1

In the first week of the study, No.8 once took her daughter to the hospital due to an emergency by ambulance because of her abdominal pain. In the fourth week her car was broken into. These two things made her worry a lot and feel more stressed.

5. Intervention

No.8 attended the 5 attention sessions on time. For the arrangement of the attention sessions see 6.2.7 *Intervention period*.

When No.8 attended the attention sessions, she seemed have a lot of things happening in her life and wanted to talk, and had difficulty in keeping calm. She complained 3 times during 5 attention sessions that her sleeping was very bad particularly when she reported two stressful events that had happened.

6. Results of outcome measures

After the 5 weeks of the attention intervention the scores of the PSS-14 and Symptom 1 and 2 in the MYMOP decreased a little, “Activity” and “Wellbeing” in the MYMOP maintained the same (see *Table Attention 8-2*).

Figure Attention 8 shows that there were no morning waking surges in No.8’s diurnal cortisol profiles during the study period except for week 4 of the intervention when the profile had a morning rise. In week 3 of the intervention Attention 8 missed providing the sample immediately upon waking in the morning.

Table Attention 8-2: Attention 8’s PSS-14 & MYMOP

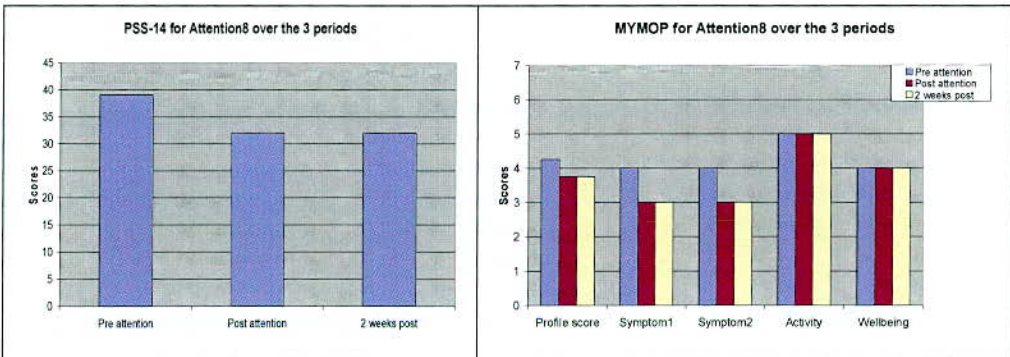
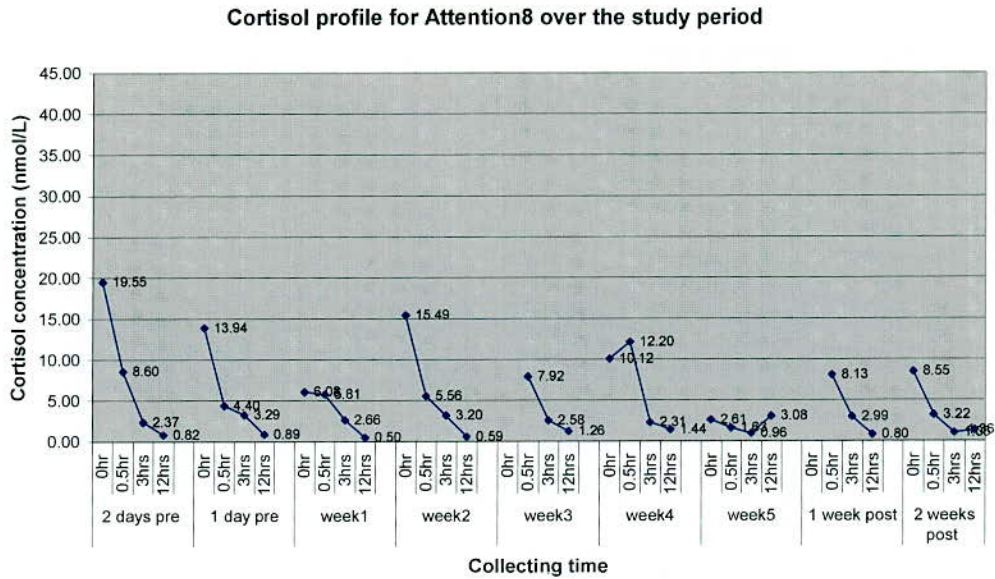


Figure Attention 8: Attention 8’s diurnal profiles of salivary cortisol concentration on 9 collection dates



No.8 missed collecting samples in week3 of the 5 week attention and 1 week after attention when immediately upon waking in the morning

7. Participant’s comments on the experience of the 5 week intervention period

“Experience was pleasant to rest at lunch time and talk to a professional doctor giving advice. I sometimes was so tired, I felt asleep for 15 minutes! Do not think, somehow that this relaxation once a week only, will make a different on my stress levels.”

8. Comments and discussion from the researcher

During the study, No.8 seemed very stressed which may have been reflected by the cortisol profile without waking surges. The data at first collecting points was very high showed that she had not properly slept before she took the samples. This was correlated with her self-reported complaints of the bad sleep.

No.12 Female, 58 years old.

1. Date of starting the study

20th January 2007

2. Reasons for joining the study and case history

No. 12 had felt stressed for 5 years and it had been particularly worse for the last year. She had separated from her husband and was going through divorce.

3. Major presenting symptoms

Irritation (Symptom 1 in the MYMOP), loss of interest in anything (Symptom 2 in the MYMOP), tiredness after getting up in the morning, impatient, depressed, not feeling happy, eating more sweet things.

4. Life events occurring during intervention period

No.12 and her husband were still living in a same house and saw each other every day. Every day when she went back home she felt very stressed.

After the intervention period, her husband was made redundant which would bring housing problems. But after one week he got a new job.

Table Attention12-1: Recent Life Events

No. 12	Events happened	Still affecting
Pre intervention	0	4
Post intervention	2	2
2 weeks post intervention	0	1

5. Intervention

No. 12 attended 5 attention sessions on time. For the arrangement of the attention sessions see 6.2.7 *Intervention period*.

During the 5 weeks of the attention intervention, her problems were up and down but always in the background. In week 3 of the 5 week intervention period, she injured her right wrist.

6. Results of outcome measures

No.12's PSS-14 scale declined after 5 week intervention period but increased in 2 weeks after. Her MYMOP scales kept decreasing (see *Table Attention12-2*).

Figure Attention 12 demonstrates that No.12 had very high cortisol concentrations at the first 2 collection time points in the morning for the first 3 collection dates (2 days and 1 day before the intervention period, and week1 in the intervention). During the 5 week intervention period, the cortisol concentrations declined. A morning rise in her diurnal cortisol profile appeared in week 2 & 5 of the attention intervention and 1 week and 2 weeks after.

Table Attention 12-2: Attention 12's PSS-14 & MYMOP

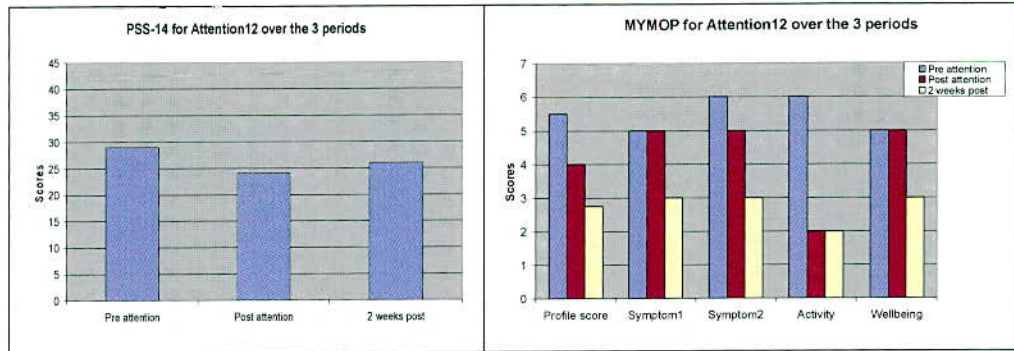
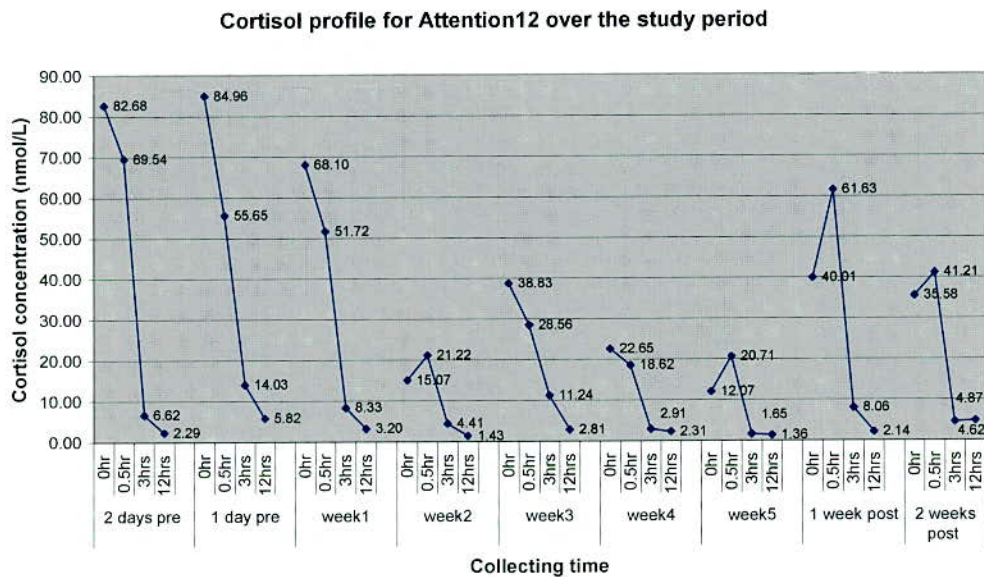


Figure Attention 12: Attention 12's diurnal profiles of salivary cortisol concentration on 9 collection dates



7. Participant's comments on the experience of the 5 week intervention period

"I was sleeping better and able to cope with sleep. Then last week my husband was made redundant and this produced worries – financial, stress, future problems, etc. Hopefully by next week he will be employed again."

8. Comments and discussion from the researcher

At the first visit for the attention intervention, No.12 looked very irritated and impatient. During the 5 weeks of the attention intervention, she looked more and

more relaxed and patient. Her husband's redundancy made her worried a lot in a short term. As he was employed again shortly afterwards, that event seemed not to affect her too much.

Attention 12 had the highest cortisol concentrations at the first 2 collection time points in the mornings at baseline and week 1 in the intervention period for all 17 participants whose salivary samples were used in the study. The scale of the figure used in No.12's cortisol profile was 90.00nmol/L rather than 35.00nmol/L which was used in the figures for other 16 participants' cortisol profiles. High cortisol concentration in the morning before the intervention period and the flattened cortisol profile indicated that No.12 was very stressed and did not sleep properly. According to No.12's history and the events record, she did suffer from a high level of stress, as well as an exaggerated response to stress. During the study, No.12's stressful environment improved and she did feel less stressed at the end of the study. Those were reflected by that the cortisol concentrations declined and a morning waking rise in her diurnal profile of salivary cortisol concentration appeared in week 2 & 5 of the intervention period and 2 weeks after.

From No.12's comments and all other outcome measures, she seemed to have had some improvement during the 5 weeks of the attention intervention. This may have in part been due to a non-specific effect, as there was the opportunity for her to speak with the same person every week about her health. She believed that "relaxation" intervention that she was involved in the study could have influenced her to approach to her health. Also No.12's stressful environment did improve as the study went on.

No.15 Female, 57 years old.

1. Date of starting the study

31st January 2006

2. Reasons for joining the study and case history

No.15 had felt stressed since 1995 because of her work and life.

3. Major presenting symptoms

“Sweet eating” (compulsive need to eat sweets) (Symptom 1 in the MYMOP), restlessness (Symptom 2 in the MYMOP), tiredness, difficulty in falling asleep.

4. Life events occurring during intervention period

Table Attention15-1: Recent Life Events

No. 15	Events happened	Still affecting
Pre intervention	0	2
Post intervention	0	0
2 weeks post intervention	0	0

No.15 reported she had not experienced special stressful life events during the 5 weeks of the attention intervention period and in the 2 weeks after the intervention period. In fact, she lived far from her work and the fact that she had to drive a long distance to the work place nearly every day was stressful. Her work made her very stressed and affected her a lot. Sometimes she had to work from 7am to 11pm and sometimes at the weekends. She could also receive a phone call concerning the work in the early morning (5am).

5. Intervention

No.15 attended 5 attention sessions on time. For the arrangement of the attention sessions see 6.2.7 *Intervention period*.

In the first week, No.15 had a cold. The stressful work made her stress levels vary. Sometimes some new symptoms appeared, e.g. palpitations, stiff and tight face and head.

6. Results of outcome measures

After the 5 weeks of the attention intervention, No.15's PSS scale increased. But the scales of the MYMOP decreased after the attention intervention and 2 weeks after (see *Table Attention 15-2*).

Figure Attention 15 shows that the cortisol concentrations were stable over the study period and there were normal morning waking rises in her diurnal cortisol profiles over the whole study period except for week 3 of the attention intervention when the morning rise disappeared.

Table Attention 15-2: Attention 15's PSS-14 & MYMOP

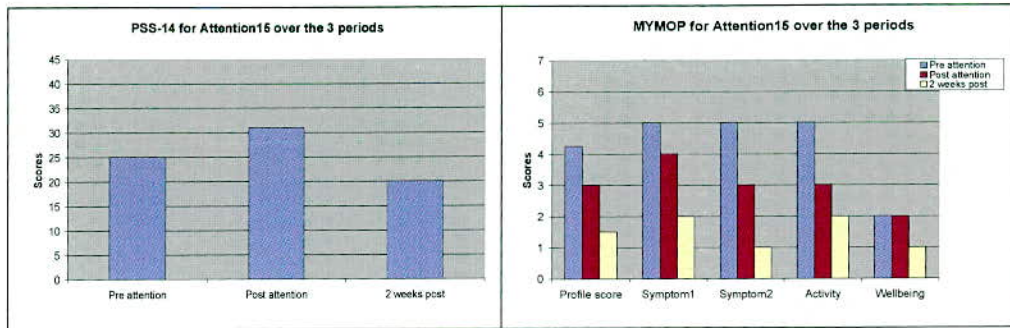
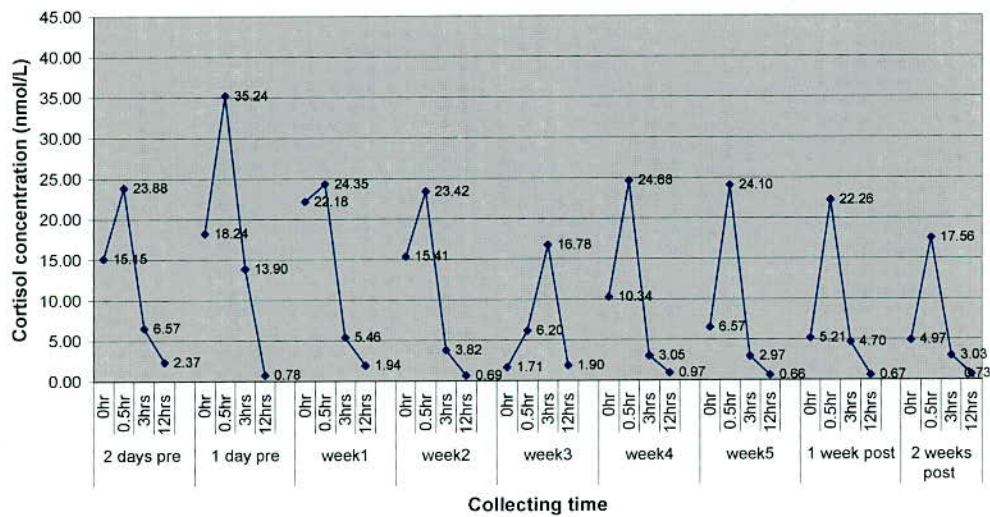


Figure Attention 15: Attention 15's diurnal profiles of salivary cortisol concentration on 9 collection dates

Cortisol profile for Attention15 over the study period



7. Participant's comments on the experience of the 5 week intervention period

"Relaxation group – felt it easier to relax as time went on, realising the benefit. All excessive work has now been accomplished, as deadlines have been met."

8. Comments and discussion from the researcher

During 8 weeks study, No.15 seemed very stressed due to her busy and stressful work and her symptoms of stress came and went, sometimes she had some new symptoms.

No.15's diurnal cortisol profiles illustrated that her hypothalamic-pituitary-adrenal (HPA) was reactive and there were sharper morning rises in her cortisol profiles over the 8 weeks of the study. All these did not reflect her self-perceived high stress levels. The abnormal cortisol profile in week 1 of the attention intervention could be caused by using the wrong tube to collect sample.

No. 16 Female, 50 years old.

1. Date of starting the study

31st January 2007

2. Reasons for joining the study and case history

No.16 had felt stressed, and it had been up and down during the last 3 years due to her work and life.

3. Major presenting symptoms

Annoyance (Symptom 1 in the MYMOP), aggression (Symptom 2 in the MYMOP), difficulty in falling asleep and waking easily, irritability.

4. Life events occurring during intervention period

Table Attention16-1: Recent Life Events

No. 16	Events happened	Still affecting
Pre intervention	0	3
Post intervention	0	0
2 weeks post intervention	0	0

During the 5 week attention intervention period and 2 weeks after the intervention period, No. 16 did not report any stressful life events which had affected her.

5. Intervention

No. 16 attended attention sessions on time. For the arrangement of the attention sessions see *6.2.7 Intervention period*.

In the first week of the attention, No.16 forgot to move her car in the street on time and had to pay a £40.00 penalty after the attention session.

6. Results of outcome measures

Table Attention 16-2 shows that the scales of the PSS-14 and MYMOP progressively decreased over the study period.

The cortisol concentrations over the study period were low. There were morning rises in cortisol profiles on most of collecting dates, except for week 2 of the intervention and 1 week and 2 weeks after (see *Figure Attention 16*).

Table Attention 16-2: Attention 16's PSS-14 & MYMOP

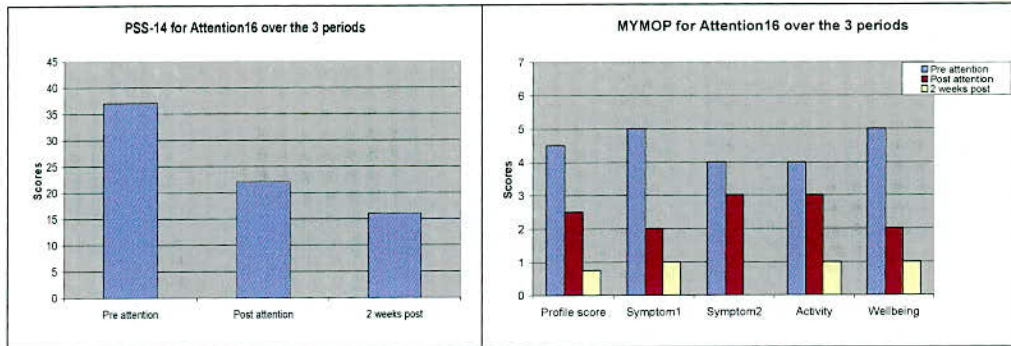
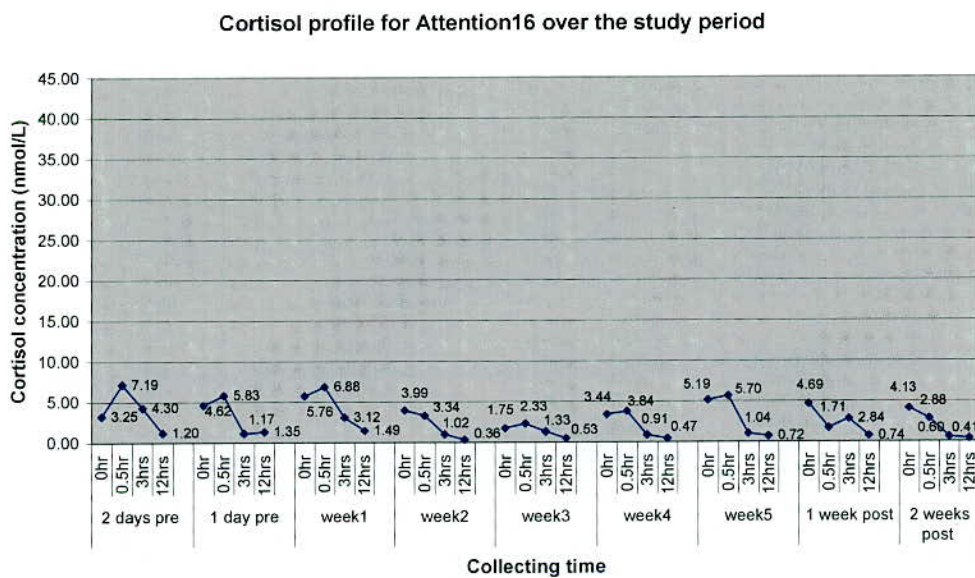


Figure Attention 16: Attention 16's diurnal profiles of salivary cortisol concentration on 9 collection dates



7. Participant's comments on the experience of the 5 week intervention period

“During the past two weeks, work pressures have decreased, leaving me more time free in the evening and weekends to spend with family; rather than working. I go to bed more relaxed.”

“It has been good to take time out for myself, a rare treat when most of my time is spent with or doing things for others. Thank you.”

“Reason for improvement: reduced work load able to achieve planned activities in required timetable and less work taken home in the evening and weekends.”

8. Comments and discussion from the researcher

During the intervention period and 2 weeks after the intervention, No. 16 had not experienced a stressful life event, and she felt her stress levels had got better and better. After the 5 weeks of the attention, her feedback was more positive. It is likely that because of the genetic environmental effects her body’s cortisol level was low compared to other participants in the study and did not positively reflect her changes in stress levels over the study period.

8.3 Control group

No.1 Female, 29 years old.

1. Date of starting the study

5th September 2005

2. Reasons for joining the study and case history

No.1 had felt stressed for 1 year because of daily pressure.

3. Major presenting symptoms

Tiredness (Symptom 1 in the MYMOP), worrying, difficulty in falling asleep.

4. Life events occurring during intervention period

Table Control1-1: Recent Life Events

No. 1	Events happened	Still affecting
Pre intervention	1	2
Post intervention	1	1
2 weeks post intervention	0	0

During the third week of the intervention period, No. 1 had an argument with her friend.

5. Intervention

Control participant. Every week the researcher went to No.1’s work place to collect the salivettes.

6. Results of outcome measures

Table Control 1-2 shows that the PSS-14 score declined after the intervention period and 2 weeks afterwards. But after the 5 week intervention period, the MYMOP scores increased except for “Wellbeing” which remained stable. By 2 weeks after the intervention period, all scales in the MYMOP declined.

During the study period, the morning rises in Control 1’s diurnal profiles of salivary cortisol concentration appeared variable. There was no a waking rise in week 2, week 3 and week 5 of the intervention period, and 2 weeks after the intervention. The cortisol concentrations were higher at the third time collecting point on 2 days before the intervention, in week 2 of the intervention and 1 week after than other collecting dates (see *Figure Control 1*).

Table Control 1-2: Control 1’s PSS-14 & MYMOP

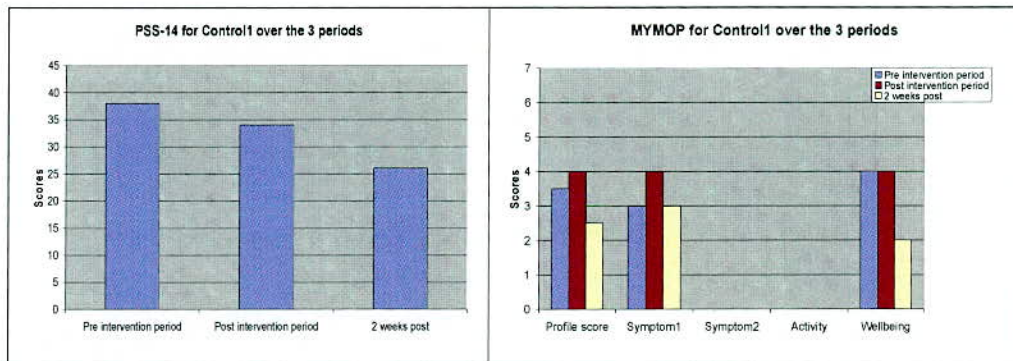
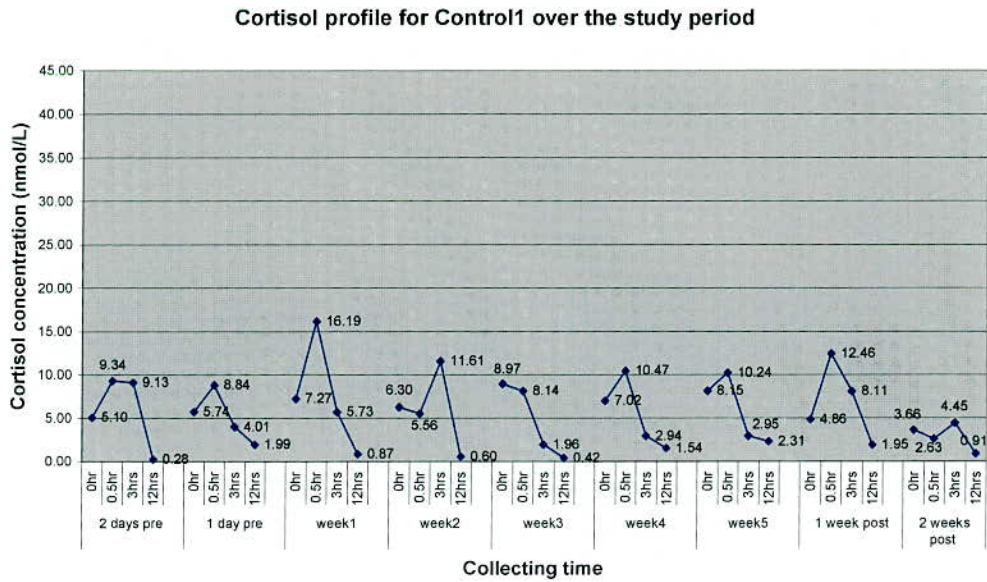


Figure Control 1: Control 1's diurnal profiles of salivary cortisol concentration on 9 collection dates



7. Participant's comments on the experience of the 5 week intervention period

"I have had an argument with a very close friend. It is not yet quite resolved. This has been very upsetting and stressful."

8. Comments and discussion from the researcher

The results of the PSS-14 and MYMOP were not correlated as after the intervention period the PSS-14 score declined while the MYMOP scores went up. No.1's cortisol profiles patterns were variable. It is difficult to interpret the relationship between the cortisol profiles' patterns and stress levels. The abnormal patterns could be caused by not taking the sample on time though the timing of collecting the samples was reported similar (see 7.8.1 Mean waking times on the day of sample collection for each group).

No. 5 Male, 19 years old.

1. Date of starting the study

7th September 2005

2. Reasons for joining the study and case history

No.5 had felt more stressed for 5 months because of his health condition and his life.

3. Major presenting symptoms

Skin allergies (Symptom 1 in the MYMOP), asthma (Symptom 2 in the MYMOP), tiredness, difficulty in falling asleep.

4. Life events occurring during intervention period

Table Control 5-1: Recent Life Events

No. 5	Events happened	Still affecting
Pre intervention	2	4
Post intervention	0	2
2 weeks post intervention	0	1

No. 5 was young and from Australia. He had asthma when he was 3 years old, and had skin allergies when he was 13 years old. At the time when he was recruited in the study, he had some financial problems.

5. Intervention

Control participant. Every week the researcher went to No.5's work place to collect the salivettes.

6. Results of outcome measures

After the 5 week intervention period, though No.5's PSS-14 score increased and the scales of the MYMOP decreased except for "Symptom2" which kept stable. In two weeks later the intervention period, the scores of the PSS-14 and "Symptom 2" in the MYMOP reduced, "Symptom 1" remained stable, and other outcomes went up (see *Table Control 5-2*).

Figure Control 5 does not show special patterns in No.5's diurnal cortisol profiles.

Table Control 5-2: Control 5's PSS-14 & MYMOP

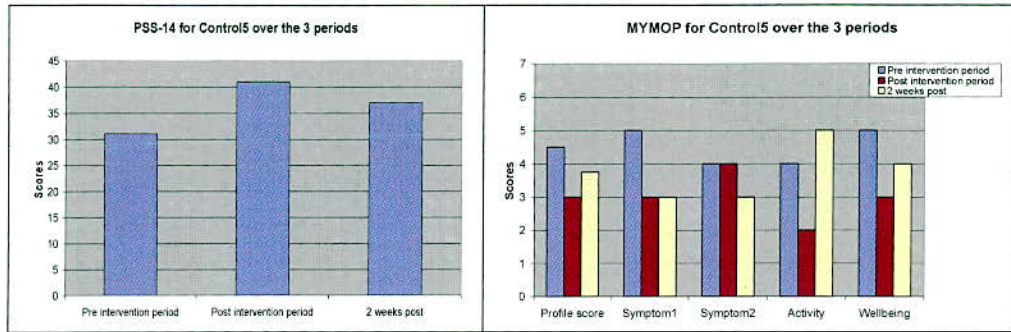
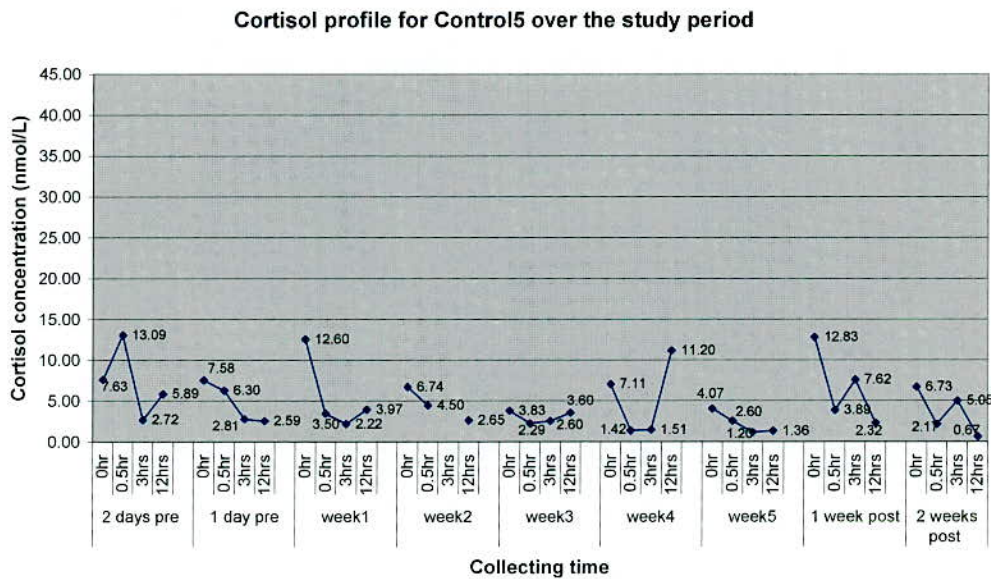


Figure Control 5: Control 5's diurnal profiles of salivary cortisol concentration on 9 collection dates



7. Participant's comments on the experience of the 5 week intervention period

"None."

8. Comments and discussion from the researcher

The diurnal profiles of salivary cortisol concentration without special patterns during the study indicated that No.5 did not collect salivary samples on time at total.

No. 9 Female, 52 years old.

1. Date of starting the study

5th October 2005

2. Reasons for joining the study and case history

No. 9 had felt stressed since 2003 because of her job.

3. Major presenting symptoms

Sleeping problems (Symptom 1 in the MYMOP), restlessness (Symptom 2 in the MYMOP), changes in bowel movements, irritability.

4. Life events occurring during intervention period

Table Control 9-1: Recent Life Events

No. 9	Events happened	Still affecting
Pre intervention	0	0
Post intervention	0	0
2 weeks post intervention	0	0

There were no any life events reported by No.9.

5. Intervention

Control participant. Every week the researcher went to No.9's work place to collect the salivettes.

6. Results of outcome measures

After the 5 week intervention period, the PSS-14 increased. The scores of the MYMOP outcomes remained the same in the follow up investigations except for "Symptom1" which decreased at the end of the study.

Generally No.9's cortisol profiles exhibited morning rises during the study, except for week 1 after the intervention period when the morning rise of the cortisol profile disappeared.

Table Control 9-2: Control 9’s PSS-14 & MYMOP

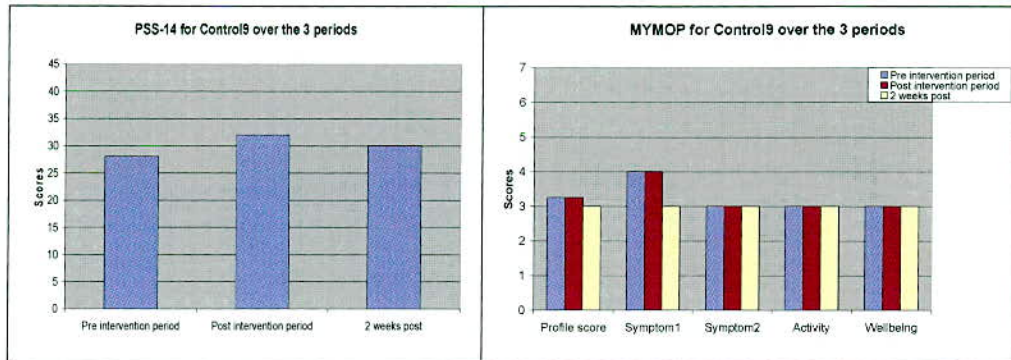
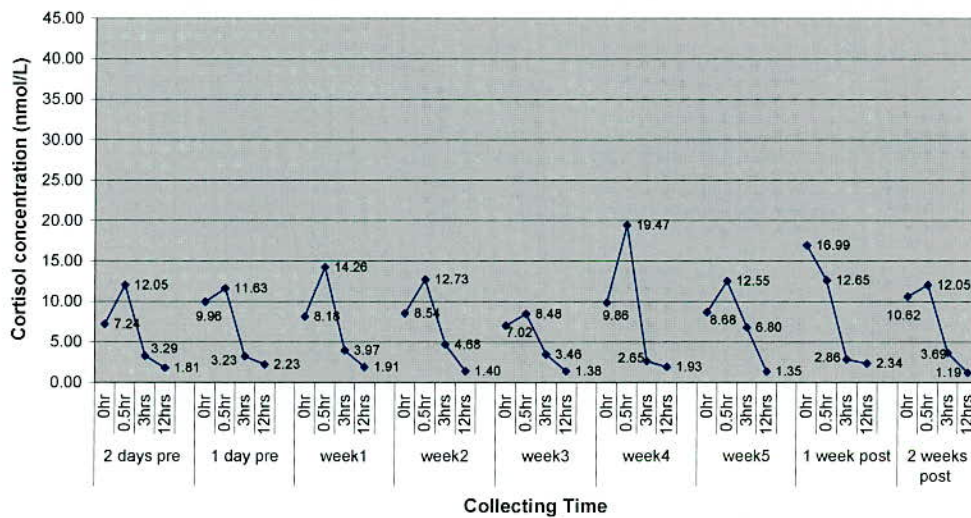


Figure Control 9: Control 9’s diurnal profiles of salivary cortisol concentration on 9 collection dates

Cortisol profile for Control9 over the study period



7. Participant’s comments on the experience of the 5 week intervention period

“No change!”

8. Comments and discussion from the researcher

The MYMOP scores did not show big changes though the PSS-14 was higher than baseline.

During the 5 week intervention period, No.9’s cortisol profiles did not reflect her self-reported increasing stress levels. The flattened cortisol profile in week 1 after

the intervention period indicated that control 9 might not be taking the sample immediately when waking up.

No. 11 Female, 29 years old

1. Date of starting the study

11 October 2005

2. Reasons for joining the study and case history

No.11 had felt stressed for 5 years and had been worse during the last month before the study, mainly because of her life.

3. Major presenting symptoms

Angry (Symptom 1 in the MYMOP), tiredness (Symptom 2 in the MYMOP), easily woken during the night, irritability.

4. Life events occurring during intervention period

Table Control 11-1: Control 11's Recent Life Events

No. 11	Events happened	Still affecting
Pre intervention	2	6
Post intervention	0	0
2 weeks post intervention	1	1

Before the study, No.11's husband's operation caused a lot of financial problems to her family. She had to do much more housework and look after him. Also she did not get along well with her sister whom she lived with, they had many arguments. This made her very stressed.

In the week 3 of the intervention period, No.11's husband started working and at the same time she got along better with her sister.

After the intervention period the problem with her sister returned.

5. Intervention

Control participant. Every week the researcher went to No.11's work place to collect the salivettes.

6. Results of outcome measures

After the 5 week intervention period, the scales of the PSS-14 and the MYMOP declined apart from "Symptom 1" in the MYMOP remained unchanged and "Activity" went up.

In 2 weeks after, the scores of the PSS-14 and “Wellbeing” in the MYMOP increased, “Activity” in the MYMOP declined and other outcomes in the MYMOP maintained stable.

Before and during the 5 week intervention period, the diurnal cortisol profiles did not change more and had morning rises. On the last 2 collecting dates, the morning rise of the cortisol profiles disappeared.

Table Control 11-2: Control 11’s PSS-14 & MYMOP

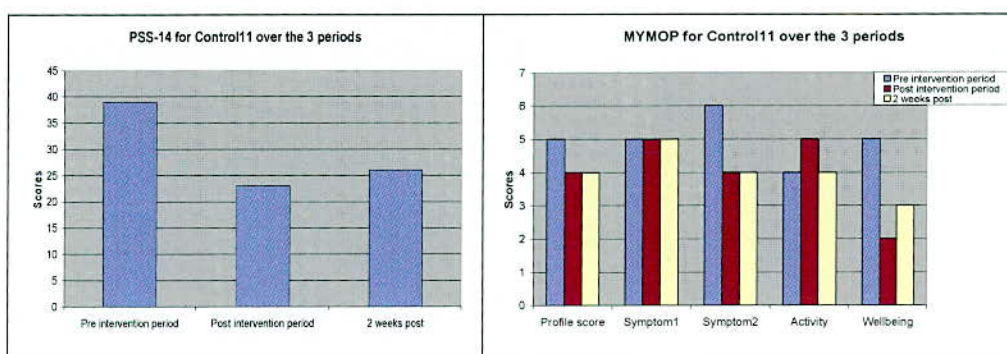
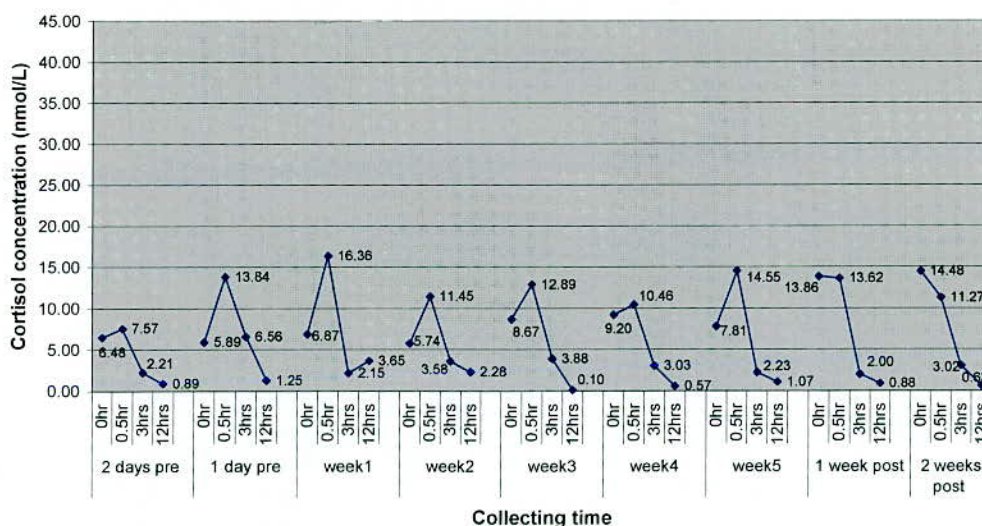


Figure Control 11: Control 11’s diurnal profiles of salivary cortisol concentration on 9 collection dates

Cortisol profile for Control11 over the study period



7. Participant's comments on the experience of the 5 week intervention period

No. 11 did not give any comments during the period of the study.

8. Comments and discussion from the researcher

The stress levels which No.11 perceived before, during and after the study were not reflected by the diurnal cortisol profiles. The flattened cortisol profiles in 1 week and 2 weeks after the intervention period suggested the participant did not take the samples immediately when waking up. Also the time records for the sample collecting showed that the time at the first collecting time point in 1 week after the intervention period was 7:55am which was later than her usual collecting time on other dates (between 7:00am and 7:40) (see 7.8.1 *Mean waking times on the day of sample collection for each group*). This indicated that 7:55am might not be the first time of her waking.

The fluctuations of the MYMOP scores correlated with her perceived stress levels, but it was not reflected by the cortisol profiles.

The life events changes also affected her stress levels and were apparently related to the fluctuations in the patient-centred outcome measures.

No. 13 Female, 39 years old.

1.Date of starting the study

23rd January 2006

2. Reasons for joining the study and case history

No. 13 had felt more stressed for the last 5 months because of her work.

3. Major presenting symptoms

Anxiety (Symptom 1), fearfulness (Symptom 2), depressed, easily woken during the night, tiredness, loss of appetite, irregular menstruation

4. Life events occurring during intervention period

Table Control 13-1: Control 13's Recent Life Events

No. 13	Events happened	Still affecting
Pre intervention	0	2
Post intervention	0	2
2 weeks post intervention	0	3

In September 2005, No.13 knew she had to leave her current job and started looking for a new job. She had been trying to get pregnant for 10 months and had not been successful. During 5 weeks intervention period, she went to the hospital for an investigation.

5. Intervention

Control participant. Every week the researcher collected the salivettes in different places which were convenient for the participant, e.g. tube station, railway station, the hospital, and different campuses in the university.

6. Results of outcome measures

No.13’s PSS-14 decreased after the 5 week intervention period and 2 weeks after. For the MYMOP, after the 5 week intervention period, “Profile Score”, “Activity” and “Wellbeing” went down, “Symptom 1” increased and “Symptom 2” was still as the same as before. In 2 weeks after, “Activity” and “Wellbeing” increased while “Symptom 1” and “Symptom 2” decreased (see *Table Control13-2*).

Figure Control 13 shows that No.13’s diurnal cortisol profiles had flattened patterns on 2 days and 1 day before the intervention period, and in week 1 & 4 of the intervention period. On the other collecting dates, the cortisol profiles showed morning rises. The cortisol concentrations at the fourth points (12 hours after waking) on 1 day before the intervention period, in week 5 of the intervention period, and 2 weeks after the intervention period were higher than the third collecting points (3 hours after waking).

Table Control 13-2: Control 13’s PSS-14 & MYMOP

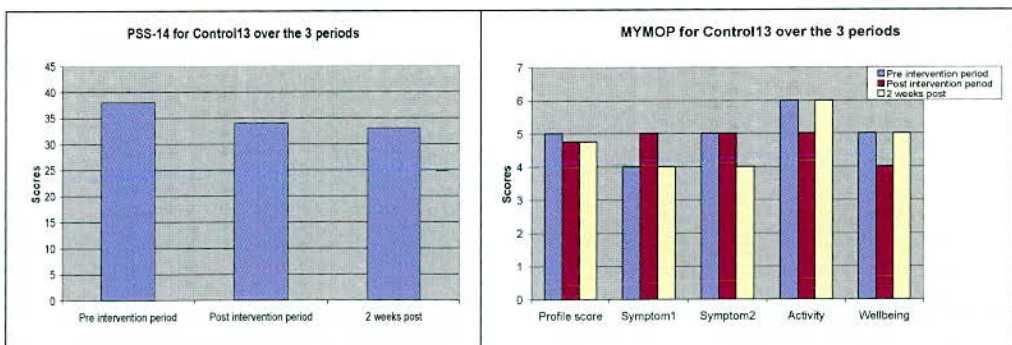
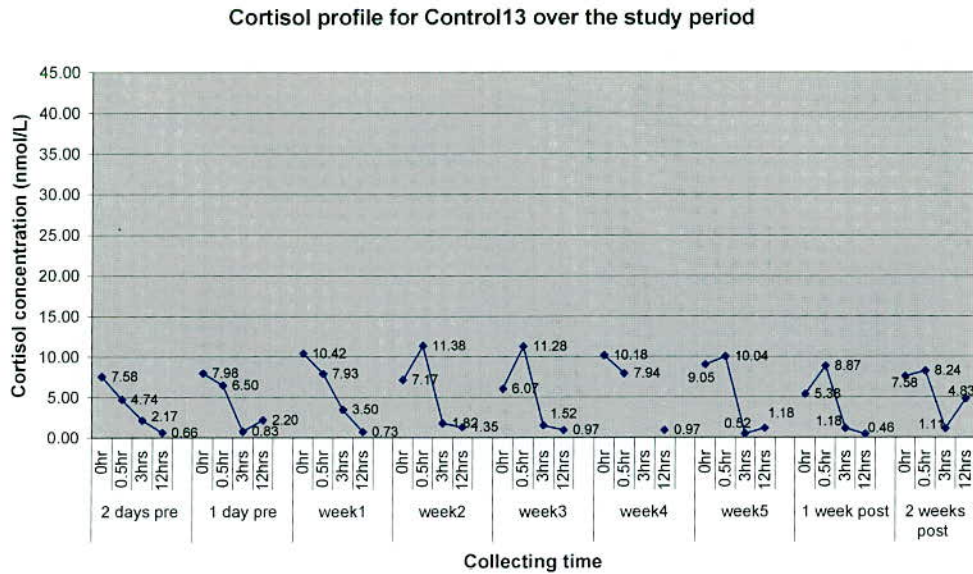


Figure Control 13: Control 13's diurnal profiles of salivary cortisol concentration on 9 collection dates



7. Participant's comments on the experience of the 5 week intervention period

"There is some improvement in morning anxiety as new work contracts stabilise and my gym attendance regulates. There were been 1-2 stressful events where I felt physically very stressed. My menstruation occurred at 21 rather than 28 days."

8. Comments and discussion from the researcher

Throughout the study period, every time when the researcher met No.13 to collect salivettes, she seemed very stressed and kept worrying a lot about her life, health and work. Though her PSS-14 score decreased, the scales of the MYMOP had fluctuations and generally did not change much.

No.13's cortisol profiles did not reflect her self-reported high stress levels. The time-record sheet showed that her first samples collecting times on 2 days and 1 day before the intervention period, and in week 1 & 4 of the intervention period were 8:30am, 7:00am, 6:30am, and 7:30am, which were later than other collecting dates (between 5:30am and 6:30am) (see 7.8.1 *Mean waking times on the day of sample collection for each group*). This suggested that the flattened patterns of the cortisol profiles could be because the time when she collected samples were not immediately on waking in the morning. The high cortisol concentrations at the fourth points on 1 day before the intervention period, in week 5 of the intervention

period, and 2 weeks after the intervention period could be due to her eating or drinking before taking the samples.

No. 18 Female, 45 years old.

1. Date of starting the study

14th February 2006.

2. Reasons for joining the study and case history

No.18 had felt stressed for 10 years and for the last 2 years had been worse because of her work.

3. Major presenting symptoms

Tiredness (Symptom 1 in the MYMOP), low self esteem (Symptom 2 in the MYMOP), irritability, sadness, more night dreams, eating more sweets.

4. Life events occurring during intervention period

Table Control 18-1: Control18's Recent Life Events

No. 18	Events happened	Still affecting
Pre intervention	0	2
Post intervention	1	1
2 weeks post intervention	0	0

As No.18 reported in the MYMOP follow-up 1 that her work was very stressful and demanding. At the same time she was doing her master's degree. This created more pressure on her everyday life.

5. Intervention

Control participant. Every week the researcher went to No.18's work place to collect the salivettes.

6. Results of outcome measures

Table Control 18-2 shows that the scales of "Symptom 1" and "Activity" in the MYMOP declined after the intervention period, while the PSS-14 increased and other outcomes in the MYMOP kept stable.

There were morning rises in No.18's diurnal cortisol profiles in every period of the study (see *Figure Control18*).

Table Control 18-2: Control 18’s PSS & MYMOP

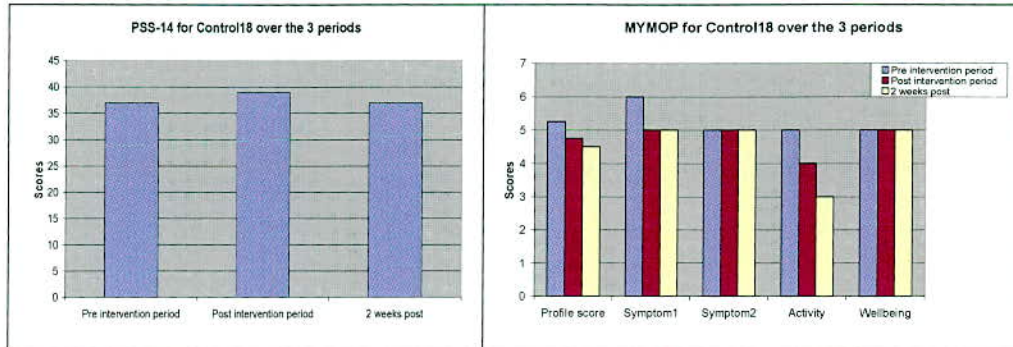
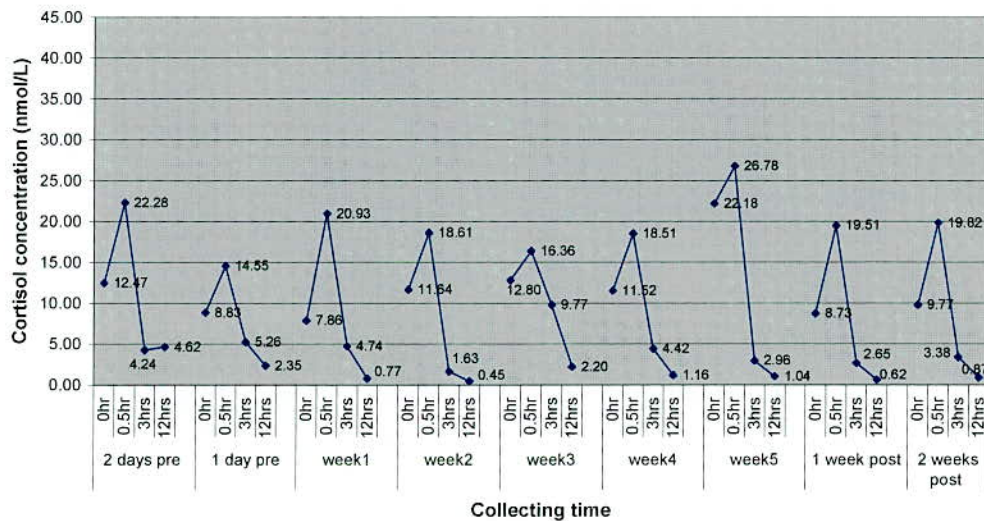


Figure Control 18: Control 18’s diurnal profiles of salivary cortisol concentration on 9 collection dates

Cortisol profile for Control18 over the study period



7. Participant’s comments on the experience of the 5 week intervention period

“Work has become particularly stressful and demanding. Trying to complete a master programme at moment. Found the process of collecting samples rather stressful at times, especially when not in office or at home.”

8. Comments and discussion from the researcher

Every time when meeting up to collect salivettes during the study period, No.18 always had some complaints about her busy and stressful work, and she seemed very nervous and stressed. Her patient-centred outcome scores did show her high

stress levels though there were some improvement on some outcomes in the MYMOP over the study period.

No.18's diurnal cortisol profiles with sharp morning surges did not reflect her perceived high stress levels.

8.4 Conclusion

These case studies demonstrate the large individual variations in the study. Stress levels are easily affected by the environment. Considering cases on an individual base and interpreting the various outcome measures in the study mean that the case studies can be helpful in excluding some non-specific effects. These results show that the participants in the TCA group did have more improvement on their stress symptoms than those in the attention group and the control group. This gives further evidence to support the results of the RCT (see *Chapter 7*). Results suggests that TCA is successful in treating the symptoms of stress, probably via a combination of specific and non-specific effects; but this may not relate directly to how a person perceives their stress.

Chapter 9 Phase 2 Results - Focus Groups Study

This chapter provides the analysis of the qualitative data obtained as a result of focus groups carried out with the TCA and the attention groups.

Out of the 4 participants in the TCA group and the 4 participants in the attention group invited to participate in a focus group, 4 participants in the TCA group and 3 in the attention group took part in 2 separate focus groups. These were held on 10 January 2006 (the TCA group) and 22 March 2006 (the attention group) respectively. Non-attendance in the attention group was due to the participant attending a conference.

Analysis of the data for focus groups was carried out after the quantitative and case studies analyses in order to avoid any bias from the researcher.

9.1 TCA focus group

The main themes emerging from the TCA focus group are given in *Table 9.1*.

Table 9.1 Main themes emerging from the TCA focus group

Main theme	Experience of using TCA for TCA (9.1.1)	Feedback on the research (9.1.2)	Expectations of acupuncture (9.1.3)
Sub-themes	Previous experience and knowledge of TCA (9.1.1.1) During TCA session(s) (9.1.1.2) After TCA session(s) (9.1.1.3) Feedback from other people (9.1.1.4) Other reasons affecting the result of TCA (9.1.1.5) Other benefits (9.1.1.6) Practitioner (9.1.1.7)	Salivary samples (9.1.2.1) Questionnaires (9.1.2.2) Venues and timing (9.1.2.3) Other drawbacks (9.1.2.4) The reasons for taking part in the research (9.1.2.5) Other people's comments on the research (9.1.2.6)	Expectations of acupuncture (9.1.3.1) Plans for acupuncture in future (9.1.3.2) NHS and GPs (9.1.3.3)

9.1.1 Experience of using TCA for stress

9.1.1.1 Previous experience and knowledge of TCA

All the participants had little knowledge about acupuncture and all but one had never used acupuncture before. But there was a consensus that they thought that was an interesting and useful experience. The individuals respected different experiences and feelings during and after TCA sessions.

9.1.1.2 During the TCA session(s)

“The first session, I did feel more relaxed and found (it) quite pleasant. In the second session, I had quite bad bruising on my abdomen. And I wouldn’t say it was painful, but it was uncomfortable. And also some on my arm. And I think the sessions after that I was a bit anxious about whether the same thing was going to happen and, um, a slight discomfort on occasions. But, once the needles were in, then I could relax a bit more. But I wouldn’t say it was a...it wasn’t a wholly pleasant experience.” (No.2)

“When I was laying there...I mean I found it quite interesting, sort of where he was putting things...the process of it I found very interesting...and different needles in different places, which I found quite interesting.” (No. 3)

9.1.1.3 After TCA session(s)

“I felt, um, less stressed afterwards...before and after treatment I felt better, immediately after....I haven’t found it helped in the long term.” (No.1)

“I was more relaxed at the end but that was a physical change.” (No.2)

“While I was having it I was fine but then, you know, getting up afterwards, I’d have to sit down for a minute and then, you know, the rest of the day I was normally quite spaced and was quite sort of tired and feeling quite sort of stomach sick in the evenings... I often felt quite ill afterwards but apparently that was normal.” (No.3)

9.1.1.4 Feedback from other people

Some participants received feedback from their colleagues and family members after the session of TCA.

“Our colleagues noticed how relaxed we were when we came back from the sessions.”
(No.4)

“When we came back from the session, our colleagues remarked how relaxed we looked... My husband has remarked that I get less up-tight about things since then.”
(No.2)

“But every time I came back from a session, everybody said to me, oh, you look very pale.” (No.3)

9.1.1.5 Other reasons affecting the result of TCA

There were discussions about some other reasons which may have affected the results of the TCA on reducing stress, e.g. traffic, different working period, fitting in the time.

“I was probably more stressed rushing to it to begin with so, on a day to day basis...it depends on the traffic on the M4 some times for me on a morning how, you know...if I’m going to be late or that sort of thing.” (No.1)

“I think actually fitting it in was quite stressful, trying to find the time to fit it in and be involved in it was quite stressful but it was a regular commitment each week.” (No.3)

“I actually found the fitting in quite difficult.....Sometimes I was a bit late and that made me quite stressful to begin with.” (No.1)

“I feel sometimes it is more to do with the environment, outside, external factors and what’s inside, you know, goes along with what...” (No.1)

“Partly...I’m not totally sure that I believe in the whole acupuncture effect but the calming effect of the person who’s doing it and the way they speak to you and the whole, you know, experience...I’m not sure about the actual theory behind it...” (No.1)

“Now, whether that was because we had...the week before had been virtually the end of this very busy time for us and here we were going for half an hour lying down, um, having someone, um, look after us in effect and say nice things, soothing things to us, or whether it was the effect of the acupuncture, I don’t know, but I did feel more relaxed.” (No.2)

“It was difficult to judge how much was that (TCA) and how much was the alleviation of some of the work stress.” (No.4)

9.1.1.6 Other benefits

Some participants benefited from TCA for other problems which they came with.

“I have had a longstanding problem with rhinitis which has left me virtually without a sense of smell. Now that has partially returned and I still can smell.” (No.2)

9.1.1.7 Practitioner

The participants appreciated the practitioner’s training background, patience, knowledge, techniques and the flexible timing arrangement in this study.

“I found it interesting in the sense that he was very good at explaining what he was doing and I asked quite a lot of questions because I was quite interested in what he was doing and why.”(No.3)

9.1.2 Feedback on the research

9.1.2.1 Salivary samples

Most participants thought providing salivary samples was quite arduous. But they thought they could sort it out.

“It was quite stressful wasn’t it, remembering. I forgot one occasion and I was late on the last one and I felt dreadful.” (No.4)

“It was more stressful than you think it would be just doing something four times a day...I quite enjoyed all that because it felt like you were actually involved in it more and that you were...there was some kind of science going on as well as having a session... I found it quite stressful keeping it in the freezer and bring it in on certain days and all of that.” (No.3)

“I think not having to have anything to eat or drink before-hand and it was remembering that.” (No.1)

“You had to almost plan the day out before and think, what am I going to do tomorrow?...” (No.2)

9.1.2.2 Questionnaires

One participant found some questions in the questionnaires were confusing for them to fill in.

“I found it very difficult rating 1-5... There was one question about symptoms. You had to list symptoms and I felt that didn’t have guidance on what I should put for that because I listed two symptoms and then... I think on a... this was the questionnaire at the end, we had two.” (No.2)

One participant reported that she doubted whether the screening questionnaire had been a good method of recruiting participants.

“I mean definitely some people that I know attended you tell that they knew what answers to say in order to get that, kind of, you know, they thought, you know, just knowing some of the people that came, you think, oh, they’re obviously not that and get this free...” (No.3)

9.1.2.3 Venues and timing

There was a consensus that the venues where the treatments took place were fine for the participants, and that the timing had been adjusted to their schedule, though some of them felt it was more stressful to fit the sessions into their working day.

9.1.2.4 Other drawbacks

One participant mentioned the privacy or the peer situation as a drawback in the research.

“I found it quite difficult that, um, if I’d have wanted to keep it private, I couldn’t have because the people that I work with were coming in and out after and before me. We were all on the same day... Because we all work in the same area and it’s very busy and it so happened that we only had limited times we could.” (No.3)

9.1.2.5 The reasons for taking part in the research

The TCA treatment in the research was free which attracted the people to take part in the research for the free treatment or a new experience.

“I also though, actually, to try it for free. I know that’s a bad thing but, being quite honest... because when do you get the chance to try something for free?”(No.1)

9.1.2.6 Other people's comments on the research

Some participants talked about their colleagues' comments on the research.

"I found on that score that most of the colleagues I work with and I'm not going to say why, but were quite unsupportive, I would say, as if, oh, what are you wasting time doing that for? Which was a bit...I found, and trying to enroll anybody else to come was very difficult because people do just... I don't think they want to open their mind to other alternatives." (No.1)

"I think our colleagues were very intrigued by it...I think they enjoyed it vicariously really. I am not sure they'd do it but they were very interested and supportive of us doing it." (No.4)

9.1.3 Expectations of acupuncture

9.1.3.1 Expectations of acupuncture

The participants' expectations of acupuncture were varied.

"Well I didn't really have any because I didn't feel as though I knew enough about it so I went in hoping that it would do something but I'm not quite sure what, um, I did actually start doing a little bit of research once I'd started but not very much. Um, and I...I'm surprised at the outcome on my situation." (No.2)

"I was expecting better, can I say, better results. Maybe that's a bit unfair but I found possibly within the day that I had it some results... Like you were saying if your could come today and have it when you've had a stressful morning, it may help, kind of that way but I haven't found it helped in the long term so maybe I've been a little disappointed but I don't really want to. You know, knock it, and I went in with an open mind."(No.1)

9.1.3.2 Plans for acupuncture in future

Some participants said they would like to know more about acupuncture and they would try acupuncture again. Some were not sure, and it would depend on other therapies available and practitioners.

"I found it very interesting and enjoyable and I suppose I would turn to it again. I also felt I'd have liked to know a lot more about it but it probably would be...you know, I

wanted a potted guide to acupuncture, where you wouldn't get a potted guide to Western medicine." (No.4)

"Definitely (try acupuncture again)... I'd want to go via my GP, always supposing your GP...that there's somebody in the practice who's sympathetic to it."(No.4)

"I might do it again with him because I felt that I'd got to know him and he... the way he talked about his background and what he'd been doing before, you know, because I asked him questions about that. I felt quite comfortable with him and that it actually was more scientific than I had anticipated it would be...there was a definite process, and I enjoyed all of that. But you know, where I live, there's (are) some shops that offer it and I don't know that I'd feel comfortable walking in and getting it done by anybody because you kind of want to know...it's really because it's inserting needles into you, you kind of want to know that it's going to be safe...I don't think I'd go to necessarily anyone else and to have acupuncture unless it was through an organized (association)." (No.3)

"I'm not sure. I would like to actually compare it to other therapies now, you know. Like there was a relaxation group. I would kind of quite like to see if that helped me more." (No.1)

9.1.3.3 NHS and GPs

Participants recognised that there were some doctors in the hospitals and GPs had training in acupuncture and used it to treat some special problems, e.g. pre-operation stress and smoking addiction. They hoped acupuncture should be promoted within NHS, and they would trust acupuncture there more than the shops in the high street.

"If it has been found to reduce pain, especially for someone who's on long-term painkillers. I mean it could only be of benefit, even if it was a slight improvement." (No.2)

"I found there were unexpected people saying, oh I had that for such and such. And I think it would help me feel it was not some funny little shop in the high street. If it is through your GP, it is an alternative or adjunct to regular treatment."(No.4)

9.2 Attention focus group

The main themes emerged from discussion in the attention focus group are given in *Table 9.2*.

Table 9.2 Main themes emerging from the attention focus group

Main theme	Experience of attention (9.2.1)	Feedback on the research (9.2.2)	Expectations of something to help reduce stress (9.2.3)
Sub-themes	General feeling and comments (9.2.1.1) During the session (9.2.1.2) After the session (9.2.1.3) Stress symptoms (9.2.1.4) Reasons affecting the result (9.2.1.5) Something learned from the intervention (9.2.1.6)	How they heard about the research (9.2.2.1) The reasons for taking part in the research (9.2.2.2) Questionnaires (9.2.2.3) Taking samples (9.2.2.4) Venues and timing (9.2.2.5)	Expectation of the research (9.2.3.1) Expectations of some help in the workplace or in NHS (9.2.3.2)

9.2.1 Experience of attention

9.2.1.1 General feeling and comments

All the participants' work and life were busy and stressful, and they had to make time to come to the attention sessions. Though the timing was a bit difficult for them, they found it helpful and worthwhile.

"There wasn't any such treatment...but there was relaxation once a week for about 20-25 minutes...It was part of a course, we were forced to so you had to make the appointment and you had to do it...After having like a very stressful working morning, just to kind of switch off for half an hour was very good for me so I found that very helpful... I found it helpful over seven weeks because my life is always busy – work... I think in the long term it teaches you, if you can take that time out to just literally switch off." (No.1)

“I think again was useful...I just found it was good for about an hour or so afterwards, just sort of cleared my head a bit.” (No.2)

“Maybe sometimes you were in the middle of something and maybe there was slight irritation to start off but at the end of the time when you came back it was really worthwhile.” (No.1)

“How much the half hour just lying down actually helped I wasn’t sure.” (No.3)

9.2.1.2 During the session

Participants talked about their feelings during the attention session. Three participants had experienced falling asleep.

“Basically trying to wipe my mind off everything.....that’s what I consciously tried to do.” (No.1)

“I’d always find the first couple of minutes just lying there trying to relax and you just have so many feelings, probably...oh, there’s that and then that and I’ve got to write??? for someone or I’ve got to get that sorted in the office. And then it would just sort of slowly go away and before you realised it, there was just no major thoughts. It was great.” (No.2)

“The last two were more sleep-inducing but the first three times I spent the whole half hour lying down thinking.” (No.3)

9.2.1.3 After the session

Participants also described the feeling after the attention session.

“My body was extremely sluggish so it was hard because it is going back to work.....it lasts for about maybe half an hour, 45 minutes and then you’re back in the stream of things.” (No.1)

“It was like -- I was fuzzy in my head. It was really...not in a bad way, that sounds terrible, but it was just nice. I managed to have a separation from all the traffic...yes, it was good to do, it was needed.” (No.2)

9.2.1.4 Stress symptoms

The consensus was that they did not think that their stress symptoms had changed or that they had received any benefit from the attention sessions.

“I wouldn’t say it’s had an impact in so far.” (No.1)

“I think just having that short break of the relaxation period...and eventually not consciously thinking about things, in some ways helped.” (No.2)

“I found it very difficult to attribute what I was feeling to the relaxation period.” (No.3)

9.2.1.5 Reasons affecting the result

The reasons which affected the results of the attention sessions were discussed.

“I felt it was a bit...related to the work I’m doing because I’m all over the place with work...The first three weeks of my five week session(s) I worked extremely hard because I had deadlines to meet and the last two weeks I’ve met all the deadlines and I’m not stressed.....the first time I didn’t think I really relaxed but by the fifth time I just got relaxed and did find that of benefit. And I though, yes, if I continue with this I can actually derive from that half hour of just chilling out.” (No.3)

“Stress varies from day to day, hour to hour. There are some things that cause stress, at least in my life, that are semi permanent and it’ll take it’s own time to go away” (No.1)

9.2.1.6 Something learned from the intervention

Though the participants could not see the changes of their stress symptoms, some of them thought that they learned how to cope with those stressful situations and make them feel better.

“I can’t answer that specifically but I can say categorically that, taking that half hour out of a busy day made a difference because, if I can do that, then obviously if you are more settled you can cope better with anything that’s thrown at you...we don’t have a typical day. However, in such a long day, to take that half hour or forty-five minutes if I could, I think would help me cope, not just with personal problems but work problems...So, yes, that’s something that I have learnt, that if things get really on top, just walk away, go away, sit somewhere for half an hour – 45 minutes, switch off and come back and I think you will feel better. At least that’s what I’ve learnt” (No.1)

“I endorse that.” (No.3)

9.2.2 Feedback on the research

9.2.2.1 How they heard about the research

All participants had heard about the research programme on the broadcast email in the university.

9.2.2.2 The reasons for taking part in the research

Free acupuncture had attracted people to join the research.

“I thought I’d be lucky enough to get the acupuncture because I’ve had acupuncture before and I found that very good.” (No.1)

“I found it on the broadcast mail and thought, great, acupuncture and then, when I got the relaxation, thought mmm.” (No.2)

But this was by no means unanimous:

“I thought, I don’t want acupuncture, but if I had (it,) it is might do me some good.” (No.3)

9.2.2.3 Questionnaires

Some questions in the questionnaires were difficult for some participants to answer, but they understood that this issue could not be avoided in a research project.

“They’re generic, they’re very difficult sometimes to put your situation in it.....I think who (you) have things in their life going on long term which will take time, so even though it’s not happened last month, the repercussions from that are very much today and they will either get worse or better depending on how those things pan out on a day-to-day, week-to-week basis... Some of the questions were fairly tedious but I suppose in research you have to be like that. No, it was OK. It’s was very hard for me personally to relate to some of the questions so I had to take help and say, well, can I go back a little bit longer and then put that in and whatever. So, yes.” (No.1)

“I’d say the same, yes. I couldn’t decide what a week was and what a month was and whether I had the headache that week and the headache was actually due to sitting in the traffic and being late. It wasn’t anything...you know, it was what happened. And

I'd also had palpitations on the fifth week and I...oh, it's new symptom. This is...well actually that's what you said five weeks ago. And I hadn't realized that, actually, all this time I'd been having palpitations. But then also going on about the timing." (No.3)

9.2.2.4 Taking samples

Participants did find taking salivary samples a bit problematic. Reasons included: their work schedule, driving to work, the availability of a freezer. All of these interfered with providing samples on time, and also taking samples made them stressful. But they did try their best to manage that.

"I was really chilled about this thing (collecting samples) because that was the least of my problems...The bits that I forgot or couldn't specifically because I didn't go to a meeting with my little swab in my hand, so if the meeting lasted longer than say 10 o'clock, then I took it at 11, whenever I came back...the first two were perfect because that was at home and whatever but in a working week I didn't really get stressed out about that." (No.1)

"It certainly makes you have to really think about everything just to fit it all in...but on the whole I think I managed to get them all pretty much on time, I hope." (No.2)

"I managed the first three because they were relatively close together but each time I'd either eaten something at half past five and I thought, oh, I'm not supposed to eat for another half hour or I thought, oh dear, it's...you know, the swab's not here. And then I couldn't put them in the freezer because they were all in the car." (No.3)

9.2.2.5 Venues and timing

Participants appreciated that the timing of attention sessions was flexible and individualised to their working schedules. They found the rooms were appropriate to the sessions. The only complaints were about the sound insulation of the room.

"The rooms are really nice so it was OK for me." (No.1)

"We had to talk quietly because somebody was being counseled in the next room." (No.3)

“The room right next to it was a toilet so there would be occasions when you’d be halfway through relaxation and suddenly you’d get ding, shhhhhh, fan with the light and they’d flush the toilet..... ” (No.2)

9.2.3 Expectations of something to help reducing stress

9.2.3.1 Expectation of the research

Participants reported that they did not have any expectations when they started this research, but they expressed interest in the results of their cortisol concentrations. They believed in complementary medicines and were interested in finding out whether and how they work.

“I didn’t actually go in with any expectations because the thing is it was a clinical research...I would be more interested actually to find out what the swabs actually told you...I would be interested more in that, but as for expectations going in with it, I really didn’t have any.” (No.1)

“I didn’t really have any expectations because I thought, just lying down for half an hour, you know, gladly really. But I was in some ways surprised with what it did and I think, well I know, I would like to try out some acupuncture just to see what it can do.”(No.2)

“I’d like to see a graph because I could say, on that day I was travelling back from Wales... I’d passed all the portfolios across and I had nothing more to do. So I’m expecting you to see relaxation in the last fortnight as opposed to the first three.” (No.3)

9.2.3.2 Expectations of some help in the workplace or in NHS

All participants agreed that some provision should be made for this type of treatment within the workplace or available in the NHS. They knew some GPs and NHS hospitals offered complementary therapies. However, taking time out during work was perceived as a problem.

“I think a simple that they could do really, the university...this is important for the health of the people working...I think the NHS is slowly starting to realize complementary medicine actually does help.” (No.1)

But participants felt there was a problem with the culture of being able to relax as part of the working process.

“Managers tend to feel, particularly senior managers tend to feel if you’re taking time out...if you’re caught staring outside the window, just taking a break, you’re not doing the job. There is a culture definitely.”(No.1)

9.3 Discussion

The purpose of focus groups study in this research project was to sample a range of opinions from participants in terms of the experience of the interventions and to obtain feedback on the research methods employed in order to add to the evaluation of the effect of the TCA for stress and assess the outcome measures used in this research project.

Due to the time lag in recruitment and the length of time required to complete the study only eight participants out of 12 (the TCA group and the attention group) were able to be invited to participate in the focus groups. Seven actually took part. The timing of the study was problematic as it was hard to recruit enough participants who could start and finish the interventions within a strict time period. In addition there was the break over the Christmas period. That meant if the focus groups were carried out once all participants finished their interventions, the time interval would be too long for some participants who had finished the intervention earlier to remember the details of their experience clearly. Then they could not give the right comment on the intervention and the research experience. This small sample size did however provide a range of opinions, and some consensus was achieved. In that way all information covered with the focus groups was helpful to inform the research.

The results of the focus group presented a range of opinions and varied feedback. These included both positive and negative opinions in two groups.

The major difference between the two groups was in their experience of the intervention for stress. The participants in the TCA group reported feeling less stressed after their

treatment. Especially in the TCA group some participants noticed that some symptoms from stress or those coming with “stress” were improved, and also reported that their colleagues and family members noticed they were more relaxed after TCA. In the attention group no one reported that either their symptoms had improved or that they had received positive feedback from other people. However they felt the benefit from relaxation and being able to lie down. TCA may help people to be relaxed and relieve some of the symptoms of stress.

The treatments in the TCA group were individualised and pragmatic. TCA was not only for stress and its symptoms, but at the same time it tried to help associated symptoms, e.g. cold and back pain. It is quite normal for some people, especially for the new people to have some reaction to TCA. This suggested TCA is one kind of treatment and generally more powerful than other types of complementary therapies. From clinical experience, the person who has some reaction to TCA is more sensitive to the treatment and may have more benefit from it.

The results from the two groups exhibited some consensus, particularly on the experience of the research and the expectation of the interventions for stress reduction.

Both groups reported that taking samples on time was arduous, which sometimes increased their stress levels. This could have been one of the factors which could have affected the results of the research. Also some participants admitted that they did not take samples on time because they forgot, and sometimes they took samples at different times due to special circumstances, e.g. No. 3 from attention group was in Wales when she provided one set of samples. This information is helpful interpreting the data for the profiles of diurnal cortisol concentration.

Regarding the participants’ comments on the questionnaires, this was the first time the researcher had used these questionnaires. The literature review conducted on the use of the questionnaires suggested that in the theory they were good for the project. As the sample size was small, it was not possible to carry out a pre-pilot. As this was a pilot

study, the researcher gave participants a general explanation and answered any questions they had, but did not discuss with them too much in case it biased their answers. In the whole research, all participants seemed to have few questions concerning the questionnaires. The problems participants mentioned in focus groups were not presented to the researcher when they were asked to fill in the questionnaires. The focus groups study gave the chance to collect more opinions and comments which the researcher did not get directly from the participants. The result of focus groups suggested that the MYMOP needed more clear guidance, e.g. symptom(s) (see *10.3.4.3 Symptoms in the MYMOP*).

Before the study the researcher did try to design the project to minimise psychological bias. For example, at the beginning of the study the participants in the attention group were informed that they were randomised in the “relaxation” group instead of the “attention” group. They did not know that they would be offered free TCA treatment until they completed all the questionnaires and provided all samples and took part in the focus group. The results of the focus groups showed that the psychological effects still existed. Two groups’ expectations before the study were different. The participants in the attention group knew there was no treatment for them though they were told that they were in the relaxation group, while in the TCA group the participants knew TCA is a kind of treatment and wanted to see what would happen and hoped there was a ‘magic’ improvement. So the expectations in the TCA group were much higher than the attention group. When the improvement of TCA was not as significant as the participant expected, they may have been disappointed, which could have affected the results of the research. The psychological effects also were reflected in the participants’ purposes of attending the research. Most of them thought the offer of free acupuncture was the best attraction. Participants’ discussion also further confirmed stress is a kind of mental disorder and could be affected by many aspects both internally and externally. This increases the difficulties in carrying out the research into stress. So in this research it was not possible to avoid and exclude the psychological influences on the result of the research. For example, the participants fell asleep sometimes during the interventions. Falling asleep happened in the TCA group which may be explained by the TCA treatment.

This also happened in the attention group. This may have been because the participants accepted the researcher as a professional and trusted him, which may have been instrumental in making them relaxed during the attention sessions.

A theme to emerge from the focus groups was that all participants agreed that some provision for stress including TCA should be available in the NHS or workplaces. Especially in the view of safety and health in the workplaces, the employers should pay attention their employees' mental problems which have been increasingly related to long term sick leave and disability (Oostrom et al., 2007). Though acupuncture is more and more popular in the UK in recent 20 years, it is still relatively new to this country. As it was mentioned in the focus group, most of people did not know how to find a qualified practitioner. More official information and scientific research evidence are needed for the public. Acupuncture practice needs to be regulated in case misleading of unqualified practitioners.

9.4 Conclusion

The focus groups in this project provided useful information on the experience and responses during and after interventions in the TCA and the attention groups. This provided more details concerning participant's general condition and some special situations which arose during the study, e.g. experience of providing salivary samples. This information is helpful for data interpretation. The useful feedback and comments on the research methods could be used in designing a large trial in the future.

During the process of the research, participants may have had no chance or found it difficult to tell the researcher the details of their feelings and opinions or comments on the research and the intervention. The focus group approach, particularly because it was carried out independently, was a good opportunity for the researcher to find out what participants exactly thought of TCA, e.g. the details of participants' feelings during and after TCA treatment. This was useful for the researcher's future clinical practice.

In conclusion, a qualitative method of this type combined with quantitative data of the RCT provided useful information and opinions, which could help to improve practice and research design as well as contributing to the evidence base.

Chapter 10 Discussion, Further Work and Conclusion

This chapter evaluates the design and methods used in this study, discusses the findings and the implications of this research, the limitations and strengths of the approach used, and provides recommendations as well as suggested areas for future research.

10.1 The study protocol

Stress is a physical and psychological response to perceived demands and pressures. The lack of clarity concerning the definition of stress makes it a complex concept to investigate. In clinical practice, the results of treatment could be affected by non-specific effects. A complex non-pharmacological treatment, such as TCA, is complicated to evaluate because it is difficult to isolate the characteristics or specific effects of the technique from the non-specific ones (i.e. the placebo effects) (Paterson and Dieppe, 2005). In the light of these considerations, a RCT with 3 arms (the TCA group, the attention group, and the control group) was designed in order to investigate the effectiveness of TCA in comparison with two types of control groups (attention only and waitlist control) with the objective of separating the specific effects from the non-specific effects.

10.1.1 Controlling for bias in a complex intervention

10.1.1.1 Attention group

All therapeutic interventions consist of a combination of a non-specific effect (placebo and /or nocebo effect) and the effect related to the specific property of the treatment (Wigley, 2007). In complementary medicine research there is much discussion regarding the importance of non-specific or placebo effects on the outcome of treatment. The complex nature of an individualised and holistic treatment, such as TCA, requires careful thought in choosing suitable controls.

The design of this study used an attention group to encourage the participants to believe they were receiving a valid treatment designated as “relaxation” (see 6.2.5 *Recruitment*). At the same time they provided a control group for the study which

controlled for the non-specific effects of relaxation, time out and practitioner attention (also received by the TCA group), but not the TCA specific treatment (see 6.2.7.2 *Attention group*). The attention group also had belief that their treatment could be effective for their stress-related symptoms. For this reason the group was not told that acupuncture was available until the end of the study. These effects of these factors could be regarded as non-specific effects.

Non-specific effects can be divided into desirable (placebo) and undesirable (nocebo) effects. They include positive or negative patient expectations that affect every treatment process (Kong et al., 2006; Bausell et al., 2005). These expectations are also affected by patient education, higher intensity of care by the acupuncturist, the physician's enthusiasm (investigator effects), the "healing ritual" that is related to East Asian culture / philosophy (Kaptchuk et al., 2002), deliberately breaking one's routine to keep regular appointment outside the home, and the experience of an invasive technique (needling). The experience of an invasive technique and belief in its efficacy may lead in itself to a reduction in symptoms (Linde et al., 2007; Kaptchuk et al., 2006 and 2000; Moerman and Jonas, 2002). Non-specific effects also include a good doctor (or healthcare professional) - patient relationship which can further enhance patient improvement (especially discussed in 10.3.3.1 *Practitioner's effects in TCA*), and negative patient expectations about "conventional medicine" which may already have been previously experienced as inadequate. In addition, the clinical setting and practitioner manner can affect the therapeutic relationship (Turner et al., 2007). Interviews with acupuncture patients have demonstrated that the holistic view of patient illness represented by acupuncture is also an essential factor in the healing process (Joos et al., 2006). The overall "effect" of acupuncture experienced by patients will comprise of both "specific" and "nonspecific" parts.

"Sham intervention" can be defined as a technique which can be used as a placebo control in an RCT. Such techniques in acupuncture may include needling wrong points (non-acupoints or points considered to be ineffective for the condition treated); "minimal" acupuncture which means needling superficially (Lewith and Vincent,

1998; Lewith et al., 1983); using specially designed placebo needles to replicate acupuncture needling with penetrating skin or without penetrating skin (Hammerschlag, 1998); mock TENS (Dowson et al., 1985); or with inactivated laser apparatus (Irnich et al., 2001).

A systematic review of sham intervention (Linde and Dincer, 2004; Dincer and Linde, 2003) showed that there was no clear association between the type of sham intervention used. Randomised trials investigating the specific effects of acupuncture have used a variety of sham interventions as controls which were often not fully explicit. Only a minority of published trials reported on information given to patients about true and sham interventions. This has not only ethical relevance but also might influence results of trials. It summarised that the different sham interventions as “placebo” controls seems misleading and scientifically unacceptable.

Many specialists in acupuncture research methodology believe that sham techniques play a role for answering specific questions about specific acupuncture techniques. Others argue that it is misleading to regard sham intervention as placebo treatment and leads to problems and difficulties interpreting their results (Birch, 2006; Dincer and Linde, 2003). Some studies have been designed to compare the effects of stimulation at appropriate points, but the control procedure themselves seem likely to have physiological effects (Le Bars et al., 1979). And some sham intervention techniques were shown to have the same total psychological impact as acupuncture which may mean that such control procedures may not be appropriate controls (Kaptchuk et al., 2000).

Whether sham interventions are appropriate for acupuncture research is still debated, and a firm and clear conclusion still cannot be drawn. Research into the specificity of a single acupoint using a non-acupoint as a sham control, may be a more valid use of sham acupuncture than using it as a control for research into a complex health issue. For example, Deng et al. (2008)’s randomised, sham controlled, cross-over trial of 20 healthy volunteers demonstrated that acupuncture at LI2 (二间, Erjian) was associated with activation of the insula and adjacent operculi, while changes were not

observed during sham acupuncture (a sham needle (Streitberger and Kleinhenz, 1998) at a non-acupoint on the ulnar side of the ipsilateral forearm, 3 cm lateral to the PC6). True acupuncture also induced saliva production significantly more than sham.

Buckle's research (2008) on the physiological effects of two different types of touch on the brain (using SPECT – Single Photon Emission Computed Tomography) showed that the light touch (The M technique) which used a pressure of 3 (scale 0-10) was more effective in relaxing the body than the heavier touch that used a pressure closer to 6. That means that the body can respond to any kind of stimulation, which may include sham intervention. So the sham intervention involved in some acupuncture research, especially the research into acupuncture with a group of acupoints, could make the results more confusing and mislead the conclusions of the study.

A large study (Haake et al., 2007) of 1162 back pain sufferers showed no significant difference between real acupuncture and sham acupuncture (superficial needling at non-acupuncture points).

In this study, the attention group was considered to be a better control to investigate the importance of non-acupuncture related placebo effects though it is acknowledged that the issue of what is a placebo control for acupuncture is complex.

10.1.1.2 Waitlist control group

The “Hawthorne effect” was initially observed and described a result of experimental studies carried out from 1924 through 1932 in the Hawthorne Works Plant of the Western Electric Company in Chicago (Parson, 1974). Man has a natural tendency to be influenced by being observed, and therefore being aware of being under observation can alter the way in which a person behaves. The Hawthorne effect has been described in various ways, for example:

“The beneficial effect of taking part in research” (Russell & Grimshaw, 1992);

“An increase in worker productivity produced by the psychological stimulus of being singled out and made to feel important” (Franke and Kaul, 1978);

“An initial improvement in performance following a newly introduced change” (Liebersohn, 1977);

“The confounding that occurs if experimenters fail to realise how the consequences of subjects’ performance affect what subjects do” (Parsons, 1974).

Although first reported in industrial research, the Hawthorne effect clearly has implications for clinical research and routine practice (McCarney et al., 2007). The Hawthorne effect is a component of the nonspecific effects of trial participation, but is not controlled by usual controlled trial designs. Most clinical trials are unable to quantify the magnitude of the Hawthorne effect, such as extra attention by researchers and higher levels of clinical observation which apply equally to treatment and control arms.

In this study, the participants in the control group acted as a waiting list control and had no intervention during the study period. Thus any positive outcomes observed in this group could be attributed to the Hawthorne effect, as there will be changes which occur naturally over time under the observation in the study.

10.1.2 Randomisation

RCTs are considered the most reliable form of scientific evidence in healthcare because they “eliminate spurious causality and bias” (Lachin et al., 1988). Randomisation is the first stage when carrying out a RCT. It reduces opportunities for bias and confounding in experimental designs, and leads to obtaining treatment groups which provide a random sample of the population sampled (Bland, 2000).

In this study, the block randomization method was chosen as being most appropriate. Random allocation is made in blocks in order to keep the sizes of treatment groups similar (Altman and Bland, 1999). The block randomization function randomised 18

participants into the 3 groups (TCA group, attention group and control group) of 6 individuals (see *Appendix 5 The result of the block randomisation*).

10.1.3 Design criteria

The inclusion / exclusion criteria were established in this study to ensure that the participants' conditions were comparable (see *6.2.3 Inclusion / exclusion criteria*).

10.1.3.1 Adherence to the study schedule

The time requirements for participation in the study were strict. Salivary cortisol has a particular pattern of secretion with large heterogeneity and complexity (see *3.2.4 The diurnal profile of salivary cortisol concentration*). Participants were requested strictly to collect the salivary samples on time and adhere to the time schedule of the study. In order to investigate chronic stress from everyday life and work, and avoid the external effects, all participants had to commit to the study and could not go away for a holiday as they had to keep the same pattern during the 8 week study period. If this happened, the participants were excluded from the study.

The intervention was only delivered Mondays to Thursdays, and salivary samples collection was carried out from Tuesday to Friday, to avoid weekends which could be variable and confound the results. Participants in the TCA group and attention group provided samples on the day after each intervention, in the control group on the same day for each week excluding weekends. Research has shown that the cortisol awakening response (defined as the difference between waking and 30 minutes later) is greater on week days than at weekends (Kunz-Ebrecht et al., 2004). On weekdays, people have to get up on time to go to work and the bodies' biochemical reactions are nearly the same. At weekends or on days off there is no pressure to get up at the usual time, and sometimes individuals fall asleep again after initially waking up in the morning. On week days this is unlikely to happen. Therefore taking a sample on waking at weekends cannot be relied on and was avoided in this study.

10.1.3.2 Participants

People who suffer from serious or life-threatening chronic medical conditions, for example, cancer, diabetes, polio, tuberculosis, epilepsy, HIV/AIDS or clinical psychoses were excluded from the study. Although obviously stressful, living with one of these conditions would make it difficult for participants to complete the 8-week study. Also the medications which they would be taking could affect the results.

Other exclusion criteria included those taking medication for psychological disorders or stress related symptoms and those using any other complementary therapies for stress. These would interfere with the effectiveness of TCA for stress. Participants having experienced a severe life event in the previous month were also excluded, because the aim of this study was to study chronic rather than acute stress. Being needle phobic could result in the intervention itself being a major stressor, and such participants were also excluded. Participants planning to change the pattern of taking the contraceptive pill during 8 weeks of study were excluded because this could affect the salivary cortisol levels (Darleen et al., 2003; Kirschbaum et al., 1995), as were those likely to be pregnant (Nierop et al., 2006). Some acupuncture points can be contra-indicated during pregnancy, and it was important to take this into consideration in the study.

10.1.3.3 Screening questionnaires

In order to ensure that the participants presented with a level of perceived stress above a certain minimum, a cut-off of score for the PSS-14 was chosen. This was based on previous research studies using the PSS-14 as an outcome measure of experienced levels of stress (see 3.2.2 *The Perceived Stress Scale – 14 (PSS-14)*).

As this study focused on chronic stress, one of the exclusion criteria was to exclude any life event which may have been as a result of an acute stress response in the last month. The RLE was therefore used as a screening instrument for the exclusion criteria. If a participant reported a severe life event in the previous month at the interview stage they were excluded from the study. Also the RLE was used as a tool to monitor whether life events happened, especially acute severe life events which

could happen during the study period and influence the results (see 3.2.1 *The Recent Life Events Questionnaire (RLE)*). This would have led to exclusion from the rest of the study. In practice, although some life events did occur during the study none were considered serious enough for exclusion to take place.

10.1.4 Outcome questionnaires

Two questionnaires were used as the outcome measures in this study. The PSS-14, a questionnaire frequently used in the psychological approach to stress research, was used to measure self-reported stress levels. In addition, the MYMOP, a patient-centred instrument developed for use in complementary medicine, was used to identify specific self-identified symptoms and whether they changed during the study. As discussed in *Chapter 2 Theory of Stress*, stress is very individual and has many symptoms, therefore it was considered important to investigate the individual's health issues. The rationale for the choice of these two outcome questionnaires is discussed in 3.2.2 *The Perceived Stress Scale – 14 (PSS-14)* and 3.2.3 *The Measure Yourself Medical Outcome Profile (MYMOP)*.

10.1.5 The diurnal profile of salivary cortisol concentration

Salivary cortisol concentration was chosen as an objective, biological measure of the body's reaction to chronic stress. It is also non-invasive technique, and the samples can be easily collected. As discussed in 3.2.4 *The diurnal profile of salivary cortisol concentration*, different methodologies and different measurement times were employed. There were a few research studies using the cortisol concentration as a measurement into acupuncture for stress (see *Chapter 5 A Systematic Review of the Use of Traditional Chinese Acupuncture (TCA) in the Treatment and Management of Stress*). All these studies investigated the differences in cortisol concentration before and after acupuncture. There had been no research into acupuncture on diurnal salivary cortisol profiles in people experiencing chronic stress.

Therefore this study was the first time the diurnal profile of salivary cortisol concentration has been used pre, during and post TCA treatment for chronic stress, to

explore whether TCA could be effective for adults who experienced self-reported chronic stress. As acupuncture is an invasive treatment which is different from other CAM treatments, it may result in a reaction to needle insertion, e.g. nervousness. In order to avoid the effect from needling, the day after the intervention was chosen as the observation point for the diurnal profile of salivary cortisol concentration during the study period.

10.1.6 Case studies

As the sample size in this study was small, it was difficult to carry out statistical analyses for the limited data set in order to draw a conclusion. It was also difficult to use statistical methods to analyse the correlation between the cortisol profile, the life events scales, the PSS and the MYMOP scores. But as part of the pilot study, case studies provided more information on the outcomes for individual participants, and were helpful in explaining the details behind the group results. Furthermore the case studies helped to explore some trends of the effectiveness of TCA for stress levels. Case studies were therefore a very important and useful research addition to this pilot study on TCA as a treatment for stress (see *Chapter 8 Phase 1 Results - Individual Case Studies*).

10.1.7 Focus group study

Paterson and Britten's qualitative research (2004 & 2003) showed that patients and practitioners valued many components of the "acupuncture experience", particularly the TCM diagnosis and consultation, thus suggesting that these interventions were independently perceived as therapeutically valuable. It would be better to define and understand acupuncture as a "Whole System" (Verhoef et al., 2005 & 2004).

This project was supported by information from previous studies which have shown that the use of focus groups within a study provides many benefits. Merton et al. (1990) suggested that group interviewing may be useful to interpret the discrepancies between anticipated and actual effects. In addition, focus groups can also help to interpret the process involved in the intervention's effects. If the intervention did not work as

planned, then the follow-up focus groups with the programme participants could help to identify the reasons behind these problems. Sometimes a programme does not work equally well for all the clients it is supposed to serve, focus groups with different categories of clients can help to locate why it works better for some types of clients than others. Finally, focus groups can evaluate the success of a programme. Investigating the success of a study design by listening to the perspective of its participants may identify whether the intervention has been successfully executed (Morgan, 1997). These issues illustrate the strengths of using focus groups to investigate the “how and why” the intervention succeeded or failed (Yin, 1994).

As part of qualitative evaluation, focus groups can support quantitative research by helping to understand the experiences and responses of study participants (Patton, 1990). Lewith et al. (2008) suggest that in acupuncture research the RCT model should be supplemented with simultaneous qualitative research to understand the patient perceived benefit of treatment. This study used both qualitative and quantitative approaches which helped the interpretation of the data (see *Chapter 9 Phase 2 Results - Focus Groups Study*).

10.2 The study findings

10.2.1 Clinical aspects

10.2.1.1 Treatment principle and diagnosis

Chronic stress and its appraisal are individual and lead to different symptoms for different people. Smolderen et al. (2007)’s research results demonstrate that personality plays an important role in the relation between stress and self-reported symptoms in terms of how and degree to which they are perceived. The degree of stress experienced by an individual is determined not only by external events but also by how a person perceives the events, responds and copes with them (Lader, 1988). Different people have different tolerances to stress. Some people are more sensitive to stress and become easily stressed out, which will adversely affect health leading to a vicious circle.

Though stress is a quite new term in CM, CM including TCA has the similar theory about the causes of stress (see *2.1 Concept and definition* and *4.2 Chinese Medicine theory of health and illness*) to that of western medicine and has a rich clinical experience with a long history.

TCA regulates and improves the body's general condition to release the symptoms of stress, and improves organ function, which in turn protects the body and helps to prevent the development of other problems. Lazarus and Folkman (1984) stressed that the analysis and treatment of stress should also be individual. This also provides a possibility for TCA, which has an individual approach, to help and treat stress and its symptoms.

While a non-specific stress reaction serves to disturb the flow of energy in the body, a specific stress reaction may involve various zang-fu organs. This typically involves the liver, heart, spleen, lung and kidney. The correct differentiation of signs and symptoms can reveal their roles. Such stress can lead to symptoms of stagnation, particularly of the qi (see *4.3 Chinese Medicine understanding of stress*). Various acupuncture points may be selected for treatment based on accurate discernment of the pattern of disharmony, with the generalized aim of treatment to redistribute and balance the qi, and strengthen the organs (if need be).

This project focused on chronic stress, in which all participants had self-reported high stress levels. They did not have serious or life-threatening chronic medical conditions, and were not taking medication for psychological disorders or stress related symptoms (see *6.2.3 Inclusion / exclusion criteria*). This meant that all participants were at the early stage of illness development in terms of their pathology in CM. Their conditions were mainly affected by liver qi stagnation. TCA treatment focused on regulating and improving liver qi's function.

In fact, the result of Chinese medicine diagnosis in the TCA group (see *7.4.1 Chinese medicine diagnosis in the TCA group*) in this study demonstrated that all participants'

diagnoses had the root of their perceived stress in liver qi stagnation. As each participant had a different medical history, a different general health condition, different complaints and symptoms from other participants, the individual diagnosis was different. During the 5 week TCA treatment period, each participant's main Chinese medicine diagnoses did not change, though there were different complaints and symptoms appeared. This showed that 5 week TCA treatment was helpful to control participants' conditions and relieve stress symptoms.

According to the individual diagnosis and the varying complaints over the course of the sessions during the TCA intervention, each participant in the TCA group received an individually tailored treatment. Five participants were treated in a supine position, and one participant in the prone position. The same position was used for each individual for each their 5 sessions. The different treatment principle for each participant and the position maintained decided the acupoints used for the treatment.

10.2.1.2 Acupoints

The aim of TCA is to treat the root of the stress, at the same time it aimed to help to release the symptoms experienced as a result of stress. A wide variety of acupoints were used. Out of a total of 39 points used, 12 points were used more than 50% of the time. One participant with back pain lay on his abdomen during the treatment, and was therefore treated differently from other cases where participants lay on their backs. As a result, points on the front of body were not chosen. SP6, a frequently used point in this study, was not affected as it can be used in either treatment position. The researcher was careful with those people who were receiving acupuncture for the first time and initially limited the number of needles used and sometimes specific areas, such as abdomen or head. Often, different and further acupoints were introduced after the first treatment. Many factors determined the selection of acupoints in the study.

Figure 7.4.2 Distribution of main acupoints used in the TCA group shows the main acupoints used in this study. A comparison with *Figure 5.2.2 Distribution of the*

acupoints used more than once indicates that in this study acupoints which were used more than 50% in the TCA group included almost all the points used in other studies in the literature, except for HT7 which was not used often in this study.

HT7, the steam point and source point of the heart meridian, can nourish the heart, and refresh and calm the spirit. It is often used to treat sleeping problems. The researcher has found that sometimes it is not easy to use this point. When the couch is narrow, for some big participants the needles may be inadvertently pressed, the participant feels uncomfortable and cannot relax. This would have affected the result of the treatment particularly for a problem, such as stress.

Compared to the literature review, RN4 and RN6 were used more often in the study. RN4 is the crossing point of the Conception Vessel and the three foot yin meridians, and enriches the Primordial Qi (Yuan Qi) which is derived from the congenital and acquired essence stored in the kidney. This point has a comprehensive function of the body-essence, and is closely linked to health and sickness. RN6 is called the sea of vitality. It enriches qi's function and is used to treat all illnesses which are related to the qi's disorder (*Classic Fundamentals of Acupuncture and Moxibustion* (《资生经》, Zishengjing) by Zhizhong Wang (王执中) in 1220 (Song Dynasty), cited by Han, 1994). Both points are on the lower abdomen. The area of their location is called "Dan Tian" (丹田), which is described as an important focal point for internal meditative techniques and refers specifically to the physical center of gravity. It is important in qigong and other breathing techniques, as well as in traditional Chinese medicine and is also widely used throughout East Asian meditation and martial arts theory. RN4 and RN6 are common acupoints for tonifying and are used to treat tiredness, menstruation problems, etc. In this study, everyone in the TCA group, most of whom were middle-aged, felt lower energy at baseline interview. This can be explained by liver qi stagnation occurring over a long period had affected the body's qi and blood circulation and participant's well being. So in this study, RN4 and RN6 were used to enrich qi's circulation and function.

The liver meridian is related to many areas of the body and organs. There are 14 acupoints on the liver meridian. Only LR3 and LR2 are often used to treat stress at this stage (see 4.4.3.4 *Rationale for the use of acupoints*). Though the root of stress has a close connection with the liver, the acupoints used do not only include the acupoints on the liver meridian, but also include acupoints on the other meridians which are directly related to the relevant organs or areas. In addition, other acupoints on the liver meridians may be used to treat stress when some special symptoms appear. For example, LR5 (蠡沟, Ligou) could combine with other acupoints to treat plum pit qi (which is also called mei he qi (梅核气) or globus hystericus) caused by stress (Institute of Acupuncture and Moxibustion China Academy of Chinese Medicine, 1991).

From clinical experience, people receiving TCA prefer to lie on the back. In this study, only one participant suffered from back pain and had to use the prone position (see 8.1 *TCA group*). That was according to the general principle of treatment of “treating the symptoms first when they are acute, and treat the root cause when these symptoms are relieved” (Cheng, 1987). This participant had felt stressed for a long period as a result of many reasons. His back pain was not from a noticeable injury or accident, had been very bad for 3 months, and become much worse. This in turn affected his stress levels, and his high stress levels probably made the pain worse. So during the 5 week TCA intervention, he used a prone position every session. His treatment focused on his back pain, and at the same time the researcher tried to choose some acupoints which could be selected in that position to help his high stress levels. Because of prone position, many acupoints on the front of the body used for treating stress could not be selected. After the 5 weeks of TCA treatment, his back pain showed a great improvement and his perceived stress level decreased (see 8.1 *TCA group No. 17*).

In this study acupuncture treatment was individualised, with diagnosis and treatment principles selected according to TCM theory. Acupoints used in the TCA group (see *Figure 7.4.2 Distribution of main acupoints used in the TCA group*) were similar to

the acupoints found in the literature review (see *Figure 5.2.2 Distribution of the acupoints used more than once*). So the current study supports previous research suggesting that these acupoints have specific effectiveness for stress and its symptoms.

10.2.2 PSS-14 and MYMOP results

10.2.2.1 The TCA group compared to other 2 groups

Though at baseline the scores of the PSS-14 and the MYMOP outcomes in the TCA groups were the lowest of the 3 study groups, they still decreased after the 5 week TCA treatment and remained the lowest of the 3 groups.

Comparing the results pre and post the 5 weeks of treatment within group, the TCA group had statistically significant improvements in Profile Score and Symptom 1 & 2 in the MYMOP, whilst the attention group only had statistically significant improvements in Profile Score and Symptom 2 in the MYMOP and the decreases in the control group did not reach statistical significance.

Comparing the results between the groups, the TCA group also showed significant improvements on Profile score, Symptom 1 & 2 compared to the control group, whereas the attention group showed significant improvements only on Profile score and Symptom 2.

Although the sample size is small, this pilot study still demonstrated that the TCA group showed a greater statistically significant improvement than the attention group. This result is more positive than other similar-designed studies with a bigger sample size. For example, Smith et al. (2007)'s study in 131 subjects compared yoga and relaxation as treatment modalities to determine if either of modality reduced stress, anxiety, blood pressure and improve quality of life. After the 10 week intervention period, the results of the study only showed that yoga was as effective as relaxation in reducing stress, anxiety and improving health status on seven domains of the SF-36

and yoga was more effective than relaxation in improving mental health. The improvement in this study did not reach statistical significance.

In addition, the results for the RCT, case studies and focus groups reports demonstrated that there were specific symptoms which improved over the 5 week intervention in the TCA group, as opposed to the other 2 groups. For example, menstruation returned for No.3, the improvement in the sense of smell in No.10, the relief of the back pain in No.17. This demonstrated that TCA was effective over the 5 week TCA intervention not only for stress, which was similar for the attention group, as well as some specific symptoms, which in certain cases had not been mentioned in the research questionnaires, but were picked up during the consultation. No similar specific symptom improvements were reported in the attention group. This is confirmed by previous studies that have found similar results where patients of traditional acupuncturists experienced benefits beyond the alleviation of their presenting condition, including improvements in physical / mental health, emotional well-being and changes in personal identity and lifestyle (Hughes et al., 2007; Paterson and Britten, 2003; Walker et al., 2003; Alraek and Baerheim, 2001; Gould and MacPherson, 2001).

The PSS-14 and the MYMOP results for the TCA group fluctuated over the study period. In the 2 weeks after TCA (when TCA had stopped for 2 weeks), the scores of the PSS-14 and the MYMOP outcomes in the TCA group increased (except Symptom 2 which remained the same), but they were still lower than the baseline. Compared with the other 2 groups, the scores in the TCA group were lower than the control group and similar to the attention group (see *Figure 7.5.1 Mean PSS-14 scores over the study period* and *Figures 7.6.3-1, 2 & 3 Histogram of mean MYMOP scores over the 3 time periods for the 3 study groups*). This indicates that TCA treatment produced improvements in symptoms and relieved stress levels after the 5 weeks of TCA, but this had not been sustained. Chronic stress is from everyday life and complex, TCA treatment may need to be given for longer than 5 weeks to consolidate the effects. This needs to be explored in the further research.

10.2.2.2 The attention group compared to the control group

In this study, the mean scores of the PSS-14 and the MYMOP outcomes in the attention group decreased over the study period. The changes in Profile Score and Symptom 2 reached statistical significance after the 5 week attention period, which lasted to the 2 weeks post attention. The attention group also showed statistical significance on Profile Score and Symptom 2 compared to the control group. These results suggest that the attention group improved over the course of the study more than the control group.

The results show that the participants in the attention group had some similar positive responses to the TCA group, which were indicated either by the outcome measures or the feedback in the focus groups study. This suggests that non-specific effects were operating, and improved levels of perceived stress and its related symptoms in this group. Actually, once a week coming to see the researcher, talking something about their stress and lying down for half an hour did help them to release their stress level, which was reflected by the results of the focus groups study. The effect of relaxing and time-out on stress levels has been illustrated by the research from Clow and Fredhoi (2006). Its result showed that the cortisol level of city workers rapidly and substantially dropped after visiting an exhibition during the lunch break, which would be expected to take about 5 hours of normal diurnal decline for cortisol levels to fall to the same extent.

10.2.2.3 Control group

In this study, the results of the control group showed that there were decreases in the PSS-14 score and the MYMOP outcomes over the study period though they did not reach statistical significance. The participants in the control group acted as a waiting list control and had no intervention, therefore their outcomes were affected by the Hawthorne effect or natural change over time.

In conclusion, this study indicates that perceived stress and its related symptoms can be affected by a variety of specific and non specific interventions. The control group

showed improvement simply from the effects of taking part in the study, whereas the non-specific effects incorporated into the attention group scenario resulted in a greater improvement. The TCA treated group showed a similar improvement with the addition of further symptomatic improvements which may be related to the specific effects of the TCA treatment.

The MYMOP showed the greatest responsiveness in the current study. This study also verified that the MYMOP was sensitive to the interventions in this study. Though there were changes of the mean PSS-14 scores in the 3 study groups during the study period, no one group reached statistical significance. This may have been due to the interventions themselves which actually did not work well enough. The literature review (see *Table 3.2.2 The mean score of the PSS-14 in the previous research*) shows that the PSS-14 is a reliable tool, but the smallest study identified had 60 subjects.

10.2.3 The impact of life events

The RLE was used as a screening instrument and as a monitoring tool in this study. The results of the RLE seemed not to be correlated with the clinical group data. For example (see *Table 7.3 Recent life events experienced by the study participants* and *Table 7.5.1 PSS-14 scores for the 3 study groups*), at baseline (pre intervention) the participants in the TCA group experienced more life events than the other 2 groups, but the mean PSS-14 score in the TCA group was the lowest in the 3 groups; after the 5 week intervention period (post intervention), the participants in the control group experienced the least number of life events, but the mean PSS-14 score was the highest in the 3 groups. This may be explained by the fact that the small sample size made it difficult to demonstrate the correlation between the life events and the perceived stress scales. But in the individual case studies, the RLE helped the interpretation of the clinical and laboratory data for some individuals.

10.2.4 Salivary cortisol results

From the results of salivary cortisol concentrations (see *Chapter 7 Phase 1 Results - Individual Case Studies*), the diurnal cortisol profiles reflected considerable individual

variability. Generally the diurnal salivary cortisol profile did not appear abnormal before the intervention, especially in the TCA group. This indicated that either the participants in the groups were not stressed enough to disturb the HPA or the HPA was not sensitive enough to reflect the participants' self reported stress. An interesting result of the cortisol measurement, and worthy of further investigation, were the changes observed in the average morning rise over the period of the study. Both the TCA and attention groups showed an overall increase in the morning rise, suggesting a normalization of diurnal profile, whereas the control group showed an overall decrease in the average morning rise, suggesting a more stressed diurnal profile. These preliminary observations suggest that a more simplified cortisol sampling schedule (the first two data points of the diurnal profile only) could be used as a research tool in subsequent studies.

Research evidence suggests that psychological variables including stress and other conditions such as novelty, unpredictability, and uncontrollability are associated with increases in HPA activity and cortisol release (Mason 1975). However, in many of these studies, a substantial percentage of subjects did not respond (i.e. do not show elevated cortisol levels) after exposure to a stressor, possibly owing to strong anticipatory effects (Kirschbaum and Hellhammer, 1989). The sensitivity of the HPA to a variety of different conditions and events may make it less useful as a specific indicator of stress, and the interpretive issues raised by nonresponders or even people who show inverted responses made the cortisol measures difficult to interpret.

Bartels et al. (2003)'s research with 12-year-old children showed that a significant genetic contribution was found in the variation of basal cortisol levels in the morning and afternoon samples. Other research concluded that childhood family environments represent vital links for understanding mental and physical health across the life span and disruptions in the stress-responsive biological regulatory systems, including the SAM and HPA functions (Repetti et al., 2002). So genetic and environmental factors could affect stress levels and decide individual differences in the cortisol concentration. Someone who has a good and stable environment will respond less to stress. Marieke

et al. (2007) found that genetic liability to depression was in part expressed as the tendency to display negative effects in response to minor stressors in daily life.

Human study groups are not genetically identical in the way animal models are, so the genetic polymorphisms natural in any population make interpretation of data so much harder. In this small sample study, it is hard to find one genetic response (Taylor-Vieira, 2008).

Studies measuring cortisol concentration have given negative results in some complementary medicine studies. For examples, the research into the effectiveness of babies massage on mothers (Fujita et al., 2006) revealed that there were no significant differences in the salivary cortisol levels between the experimental group and control group at 3 months after delivery though significant differences in the Profile of Moods States (POMS) score were seen for depression and vigour. Also salivary cortisol did not change significantly after the reflexology in Vicar's study (2007).

Apart from the morning rise of cortisol concentration, which may be a potential useful chemical outcome to measure the effectiveness of acupuncture for stress and requires a large study to confirm, it is difficult to draw a firm conclusion that cortisol concentrations demonstrated positive changes in this small sample.

10.2.5 Discussion of the case studies

Case reports consist of personal details which can be powerful in illustrating the rationale for diagnosis and treatment. The case study has been central to the knowledge base of Chinese medicine (see 6.1.4.2 *The case study reports*).

As part of pilot study, case studies provided more information in the results of the outcomes for individual participants, and were helpful to investigate more details behind the group results. Furthermore they were used to explore some trends in the effectiveness of TCA for stress levels. For example, TCA 3's menstruation had been irregular for 2 months before she started the TCA treatment. After 4 sessions of the

TCA, her menstruation came on time. The participant did not recognise and did not report this problem in the questionnaires and focus groups meeting. The researcher collected this information in the TCA consultation. This change would seem to show that the TCA helped her to release her stress levels and rebalance her hormone levels to regulate her menstruation.

The PSS-14 scores for the intervention group showed a decrease during the study period, but these were not large enough to show a significant difference. One reason may be related to the questionnaire itself (see *10.3.1 Small size of samples*). Another reason is because stress is a complex problem and can be easily affected by any internal and external factors. The case studies provided an opportunity to combine all the information collected from the study (including objective and subjective, from the participant and the researcher) to allow an exploration of the individual results (*Chapter 8 Phase 1 Results - Individual Case Studies*).

Case studies also demonstrated that over the study period the participants in the TCA group reported more complicated life events than the 2 other groups. This was helpful to explain why there was a fluctuation of the scores of the PSS and the MYMOP in the TCA group over the study period.

To sum up, the use of case studies to explore the patient's perspective on treatment and TCA delivery was a very important and a useful research approach in this study.

10.2.6 Discussion of the focus group study

In this small sample pilot study, the purpose of using focus groups was to sample the range of opinions from participants in terms of their experience of the interventions and to obtain feedback on the research methods employed. This would help to identify whether there were additional effects as a result of using TCA for stress. This focus group approach also allowed the opportunity to assess whether the outcome measures used in this research project were appropriate and acceptable.

The major difference emerging between the TCA group and attention group was in their experience of the intervention used for stress. The participants in the TCA group appeared to report feeling less stressed after their treatment, in addition, some participants noticed that other symptoms improved as well as some of their symptoms of stress. This was consistent with the results of the MYMOP which showed that the TCA group reported more symptoms which had improved compared with the attention group after the 5 week intervention period (see 7.6 *Measure Yourself Medical Outcome Profile (MYMOP)*). The participants in the TCA group also reported that their colleagues and family members had noticed they were more relaxed after TCA. In the attention group, participants reported that they felt the benefit from relaxation and being able to lie down, but no one reported that the stress symptoms had improved or that they had received positive feedback from other people. The attention group experienced transient benefits on the day of the treatment and remarked on having the opportunity to physically lie down and have a rest during a busy working day (three participants actually reported falling asleep). As a result of taking part in the study two participants reported that they had learned the importance of taking time out of a busy day or had learned how to cope with their stress. Participants receiving TCA reported that their colleagues / partners had commented on the fact they appeared less stressed (more discussion is given in 10.5.2 *Attention only intervention in TCA research*). TCA appeared to not only to have helped people to relax and relieve symptoms of stress but in addition helped unrelated health problems that occurred during the 5 week period which were also treated.

The results from the focus groups were not only helpful when analysing the data for this study, they also provided useful contextual information concerning the participant's perception of the research design. Some participants reported problems in completing the questionnaire and collecting samples. These issues could be taken into account in future studies, either through more in depth discussion of how participants should complete the questionnaires or by using different outcome measures. The problems experienced with sample collection at 4 time points proved stressful in itself

and the quantitative data and results from none TCA research suggests that the morning rise alone can be used as a sensitive measure for demonstrating change.

More discussion on the focus group study and the results are given in *9.3 Discussion (Focus groups study)*.

10.2.7 Mechanisms of the intervention for stress

The results of both the quantitative and qualitative phases of this study suggest that the TCA group demonstrated a greater improvement in their perception and symptoms of stress than the attention group. This could be explained by the different routes by which TCA and relaxation work in the process of cognitive appraisals and coping with stress (see *Figure 10.2.7 TCA in the process of cognitive appraisals, coping mechanisms and their possible health outcomes*).

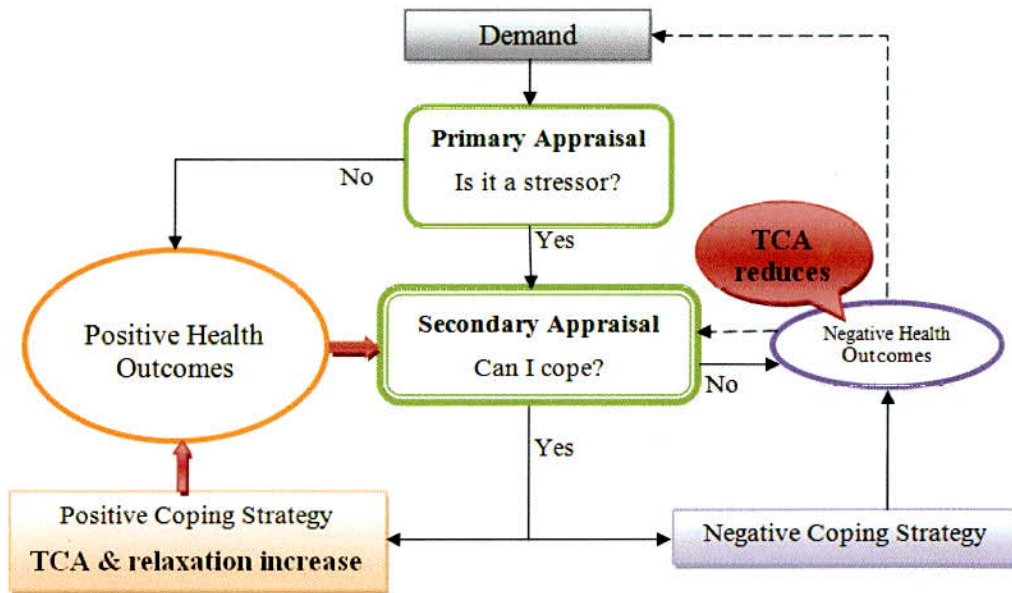
As discussed in *2.4 Cognitive appraisals and coping mechanisms*, there are two types of appraisals, primary and secondary. Primary appraisals refer to “a set of cognitions regarding the importance of a stressful situation for a person” (Chang & Strunk, 1999). Secondary appraisals are “a set of cognitions concerning an individual's resources for dealing effectively with the situation”. Both appraisals affect a person's ability to cope and adjust to stressful situations.

At secondary appraisal, a positive coping strategy can lead to positive health outcomes. The TCA and relaxation (attention in this study) are part of these positive coping strategies (to increase positive coping strategy). When either no coping strategy is available or a negative coping strategy employed, negative health outcomes occur. If there is no treatment or management at this stage to help and control stress levels, negative coping strategy can either become another stressor which creates a vicious circle or could be appraised as a failure which makes it even more difficult to cope. Successful treatment of stress through improving coping mechanisms by “maintaining a positive self-image, maintaining an emotional equilibrium and further more

continuing a satisfying relationship with another” were proposed by Lazarus and Folkman (1984) (see 2.4 *Cognitive appraisals and coping mechanisms*).

According to TCA theory and its clinical experience (see *Chapter 4 Traditional Chinese Acupuncture (TCA) in the Treatment and Management of Stress*), TCA can not only treat stress symptoms and stress-induced illnesses (reduce negative health outcomes), but may also improve these coping strategies (improve positive coping and health outcomes). So TCA could work at this stage to break two pathways and stop the vicious circle. The process is shown in *Figure 10.2.7*. Relaxation, as experienced by the attention group in this study, helps to improve positive coping and health outcomes, but does not directly affect symptoms.

Figure 10.2.7 The effect of interventions in the process of cognitive appraisals, coping mechanisms and their possible health outcomes*



*: Adapted from Howie’s work (2008)

In addition, the Hawthorne effects may also cause some positive results in the control group by affecting the coping mechanisms. Because this study was about stress, the participants in the control group may be more aware of stress, and they may look after

themselves better and choose positive coping strategies. This may explain why the scores of PSS-14 and the MYMOP in the control also decreased during the study period.

Acupuncture is very effective for promoting relaxation in cases of heightened excitation and restlessness (Flaws and Lake, 2003). Stress affects everyone. Acupuncture can induce relaxation as well as providing treatment for other problems through regulating qi and blood circulation, improving organ's function and repairing body's yin-yang balance. Furthermore TCA can improve the body's general condition and prevent chronic stress and its symptoms from developing or deteriorating into a more serious disease. As Sher (2004) states, one of the goals of prevention of stress-related disorders is to help individuals be more competent in managing their behavior and emotions in reaction to negative aspects of their environment. TCA may help individuals to achieve this goal.

10.3 Strengths and limitations

10.3.1 Small size of samples

As this was a pilot study and also the study budget was limited, small numbers of participants were recruited. A small sample size poses a challenge to any statistical analysis (McPherson et al., 2004; Stockwell and Peterson, 2002). Especially in this study, stress and its measures including the PSS-14, the MYMOP and salivary cortisol concentration could vary, one participant's data could affect the groups' mean data significantly.

The small size of the samples was also problematic regarding the sensitivity of the outcome measures. It was difficult to see a positive trend in the results and also hard to interpret the results. For example, though there were changes in the mean PSS-14 scores in the 3 study groups during the study period, no one group reached statistical significance; and there was no consistency between the RLE and the PSS-14. This may have been due to interventions themselves that actually did not work well enough in this small group.

Comparison of the type of symptoms identified in the MYMOP could not be carried out because of their diverse nature. For example, for the MYMOP each respondent reported a different symptom, except “tiredness”.

The cortisol concentration results exhibited a wide variation between individuals. Participants were probably not stressed enough, as no negative trend of salivary cortisol profiles was found in those participants who self-reported high stress levels. Normally studies of 30 or more people would reduce the standard deviation of the individual differences of cortisol concentration (Taylor-Vieira, 2008).

Though the sample size was small, some positive trends of outcome measures in this study including the PSS-14, the MYMOP, and the morning rise of the cortisol concentration (Δ cortisol) were found. Particularly some MYMOP outcome scores reached the statistical significances (see 7.6 *Measure Yourself Medical Outcome Profile (MYMOP)*). This partly can be explained by the design of the questionnaires. For example, the score range of the MYMOP is between 0 and 6, while the score range of the PSS-14 is from 0 to 56 (see 3.2.2 *The Perceived Stress Scale – 14 (PSS-14)* and 3.2.3 *The Measure Yourself Medical Outcome Profile (MYMOP)*). The MYMOP therefore worked better in the small sample size study compared with the PSS-14.

Based on the literature review and under supervisors and other experts' help, a combination of quantitative and qualitative methods was employed in the study in order to reduce the effect of the weakness of a small sample size and collect more detailed information on each subject throughout the study in order to test the methodology and outcome measures and explore the trends in results of the pilot study.

10.3.2 Gender and age

Taylor et al. (2000) has suggested that females respond differently to a threat by seeking social support and protection of their offspring. This process may be triggered by the addition of sex hormones which are produced by the stress reaction. Kajantie

and Phillips (2006)'s research found that between puberty and menopause, adult women usually show lower HPA axis and autonomic responses for men of same age. However, the HPA axis response is higher in the luteal phase, when for example post stress free cortisol levels approach those of men. This result supported the result of the research carried out by van Cauter et al. (1996), who found that mean cortisol levels of premenopausal women was slightly lower for men in the same age range, primarily because of lower morning rise. In addition, their research indicated that an age-related elevation in the morning rise occurred in women, but not in men. Bruce (2005)'s study showed that males and females experience different patterns of chemical response to novel, or non-persistent work stress.

Besides gender, age may affect the results of the cortisol concentration. Asnis et al. (1981) carried out research into 25 hospital patients, ages 26-64, with severe major depressive disorders and found that a significant relationship between cortisol secretion and age during endogenous depressive illness. Hyper-secretion of cortisol occurred primarily in the older patients, especially those over 50 years old. After clinical recovery, when plasma cortisol levels returned to normal, there was no significant relationship between cortisol secretion and age. van Cauter et al. (1996)'s study on 177 normal people (90 men and 87 women, 18-83 years old) showed that the diurnal rhythmicity of cortisol secretion was preserved in old age, but the relative amplitude was dampened, and the timing of the circadian elevation was advanced. The research on 94 healthy individuals aged 6-14 years found that there was an increase in morning salivary cortisol levels as the subject ages (the older the child, the higher salivary cortisol levels at 8:00am) and no significant sex difference in salivary cortisol levels among the subjects (Safarzadeh et al., 2005). These results were in agreement with the results from Kiess et al. (1995)'s study on children and adolescents. Though so far there has been no other research into the relationship between the stress response and age, these results of previous studies indicated that age may affect the results of stress.

In this research, more females than males took part though they equally randomised into the 3 study groups. As the sample size was small, this study cannot be generalised

to population and also cannot investigate the difference between the genders. In terms of age, the ages of the control group were younger than the other 2 groups, but there was no statistical significance between the groups (see 7.2 *Demographic characteristics*). Because of the small size in this study, no specific trend was shown between participants' ages and their cortisol concentrations (see *Chapter 7*).

As this was a pilot study into chronic stress over a limited time, and also the effects of gender and age on stress were not very clear, it was better to recruit both genders and different ages to investigate and collect the general information, rather than limiting research areas (single gender or specific age range).

10.3.3 Clinical practice

10.3.3.1 Practitioner's effects in TCA

As discussed in 10.1.1.1 *Attention group*, the increased interaction between patients and therapists will invariably cause non-specific effects – placebo effects – that will affect treatment outcomes to various extents. Di et al. (2001)'s systematic review concludes that the health care setting is one component of the placebo (or context) effect. While placebo effects were explored in all branches of medicine for achieving positive clinical outcomes, Kaptchuk (2002) suggested that CAM may be an “especially successful placebo-generating system”; he argued that conventional trials which are designed to test specific efficacy and exclude placebo effects neglect the fact that clinical outcomes can be greatly enhanced by optimising these effects. In terms of the health care setting, he acknowledged its importance, and suggested that CAM settings have a “special allure of mystery and power”. The philosophy of health and holism are conveyed in a variety of ways (Long, 2002; Bell, 1987), both verbally and non-verbally, through the practice environment and attitudes of practice staff.

TCA is a holistic approach to health underlined by the ancient philosophical and medical theories of China combined with western medicine theory, and its treatment is based on a Chinese medicine diagnosis, while western-style acupuncture is based on a modern interpretation of acupuncture which is supported by anatomical,

physiological and pathological principles (British Medical Association, 2002). TCA treats various conditions and maintains health, not just pain relief where western-style acupuncture is often used (Paterson, 2007). Research has shown that differences typically exist in the training and practice between TCA and western-style acupuncture (British Medical Association, 1993 & 2000; Dale, 1997). Specifically, traditional acupuncturists generally complete longer periods of training, and administer a more practised treatment incorporating a greater range and number of needle insertion points than western acupuncturists. Liu (2006) states that TCA as a complex non-pharmacological therapy depends solely on the acupuncturists' skills, competence and understanding of Chinese medicine theory to work and necessitates an active and central role of acupuncturists in acupuncture treatment.

The characteristics of TCA could be reflected by the practice of a TCA practitioner. The researcher as a practitioner in this study is a qualified acupuncturist and doctor of Chinese Medicine with an 8-year, full time training in Beijing University of Chinese Medicine (BUCM). In order to investigate and exclude the practitioner's effect, the attention group was established which the same practitioner attended and managed the time at the clinical sites in the same way as the TCA group. This was helpful in interpreting and analysing the results where both groups experienced the same condition except for the process of TCA which also included a Chinese medicine consultation and needling technique. As the same acupuncturist worked through the whole study period, the personal acupuncture style and skill was consistent for all TCA treatments. The personality of the practitioner and his attention given were also consistent for both groups.

10.3.3.2 Participants' influences

During the whole 8 weeks of the study, the participant's environment was ongoing and complex. This directly affected the participant's feelings and stress levels, and furthermore could have affected the results of questionnaires.

As the study was designed over an 8 week period including the 5 week intervention period, it was unavoidable that some participants would experience some additional health problems. For example, No.17 had a skin problem during the study which affected his sleep and he also started using steroid cream. The skin problem may have been induced by his high stress levels due to a stressful life and work, and change of his job. One participant suffered from a cold, and another had a headache. Because of the ethical issue, also the limited time and budget of the study, participants experiencing such symptoms during the study were not excluded in the study.

Also there were a lot of human factors which may have acted as confounders during the process of taking salivary samples. Every time when the researcher gave a participant the introduction sheets (see *Appendix 6.1 Instructions for collecting saliva with the salivette* and *6.2 Introduction and time-record sheet*), he had to remind them that saliva should be collected before they brush their teeth in the morning to avoid damaging the gum and bleeding; during the day, saliva had to be collected no earlier than 30 minutes after eating or drinking in case of the food interference. But this was difficult for some participants (see *Chapter 9 Phase 2 Results - Focus Groups Study*). For example, in the focus group, one participant said: “I managed the first three because they were relatively close together but each time I’d either eaten something at half past five and I thought, oh, I’m not supposed to eat for another half hour or I thought, oh dear, it’s...you know, the swab’s not here. And then I couldn’t put them in the freezer because they were all in the car.” In the focus groups, both groups expressed that taking samples on time was arduous, which increased their stress sometimes. This could be one of the factors which could have affected the results of the research. Also some participants reported that sometimes they did not take samples on time and sometimes they had to take samples at some special situation, e.g. No. 3 (in attention group’s focus group) was having a break in Wales when she provided one set of samples.

All these effects were reflected in the fact that the results of the diurnal salivary cortisol profiles were not stable (see *7.8 Cortisol response*). Variable salivary cortisol

profiles actually suggested that some participants did not take samples immediately when waking, or did not follow the instructions and ate or drank before taking the sample, or totally forgot to take the samples (see *Chapter 8 Phase 1 Results - Individual Case Studies*). Also later on in the study, e.g. intervention week 4 or 5, or 2 times in the 2 week post intervention, some participants may have become lazy and did not take the samples on time. This was independent of whether the participant belonged to the TCA, attention, or control group.

There were some problems around the sample collection given, especially that the study was small, and this would directly affect the results of the study. The pilot had a major aim to test the methodology and outcome measures and explore the trend of positive results through the combination of qualitative and quantitative research methods. The design of the study was feasible, but a larger study is needed to confirm these observations.

10.3.4 Questionnaires' limitations

10.3.4.1 Inconsistency of the stress levels

Over the study period, *Table 7.3 Recent life events experienced by the study participants* indicated that the participants in the TCA group overall experienced more life events (42) than the control group (35) and the attention group (29). The results of the case studies and focus group study show that over the study period the participants in the TCA group were more stressed than the other 2 groups, but this was not reflected in the results of the PSS-14 and the MYMOP.

In fact, in the TCA group the PSS-14 scores were the lowest of the 3 study groups pre and post intervention, and 2 weeks post intervention they were higher than the attention group and lower than the control group (see *Table 7.5.1 PSS-14 scores for the 3 study groups* and *Figure 6.5.1 Mean PSS-14 scores over the study period*).

The results of the MYMOP scores were similar to those of the PSS-14. The TCA group had the lowest MYMOP scores of the 3 groups pre and post intervention. In 2

weeks post intervention, the MYMOP scores in the TCA group increased and were slightly higher than the attention group except for “Symptom 2” which was the same as the attention group, and were still lower than the control group. (See *Table 7.6.3 Mean MYMOP scores for study participants over the 3 time periods* and *Figures 7.6.3-1, 2 & 3 Histograms of mean MYMOP scores over the 3 time periods for the 3 study groups*).

The above inconsistency in the results of RLE, case studies, focus groups study, and the results of the PSS-14, the MYMOP suggests that the questionnaires did not directly reflect the stress levels that participants really had. So the results of the study may not relate directly to how a person perceives their stress.

10.3.4.2 The design of the questionnaires

There were some problems with subjects’ recall of symptoms and stressful occurrences over the time period, particularly when the type and number of symptoms varied. This may have affected the way the questionnaires were completed.

The MYMOP investigated participants’ feelings in the previous week. Chronic stress symptoms were variable, and some of them occurred only briefly. Therefore, the results of the MYMOP follow-up 1 may not have reflected all the changes during the 5 week intervention, and the results of the MYMOP follow up 2 may not have reflected all changes during the 2 weeks after the intervention period. In hindsight, the MYMOP should ideally have been completed at each weekly session to monitor any rapid changes, or the MYMOP follow-up 1 should have referred to all 5 weeks of the intervention period and the MYMOP follow-up 2 should have referred to the whole 2 weeks after the intervention.

The PSS-14 and the RLE had different cut-off periods from the MYMOP: for the follow-up 1, the cut-off period for the PSS-14 was for the previous 1 month, and the RLE was for the previous 5 weeks; for the follow-up 2, the cut-off period for the PSS-14 and the RLE were for the previous 2 weeks (see *Appendix 7 Questionnaires*).

Participants may have been confused when completing the 3 questionnaires at the same time, all of which had different cut-off periods. That could have affected the questionnaire results.

When using more than 2 questionnaires, questionnaires are better to be used if they follow the same or similar process. This is helpful for the participants to fill in the questionnaires more easily and ensures the results of the questionnaires are more reliable.

10.3.4.3 Symptoms in the MYMOP

In the study, some of symptoms reported in the MYMOP consist of a group of symptoms which were included in an illness, rather than a single symptom, e.g. heavy cold, asthma (which have a range of symptoms). The researcher did ask participants to clarify but it was difficult for them in some circumstances. In future the symptoms which may be recorded in the MYMOP could be made clearer to the participants (see *Table 7.6.1-1 Symptoms reported in the first MYMOP*).

In summary, due to the limited study budget and time, the complex nature of the intervention, and the small numbers of participants available who matched the strict inclusion criteria, it was not possible to reveal differences between the gender, age and groups identified by patterns in Chinese medicine in this project. In order to compensate for the small sample size and strengthen the understanding of the complex nature of stress, a mixed methods approach was employed. The methods included a number of sequential quantitative measurements covering both physical and psychological aspects of stress, as well as qualitative methods which explored the experience of treatment. This enabled collection of a large amount of data for each participant. The results suggest that the design of the study was feasible, but needed a larger number of participants to allow meaningful statistical analysis.

10.4 Reflections on the treatment protocol

The researcher's reflections on the experience of the process of carrying out this research project, its strengths and weaknesses have been discussed in *10.3 Strengths and limitations*. Reflecting on the individual case studies encouraged the deeper consideration about his own TCA clinical practice as well as how this fitted into a research paradigm (see *Chapter 8 Phase 1 Results - Individual Case Studies*).

Chinese medicine is a system of diagnosis and health-care approaches that has evolved over the last 3,000 years. The Chinese approach to understanding the human body is unique. It is based on the holistic concept of the universe, and it has produced a highly sophisticated set of practices designed to cure illness and to maintain health and well-being (Williams, 1996). Identification of CM patterns is the method of recognizing and diagnosing diseases. According to the basic knowledge of CM, this method involves a comprehensive analysis of the symptoms and signs obtained by applying the four diagnostic methods. In CM theory every illness has different patterns, which influence individual treatment in clinical practice. TCA is an important part of Chinese traditional medicine. Its clinical practice and research should follow the CM theory and treat patients individually by using identification of patterns.

In this project, according to CM theory, literature review and the researcher's clinical experience, five common pattern types of stress were identified and their related treatment protocol were designed (see *Chapter 4 Traditional Chinese Acupuncture in the Treatment and Management of Stress*). The researcher used this identification of CM patterns and related treatment protocols to treat the participants in the TCA group. However during the 5 week study period, some participants reported further symptoms which required the use of additional acupoints for treatment. For example, No.10 had a heavy cold; No.17 had a back pain and skin problem. The researcher also adjusted the treatment protocol to treat their current symptoms as well as treating their stress. The results of the PSS-14 and MYMOP and the participant's feedback showed that when their current symptoms improved, their stress levels also improved correspondingly. It was important for the pragmatic design of this project that individual treatments should

follow the reality of clinical practice whilst maintaining the overall aims of the research. Thus the individual treatment according to different identification of CM patterns and the protocol used in this research project reflects the character of TCA and clinical practice.

In research, it is important to set up a standard treatment protocol, but when using a pragmatic approach, research studies must use a protocol which depends not only on the design of the study but on the treatment of each individual subject as well. For example, when the project is restricted to the study of specific acupoints, then the treatment protocol must be limited to these. When the project is related to the use of TCA for a condition or an illness, its protocol can include a wide group of acupoints and may also allow for the adjustment of treatment according to the individual symptoms presented “on the day”. This reflects TCA training and clinical practice. It was this balance between the use of specific points which could alleviate stress and the treatment of new symptoms as they presented which challenged practitioner himself as a researcher. The results from this project therefore contribute both to the evidence base and to development of TCA clinical practice in the field of stress management.

10.5 Implications for future work

According to the experience of the research, further suggestion on the design and methods for future work is outlined.

10.5.1 A combination of quantitative and qualitative methods in TCA research

This was the first time the researcher had used qualitative methods combined with quantitative methods in this type of project (see *6.1.4 Rationale for the study design*, *10.1.6 Case studies*, *10.1.7 Focus group study*, *10.2.5 Discussion of the case studies* and *10.2.6 Discussion of the focus group study*). Quantitative methods are considered more objective, more scientific and more suitable to be used in research into natural science, and acupuncture belongs to natural science. Especially in China quantitative results are preferred and much research is in the form of animal studies into the

physiological effects of acupuncture. The researcher believes that the study design used in a research topic as complex as stress should use methods which reflect the need to explore this complexity. As TCA is a “whole system” (Verhoef et al., 2005 & 2004) and has many components, particularly the TCM diagnosis and consultation (Paterson and Britten, 2004 & 2003), it is important and necessary for TCA human clinical research to employ qualitative methods, like the case study and focus group study, in order to interpret the process involved in the intervention’s effects and help to understand the experiences and responses of study participants. So a combination of quantitative and qualitative methods can help to reveal the effectiveness of the pragmatic use of TCA in the clinical research of a complex problem such as stress. It also enables the intervention to be provided in a form much closer to the actual experience of the subject receiving TCA healthcare. This type of approach is therefore suggested for any future TCA clinical research.

10.5.2 Attention only intervention in TCA research

In order to investigate non-specific effects in TCA treatment, the different “sham intervention” techniques are commonly used as a placebo control in the RCTs, but there is a lot of controversy about “sham intervention” and no clear conclusion is drawn from it (See *10.1.1.1 Attention group*). For small sample sizes it is difficult to show a difference between the outcomes of “true” versus “sham” acupuncture. The “sham intervention” itself adds another dimension to the treatment protocol with the possibility that skin pressure, slight pricking of the skin or non-point needling have some kind of therapeutic effect. There is currently no consensus on the best type of “sham intervention” or its value as a placebo control (Linde and Dincer, 2004; Dincer and Linde, 2003).

In this study, the attention group (see *6.2.7.2 Attention group*) was set up as a control group to investigate any non-specific and placebo effects in TCA. Though this was the first study to use an attention group in TCA research, the attention group did demonstrate that there were some differences compared with the waiting list control and TCA groups, even with such a small sample size. The attention only intervention

retained some aspects which were similar to the TCA intervention (lying down, completing questionnaires and collecting saliva samples, etc), but did not include the physiological and psychological needling effects. However in providing an alternative “treatment” the subjects in this group may have potentially experienced a placebo effect as a result of their belief in the effectiveness of an opportunity for “relaxation” during a working day. They in fact received the non-specific benefits of the attention from the practitioner as well as the relaxation. In contrast, the waiting list control only benefited from either an unrelated improvement in their health and personal circumstances or the Hawthorne effect (see 10.1.1.2 Waitlist control group). The attention only group provided a better comparison to investigation the different therapeutic effects operating within TCA clinical practice, such as a Chinese medicine consultation and needling. The combination of an attention group and a waiting list control was an effective tool for research into complex interventions (such as those operating in complementary medicine) by exploring the effects of a specific therapeutic intervention as well as the non-specific and placebo effects. As this was the first time that an attention only intervention has been used as a control group in TCA research, it may require further investigation, particularly in the role that expectation plays in health improvement.

10.5.3 Morning rise of cortisol concentration

The incremental change in cortisol concentration is called “delta (Δ) cortisol” (Daniel et al., 2006; Marik, 2006). The literature showed that burnout and exhaustion are associated with reduced cortisol secretion in the first 45 minutes after awakening (Pruessner et al., 1999). There is clear evidence that the first 30-45 minutes post-awaking is very sensitive to the effects of stress (Bauer et al., 2000). This part of the cycle is more likely to reflect underlying stress rather than be affected by events during the day.

Table 7.8.3-1 Data on morning rise of cortisol concentration for the 3 groups and Figures 7.8.3-1, -2&-3 Mean morning rise of cortisol concentration during the 5 week intervention period for the 3 study groups illustrate that the TCA group had the greatest

level of change in week 4 (9.28nmol/L) in the 3 groups. Generally during the 5 week intervention period, the mean morning rise in the TCA group was greater than for the other 2 groups except for week 5 when it was lower than the attention group. The initial rise in cortisol levels after waking showed an average increase during the intervention in the TCA group and the attention group, with both groups showing upward trends. The control group showed an overall decrease in the average morning rise over the same period. One participant in the attention group had a wider range in the morning rise of cortisol concentration and these results affected the mean morning rise of the group (see 9.2 *Attention group* (case studies)). It was therefore difficult to compare the morning rise between the TCA group and the attention group. Though the trend did not reach statistical significance due to individual variation in this small sample, the upward trends in the TCA group and the attention group compared to the control group during the intervention period suggested that the intervention did affect the morning rise of cortisol concentration in this study and that the morning rise could be a useful outcome measure for monitoring the effects of treatment on perceived stress. This result has some important implications in the treatment of stress. It suggests that the cortisol profile has been normalised by the effects of both the TCA and attention interventions. This could lead to longer term improvements in stress and coping which may not have been measured during this study. The result also has implications for the number of treatments, with the possibility that further treatment would be beneficial.

The implication of the change in the morning rise of cortisol concentration is substantiated in this study. Therefore for future work, it would be sufficient to measure changes at the first 2 collecting time points (immediately upon waking in the morning and 30mins after waking). This would reduce the cost of the study to the investigator and make collection easier for participants.

10.5.4 Diagnostic criteria

Standard diagnostic criteria are needed to guarantee the participants are stressed enough and comparable. In this pilot study, the RLE seemed unrelated to the PSS-14

scores. If a similar study was carried out in future, randomisation should be stratified to include a similar range of life event within each group. The participants' cortisol profiles did not appear to reflect their perceived high stress levels. In future, if the lab analysis is quick and convenient, the cortisol profile could be used as a screening tool to ensure all participants had an abnormal profile. The participants should be significantly stressed with a high self-perceived high stress levels and abnormal cortisol profiles.

10.5.5 Timing

Due to limited finance and equipment availability, and length of time required to carry out the programme, the salivary sample analysis could not be done immediately and was carried out once all the samples had been collected. This meant that the researcher could not track and record the participants' condition if there were any enquiries regarding the cortisol concentration results. For example, No. 3 had a gap of about 15 months between the time when she finished collecting samples and the time when her cortisol concentration result came out and she could not remember details around that time in relation to enquires about unusual results. So in the future, it would be better to carry out the laboratory analysis as soon as possible and give the researcher enough time to speak to the participants to collect more information which can aid the interpretation of outcomes.

10.5.6 TCA for stress

As a pilot study this project has shown that even with a very small sample size, differences in the outcome measures could be observed after TCA treatment, over and above the non-specific effects experienced by the control groups. The wide variability in stress levels, life events, symptoms, and response to treatment have shown that a much larger sample size would allow an improved statistical analysis and an investigation of any possible correlation between any of the outcome variables.

Because of the complexity of stress, individual TCA treatments according to the individual identification of CM patterns were used in this project. This mirrors CM

practice and was successful in demonstrating change and the effectiveness of using TCA for stress. It also provided a useful guide for the clinical practice. Future research could consider concentrating on treating people with different pattern identifications by TCA.

Acupuncture is currently widely used for people with pain, cancer, HIV/AIDS and other chronic illnesses. In future, it would be interesting to research whether acupuncture is equally as effective for treating stress in people who suffer from specific long term illnesses.

Stress is a physical and psychological response to perceived demands and pressures and it can present psychological and physical symptoms. In future clinical practice, it could be more effective to combine other therapies, such as music, and psychotherapy, as the literature in China showed the developments in the combined treatment for “焦虑” (jiao lü, anxiety) (see *Chapter 5 A Systematic Review of the Use of Traditional Chinese Acupuncture (TCA) in the Treatment and Management of Stress*).

10.6 Conclusion

This pilot study showed that the specific effects of individual treatment for stress provided by a trained TCA practitioner appear to indicate greater improvements than the non-specific effects of attention relaxation and that both the interventions were more effective than no treatment. This is the first time that this combination of quantitative and qualitative research methods has been used to explore the role of TCA in moderating stress. The use of diurnal profile of salivary cortisol concentration as a potential outcome measure to investigate the effectiveness of TCA for chronic stress in adults before, during and after TCA treatment was novel.

This pilot study suggests that TCA could improve perceived stress and its symptoms after 5 sessions of treatment, and TCA could provide improved outcomes compared with waiting list control. This is probably via a combination of specific and non-specific effects; but may not relate directly to how a person perceives their stress, because the

improvement in symptoms was not correlated with the improvements in perceived stress. It also suggests that TCA could increase the normalisation of the diurnal salivary cortisol profile through increasing the morning rise of the cortisol profile. Thus the morning rise could be a useful outcome measure for monitoring the effects of treatment on perceived stress.

As a pilot study, this project had 3 main aims:

1. To use a novel combination of qualitative and quantitative methods to explore the effect of pragmatic approach;
2. To use placebo controls which allowed an improved deconstruction of the specific and non-specific effects of TCA treatment;
3. To test the methodology and outcome measures in order to inform the design of a future RCT.

Despite some of the discussed limitations of this pilot study and indication of how this research could be improved, the researcher demonstrated that the study design in this project was feasible. This study has added to the evidence base for acupuncture as a treatment for chronic stress in the general population.

The researcher has tried to demonstrate the theoretical and practical implications of the results and to provide new insights for further research. Future research will require a larger sample size to answer the questions which have been posed, and to both replicate and expand the results from this dissertation.

In conclusion, acupuncture is efficacious physically and psychologically, yet gentle, and nourishes on the deepest level of the existence of human being – the spirit. The scientific research needs to continue to provide more evidence of its effectiveness by using methods which reflect the complexity of this treatment and its use in medical practice. The use of acupuncture as an intervention to treat chronic stress has strong clinical relevance given the current economic climate and the stresses of daily life in the 21st century.

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Appendices

Appendix 1 Advertisements for participants recruitment

STRESSED OUT?!

Volunteers Sought

At the Centre for Complementary Healthcare and Integrated Medicine at Thames Valley University, we are currently investigating the effectiveness of two methods (acupuncture and relaxation) for the treatment of stress in adults.

In order to do this we would like to recruit some volunteers who are over 18 years old and currently suffering from the stress of everyday life. Volunteers to the study will be offered a free course of treatment for 5 weeks.

Time and venue:

Mondays, TVU campus in St Mary's Road, Ealing;

Tuesdays, Westel House – TVU campus in Uxbridge Road.

If you are feeling stressed and are interested in taking part in this project, please contact Weidong Huang for further information.

Email address: Weidong.Huang@tvu.ac.uk



Appendix 2 Research information for participants

Research into Complementary Medicine and the Treatment of Stress Information for Participants

Who am I?

I am a postgraduate student currently researching into the effects of complementary medicine on stress levels at the Centre for Complementary Healthcare & Integrated Medicine (CCHIM), Faculty of Health & Human Sciences at Thames Valley University.

I spent eight years in full-time training in Chinese medicine and western medicine at Beijing University of Chinese Medicine (BUCM) where I was a lecturer and doctor specializing in acupuncture and Chinese medicine. I have practised acupuncture and Chinese medicine in the UK since 1999, and I am a member of the Association of Traditional Chinese Medicine (UK).

What is the purpose of the research?

The purpose of this research is to investigate the effectiveness of Traditional Chinese Acupuncture (TCA) when compared with relaxation for the treatment of stress and its symptoms in adults. Specific attention will be paid to their effect on:

1. The changes in your self-reported health symptoms and attitudes to stressful situations;
2. The changes in your salivary diurnal cortisol profile. Measuring the changing levels of the hormone cortisol in the body during a normal day indicates how the body is coping with stress.

What will you have to do?

You will be randomly allocated to one of 3 groups. You will receive either weekly sessions of TCA, relaxation or no treatment for a period of 5 weeks. Those allocated to the no treatment group will be offered treatment after the data collection period has ended. There will be no charges for any of the treatments. Each session will generally last about 30-45min, however at the first and last sessions more time will be needed, as you will be asked to complete some questionnaires which should take about 10 minutes.

Whichever of the groups you are in, you will be asked to provide salivary samples which you will take at 4 points on selected days (a. immediately upon waking in the morning; b. 30mins after waking; c. 3hrs after waking; d. 12hrs after waking) and you will be asked to record the exact time. These samples will be taken on two consecutive days prior to commencement of the study, on the day following each TCA/relaxation session and on the same day for each of the next two weeks. People in the no treatment group will be required to provide samples on two given consecutive days followed by samples taken on a given day each week for the next seven weeks. So there are 9 days in total when you will need to collect salivary samples.

In order to take a sample of saliva you will be given small plastic tubes, known as salivettes. You will be given an information sheet on how to collect a sample of saliva. Filled salivettes need to be kept as cold as possible, so should be placed in the freezer or ice compartment of your fridge until they can be collected by the researcher. Collection will be at a convenient time agreed between yourself and the researcher.

To take part in this study you need to answer “yes” to the following questions:

1. You are over 18 years old;
2. You are able to attend the treatment at the specified clinic times;
3. You are able to complete the successive 5 sessions of treatment;
4. You are willing to give the sample of your saliva for the research;
5. You do not have serious or life-threatening medical conditions;

6. You are not currently taking medication for psychological disorders or stress related symptoms;
7. You can accept the use of acupuncture needles;
8. You do not intend to take any complementary therapies for stress during the study;
9. You have not experienced a severely stressful life event in last month;
10. You are not pregnant;
11. You do not intend to change the pattern of taking the contraceptive pill during the study.

You may be asked to attend a focus group at the end of the study.

If there are any changes in your circumstances, please let the researcher know as soon as possible.

How will we protect your identity?

You will be assigned a study code number to maintain your anonymity. Your identity and that of any person named by you during the completion of questionnaires will be kept entirely confidential and no names will be attached to written or machine readable schedules.

If you agree to participate in the study your consent form will be kept in a confidential, locked file by the researcher. All the information you give will be kept in confidential files and will only be used for research purposes.

Are there any risks associated with the research?

There are very low risks associated with participating in this research; however some people may experience discomfort from acupuncture treatment.

All acupuncture needles will be sterile and single use.

Please feel free to discuss any issues with the researcher, however, you need not answer any questions you find upsetting or unacceptable and you may withdraw from the research at any time if you so wish.

How will the information you give be used?

The information you give to this research will make a valuable contribution to the development of complementary medicine in the treatment of stress. It will help us to understand whether acupuncture or relaxation have had a demonstrable effect in reducing stress, and whether the diurnal cortisol profile is a useful measure for research into complementary medicine and the treatment of stress.

The result of the research will be published in scientific journals and presented at appropriate conferences.

What do you do now?

If you have any further questions about the research please ask the researcher. If you are willing to participate in the research, please contact Weidong to arrange the first meeting to do the stress test which lasts 20 – 30 minutes or less.

Thank you for your time.

Weidong Huang

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Appendix 3 Response records

Responses Records

No.	Responding time and date	Agreed and attention time	Not-agreed and reasons	Interview	ID No. In the study	Reasons for elimination	Reasons for dropping out	Collecting salivettes
1	Fri 19.08/2005 16:00		Needle phobia					
2	Fri 19.08/2005 16:00							
3	Fri 19.08/2005 16:17							
4	Fri 19.08/2005 16:32							
5	Sat 20/08/2005 10:57							
6	Mon 22.08.05 09:24							
7	Mon 22.08.05 09:34							
8	Mon 22.08.05 10:02		No time					
9	Mon 22.08.05 10:38		A trapped nerve in her arm					
10	Mon 22.08.05 11.07		For his family member					
11	Mon 22.08.05 11:33	✓ 4:30pm						
12	Mon 22.08.05 13:50							
13	Mon 22.08.05 15:35	✓ after 6pm						
14	Mon 22.08.05 18:04		Not work here on Mondays					
15	Mon 22.08.05 21:02							
16	Tue 23.08.05 10:43	✓						
17	Tue 23.08.05 15:24							
18	Tue 23.08.05 16:22	✓		9am 06.09.05 West House 1005	(4)-1		10/10-14/10 holiday. Rang Judy on 07/10 to drop out	Missed No.1 on 13/09
19	Wed 24.08.05 13:50							
20	Wed 24.08.05 15:09	✓ after 4:30pm		5pm 05.09.05 Walpole House	\	PSS-14 scores =18<20		
21	Wed 24.08.05 15:18	✓ 12-2pm		12:30pm 05:09:05 Spescom House	1			
22	Wed 24.08.05 15:21	✓ 12-2pm or after 4:30pm		1:10pm 05:09:05 Spescom House	2			
23	Fri 26.08/2005 13:59	✓ 12-2pm		4:30pm 05:09:05 Walpole House	3			
24	Tue 06.09.05 11:16		Taking medication for high BP and thyroid problem; in Slough					
25	Tue 06.09.05 11:19	✓		9:30am 07:09:05 Spescom House	5			
26	Tue 06.09.05 11:20							
27	Tue 06.09.05 11:20							
28	Tue 06.09.05 11:21							
29	Tue 06.09.05 11:21							
30	Tue 06.09.05 11:26							

30	Tue 06/09/05 11:26							
31	Tue 06/09/05 11:32							
32	Tue 06/09/05 11:38					Taking medication		
33	Tue 06/09/05 11:49							
34	Tue 06/09/05 11:52							
35	Tue 06/09/05 12:09	✓ Leave on 23-30 Sep.		8:00 on 5/10 Westel House 1005	9			
36	Tue 06/09/05 12:33							
37	Tue 06/09/05 13:18							
38	Tue 06/09/05 14:21							
39	Tue 06/09/05 15:31							
40	Tue 06/09/05 17:55							
41	Wed 07/09/05 17:21							
42	Thu 08/09/05 13:40	✓		17:30 on 04/10 in Room 1312 in Westel House		Severe life event		
43	Thu 08/09/05 18:16							
44	Thu 08/09/05 20:30							
45	Fri 09/09/05 13:46							
46	Fri 09/09/2005 13:46		Trying to get pregnant					
47	Fri 09/09/2005 13:55							
48	Fri 09/09/2005 13:58							
49	Fri 09/09/2005 14:22		Busy before 11 th October 2005					
50	Fri 09/09/2005 14:56							
51	Fri 09/09/2005 15:11							
52	Fri 09/09/2005 15:39	✓		19/09/05 8:45 Westel House 602	7			
53	Fri 09/09/2005 16:00	✓		05/10/05 9:00 N201 SMR	10			
54	Fri 09/09/2005 16:04							
55	Fri 09/09/2005 16:40		Based in Reading					
56	Fri 09/09/2005 20:26							
57	Sat 10/09/2005 16:46							
58	Sat 10/09/2005 18:14							
59	Sat 10/09/2005 20:34							
60	Sun 11/09/05 21:36							
61	Sun 11/09/05 23:45							
62	Mon 12/09/05 08:27							
63	Mon 12/09/05 09:40		Travelling to Czech from 14 th to 22 nd October					
64	Mon 12/09/05 11:21	✓		11:00 03/10 N201 St. Mary's Road	6			
65	Mon 12/09/05 13:07							
66	Mon 12/09/05 17:03	✓		11:50 am 03/10 St Mary's Road	8			

67	Tue 13/09/05 09:32							
68	Tue 13/09/05 10:22							
69	Tue 13/09/05 11:03	✓		(19/09/05 8:00 Mon Walpole House 401) (25/10/05 Tues 12:00 in Westel House 1312)	(6)	Postpone as holiday from 10-24/10 Severe life event		
70	Tue 13/09/05 14:08							
71	Wed 14/09/05 09:51		No time					
72	Wed 14/09/05 11:25							
73	Wed 21/09/05 13:51		Based in Slough					
74	Sun 02/10/05 15:05		Not sure high stress level					
75	Mon 03/10/05 08:44							
76	Mon 03/10/05 09:10		Not sure high stress level					
77	Mon 03/10/05 10:00		No time					
78	Mon 03/10/05 10:07							
79	Mon 03/10/05 10:54			12:45 14/10/05 Walpole House	12		Have to be away to visit her mum who is ill	
80	Mon 03/10/05 16:05							
81	Tue 04/10/05 08:52							
82	Tue 04/10/05 13:47	✓ after New Year 2006						
83	Wed 05/10/05 09:51			10:00 10/10/05 SMR medical Centre	(4)-2	Difficult to cope with discipline	Missed No 3 on 18/10/05, made mistake No 1 & 3 on 13/10/05	
84	Wed 05/10/05 10:35							
85	Thu 06/10/05 12:28							
86	Mon 10/10/05 16:07							
87	Tue 11/10/05 09:32			16:00 11/10/05 SMR TC212	11			
88	Sun 16/10/05 13:04							
89	Mon 17/10/05 12:19							
90	Wed 19/10/05 16:19		1. On continuous medication for depressive illness. 2. His mother died 3 weeks ago.					
91	Tue 28/11/05 13:08							
92	Thu 1/12/05 18:00		Too busy to have time					
93	Tue 10/01/06							
94	Thu 12/01/06 11:30			13:15 24/01/06 Rotunda Slough 02/07 again illness delay				
95	Thu 12/01/06 11:35							
96	Thu 12/01/06 11:47							

97	Thu 12/01/06 14:11							
98	Thu 12/01/06 14:46							
99	Thu 12/01/06 14:55			16:00 16/01/06 Walpole House 401	4			
100	Thu 12/01/06 15:54		Leave on 17 Feb at TVU on a temporary basis					
101	Mon 16/01/06 11:32	13/02/06 back						
102	Mon 16/01/06 11:32			15:00 20/01/06 Walpole House 401	12			
103	Mon 16/01/06 11:46							
104	Mon 16/01/06 12:22							
105	Mon 16/01/06 13:10		Beta-blockers for occasional bouts of tachycardia					
106	Mon 16/01/06 13:49							
107	Mon 16/01/06 15:34							
108	Mon 16/01/06 16:29			16:00 the health centre SMR 23/01/06	13			
109	Thu 19/01/06 11:26							
110	Mon 23/01/06 12:11		Not highly stressed					
111	Mon 23/01/06 14:07		Diabetes					
112	Tue 24/01/06 11:07			10am 25/01/06 (CX) 9am 26/01/06 (CX) H15 SMR - too busy to make				
113	Tue 24/01/06 15:57							
114	Tue 24/01/06 15:57							
115	Tue 24/01/06 16:00							
116	Tue 24/01/06 16:13							
117	Tue 24/01/06 16:15	19/02/06 back						
118	Wed 25/01/06 08:32							
119	Wed 25/01/06 08:54							
121	Wed 25/01/06 10:13			30/01/06 13:00 Slough	14			
122	Wed 25/01/06 09:48							
123	Wed 25/01/06 11:21						Taking the thyroxine	
124	Wed 25/01/06 11:29							
125	Wed 25/01/06 12:11		Too busy to find time					
126	Wed 25/01/06 14:03			31/01/06 12:30 Westel House	15			
127	Wed 25/01/2006 14:07							
128	Thu 26/01/2006 13:29							
129	Fri 27/01/2006 12:08			31/01/06 14:30 Westel House	16			
130	Fri 27/01/2006 12:19							
131	Fri 27/01/06 12:27			31/01/06 16:30 Westel House			Taking acup. and Chinese herbal Medicine for tinnitus	

132	Fri 27/01/06 12:30			07/02/06 12:45 D Block Slough	17			
133	Fri 27/01/06 12:41			14/03/06 14:00 Room 411 Walpole House (CX) going on holiday for 2 weeks on 19 March				
134	Tue 31/01/06 10:09							
135	Tue 31/01/06 15:43						Taking anti- depressants	
136	Tue 31/01/06 16:39						In Reading	
137	Tue 31/01/06 16:51						To take part in a week meditation class and attending psychotherapy	
138	Fri 03/02/06 14:31		Too hard to fit into my schedule					
139	Fri 03/02/2006 14:48						Taking acupuncture	
140	Sun 05/02/06 12:50							
141	Tue 07/02/06 07:56							
142	Tue 07/02/06 10:51							
143	Tue 07/02/06 13:18							
144	Wed 08/02/06 10:38	For her husband						
145	Mon 13/02/06 17:13							
146	Tue 14/02/06 08:34			17:00 14/02/06 Room 1312 Westel House	18			
147	Tue 14/02/06 17:36		Not stressed enough					
148	Tue 07/03/06 03:35							
149	Wed 08/03/06 10:59							

Appendix 4 Consent form

STATEMENT OF GENERAL INFORMED CONSENT

By my signature below I give my informed voluntary consent to participate in this research conducted by the Centre for Complementary Healthcare and Integrated Medicine (CCHIM), Thames Valley University. The research is designed to investigate the effectiveness of traditional Chinese acupuncture (TCA) for the treatment of stress in adults.

I understand:

- that any information I give will be used for research purposes only.
- that my identity in the research will be kept entirely confidential.

I confirm that I have:

- read the participant information sheet.
- had the opportunity to discuss the research and ask questions.
- received satisfactory answers to my questions.
- received enough information about the study.

For my part, I promise I will give answers and cooperation which to the best of my ability are honest and accurate. I also understand that I may withdraw my participation in the research if I choose to do so at any time without giving a reason for the withdrawal.

Signature: _____ Date: _____

Appendix 5 The result of the block randomisation

The block randomisation was carried out by an administrator in the Centre for Complementary Healthcare & Integrated Medicine at TVU on 30th April 2005.

The result was:

Randomisation Number	Study group*
1	C
2	B
3	A
4	B
5	C
6	A
7	A
8	B
9	C
10	A
11	C
12	B
13	C
14	A
15	B
16	B
17	A
18	C

*: Group A = TCA group; Group B = Attention group; Group C = Control group.

Appendix 6 Documents in the study pack

Appendix 6.1 Instructions for collecting saliva with the salivette

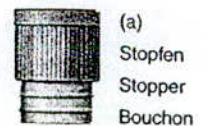
Für den Patienten

Gebrauchsanleitung zur Speichelgewinnung mit Salivette

- 1) Führen Sie die Speichelgewinnung zu den Zeitpunkten durch, die Ihnen von Ihrem Arzt verordnet worden sind.
Sollten Sie keine besonderen Hinweise erhalten haben, so ist es zweckmäßig, die Probeentnahme morgens vor dem Zähneputzen vorzunehmen. Soll die Speichelgewinnung im Laufe des Tages erfolgen, so darf sie frühestens 30 Minuten nach der Aufnahme von fester und flüssiger Nahrung durchgeführt werden.
- 2) Halten Sie die Salivette am Rand des eingehängten Gefäßes (c) fest, und entfernen Sie den Stopfen (a). Das Abnehmen des Stopfens wird erleichtert, wenn man ihn beim Öffnen des eingehängten Gefäßes ein wenig zur Seite abknickt.
- 3) Entnehmen Sie die Watterolle (b) der Salivette.
- 4) Führen Sie jetzt die Speichelsammlung nach den Anweisungen des Arztes durch.
Sollten Sie keine Hinweise erhalten haben, so können Sie entweder auf der Watterolle kauen oder diese

einfach nur unter die Zunge legen. Behalten Sie die Watterolle so lange im Mund, bis Sie das Gefühl haben, daß Sie den gesammelten Speichel nicht mehr im Mund halten können.
Normalerweise sind hierfür 30 bis 45 Sekunden ausreichend. Wenn Sie für die Speichelsammlung die Watterolle nur unter die Zunge legen, so kann es etwas länger dauern, bis sich eine größere Speichelmenge gebildet hat.

- 5) Geben Sie die eingespeichelte Watterolle (b) nun wieder in das Einhängegefäß (c) zurück, und verschließen Sie die Salivette fest mit dem Stopfen (a).
- 6) Die benutzte und fest verschlossene Salivette können Sie nun an Ihren Arzt zurückgeben.
Ist es nicht möglich, die Salivette sofort abzugeben, oder ist es notwendig, mehrere Speichelproben zu sammeln, dann sollten Sie die Salivetten im Kühlschrank aufbewahren.



(a)
Stopfen
Stopper
Bouchon



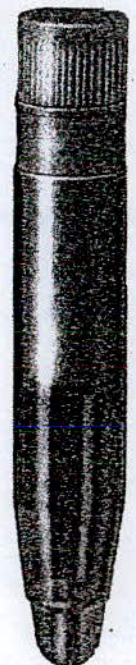
(b)
Watterolle
Swab
Tampon



(c)
Einhängegefäß
Suspended insert
Réceptif suspendu



(d)
Zentrifugegefäß
Centrifuge vessel
Réceptif de centrifugation



Patient Instructions

Instructions for collecting saliva with the Salivette

- 1) Collect saliva at the times prescribed by your doctor.
If no instructions have been given, saliva should be collected before you brush your teeth in the morning.
During the day, saliva should be collected no earlier than 30 minutes after eating or drinking.
- 2) Hold the Salivette at the rim of the suspended insert (c) and remove the stopper (a). Removal of the stopper is easier if you slightly push it to the side when opening the suspended insert.
- 3) Now remove the swab (b) from the Salivette.
- 4) Collect the saliva as instructed by your doctor.
If no instructions have been given you can either chew the swab or just place it under your tongue. Keep the swab in your mouth until you feel

that you can no longer prevent yourself from swallowing the saliva produced. This normally takes about 30 to 45 seconds. However, it can also take a little longer if you just place the swab under your tongue.

- 5) Now return the saturated swab (b) to the suspended insert (c) and close the Salivette firmly with the stopper (a).
- 6) The Salivette can now be returned to your doctor.
If it is not possible to return it immediately after use, or if you have to collect several saliva samples, you should keep the used Salivettes in a fridge.

Destiné au malade

Mode d'emploi de la Salivette pour le recueil de salive

- 1) Procéder au recueil de salive aux heures prescrites par votre médecin. Si aucune indication ne vous a été donnée, il importe de recueillir l'échantillon le matin avant le brossage des dents. Si le recueil doit être effectué pendant la journée, il doit se faire au minimum 30 minutes après l'absorption d'aliments solides ou liquides.
- 2) Tenir la Salivette au bord du réceptif suspendu (c) et enlever le bouchon (a). Le bouchon s'enlève plus facilement en lui imprimant une poussée latérale avec le pouce.
- 3) Sortir le tampon (b) de la Salivette.
- 4) Procéder au recueil de salive suivant les indications de votre médecin. Si rien ne vous a été spécifié, vous pouvez soit mastiquer le tampon, soit le mettre simplement sous la langue. Garder le tampon dans la

bouche jusqu'au moment où vous avez l'impression de ne pouvoir le conserver plus longtemps. Normalement, 45 secondes suffisent. Lorsque le tampon est mis sous la langue, l'opération peut durer un peu plus longtemps jusqu'à l'obtention d'une quantité de salive suffisante.

- 5) Remettre le tampon (b) imbibé de salive dans le réceptif suspendu (c) et refermer la Salivette avec le bouchon (a).
- 6) La Salivette remplie et fermée est rendue à votre médecin. Si la Salivette ne peut pas être rendue de suite ou si plusieurs échantillons de salive sont à prélever, il est conseillé de conserver les Salivettes remplies dans le réfrigérateur.

SARSTEDT
Aktiengesellschaft & Co.
D-51588 Nümbrecht

⊗/For single use only
Lagern bei Raumtemperatur - Technische Änderungen vorbehalten
Store at room temperature - Technical modifications reserved
Conservation à température ambiante - Modifications techniques réservées

CE

GB 53-4

Appendix 6.2 Introduction and time-record sheet

Introduction and Time-record Sheet

ID Number:

Date of the treatment:

In order to obtain samples correctly, please look carefully at the introductions.

Time-record Box

No. of salivette		Please write down exact time when you take a salivary sample
1.	Immediately upon waking in the bed in the morning before you brush your teeth	
2.	30 minutes after waking (Please do not brush your teeth and take breakfast before collecting saliva.)	
3.	3 hours after waking (Please collect saliva at least 30 minutes after eating or drinking)	
4.	12 hours after waking (Please collect saliva at least 30 minutes after eating or drinking)	

HOW TO GET A CORRECT SALIVARY SAMPLE:

1. Do not collect and submit a sample if your gums or the inside of your mouth is **bleeding**;
2. Use the **correctly numbered** salivary sample tube (salivette) to collect saliva;
3. Either chew the swab or just place it under your tongue to keep the swab in your mouth until you feel that you can no longer prevent yourself from swallowing the saliva produced;
4. Return the saturated swab to the suspended insert and close the salivette firmly with the stopper; (See an enclosed diagram)
5. Record the time in the recording box when you take a salivary sample;
6. Put the salivette into the marked plastic bag and seal it;
7. Put the sealed plastic bag into a freezer;
8. Bring back the plastic bag with 4 salivettes and this sheet when you come to the next session of intervention or salivettes will be collected by the researcher.

Thank you very much for your time and cooperation!!!

Appendix 7 Questionnaires

Appendix 7.1 The Recent Life Events Questionnaire (RLE)*

Recent Life Events QUESTIONNAIRE

ID Number:

Time:

Listed below are a number of events. Please read each item carefully and then indicate whether or not each event has happened to you in the PAST month.

Please tick the **YES** box if the event has occurred.

Please tick the 'still affects me' box if the event is still having an effect on your life

**'Immediate' family includes: mother, father, sister, brother, partner, child*

EVENT	YES	Still affects me
Have you had a serious illness or been seriously injured?	<input type="checkbox"/>	<input type="checkbox"/>
Has one of your immediate family* been seriously ill or injured?	<input type="checkbox"/>	<input type="checkbox"/>
Have any of your close friends or other close relatives been seriously ill or injured?	<input type="checkbox"/>	<input type="checkbox"/>
Have any of your immediate family died?	<input type="checkbox"/>	<input type="checkbox"/>
Have any of your other close relatives or close friends died?	<input type="checkbox"/>	<input type="checkbox"/>
Have you separated from your partner (not including death)?	<input type="checkbox"/>	<input type="checkbox"/>
Have you had any serious problem with a close friend, neighbour or relative?	<input type="checkbox"/>	<input type="checkbox"/>
Have you or your partner been unemployed or seeing work for more than one month?	<input type="checkbox"/>	<input type="checkbox"/>
Have you or your partner been sacked from your job or made redundant?	<input type="checkbox"/>	<input type="checkbox"/>
Have you had any major financial difficulties (e.g. debts, difficulty paying bills)?	<input type="checkbox"/>	<input type="checkbox"/>
Have you, or an immediate family member had any Police contact or been in a court appearance?	<input type="checkbox"/>	<input type="checkbox"/>
Have you or an immediate member of your family been Burgled or mugged?	<input type="checkbox"/>	<input type="checkbox"/>
Have you or another individual who lives with you given birth?	<input type="checkbox"/>	<input type="checkbox"/>
Have you or another individual who lives with you suffered a miscarriage or had a stillbirth?	<input type="checkbox"/>	<input type="checkbox"/>
Have you moved house (through choice)?	<input type="checkbox"/>	<input type="checkbox"/>
Have you moved house (not through choice)?	<input type="checkbox"/>	<input type="checkbox"/>
Have you had any housing difficulties?	<input type="checkbox"/>	<input type="checkbox"/>
Have you had any other significant event (please specify)?	<input type="checkbox"/>	<input type="checkbox"/>

*: The above RLE is for the baseline data before the intervention period. The cut-off times for the follow up 1 and 2 RLE are the past 5 weeks and the past 2 weeks.

Appendix 7.2 The Perceived Stress Scale – 14 (PSS-14)*

Perceived Stress Questionnaire**CONFIDENTIAL**

ID: _____

Date: _____

Instructions

The questions in this scale ask you about your feelings and thoughts during **the last Month**. In each case, you will be asked to indicate how often you felt or thought a certain way. Although some of the questions are similar, there are differences between them and you should treat each one as a separate question. The best approach is to answer each question fairly quickly. That is, don't try to count up the number of times you felt a particular way, but rather indicate the alternative that seems like a reasonable estimate.

1. **In the last month, how often have you been upset because of something that happened unexpectedly?**

never almost never sometimes fairly often very often

2. **In the last month, how often have you felt that you were unable to control the important things in your life?**

never almost never sometimes fairly often very often

3. **In the last month, how often have you felt nervous and stressed?**

never almost never sometimes fairly often very often

4. **In the last month how often have you dealt successfully with irritating life hassles?"**

never almost never sometimes fairly often very often

5. **In the past month, how often have you felt that you were effectively coping with important changes that were occurring in your life?**

never almost never sometimes fairly often very often

6. **In the last month, how often have you felt confident about your ability to handle your personal problems?**

never almost never sometimes fairly often very often

7. **In the last month, how often have you felt that things were going your way?**
 never almost never sometimes fairly often very often
8. **In the last month, how often have you found that you could not cope with all the things you had to do?**
 never almost never sometimes fairly often very often
9. **In the last month, how often have you been able to control irritations in your life?**
 never almost never sometimes fairly often very often
10. **In the last month, how often have you felt that you were on top of things?**
 never almost never sometimes fairly often very often
11. **In the last month, how often have you been angered because of things that happened that were outside of your control?**
 never almost never sometimes fairly often very often
12. **In the last month, how often have you found yourself thinking about things that you have to accomplish?**
 never almost never sometimes fairly often very often
13. **In the last month, how often have you been able to control the way you spend your time?**
 never almost never sometimes fairly often very often
14. **In the last month, how often have you felt difficulties were piling up so high that you could not overcome them?**
 never almost never sometimes fairly often very often

* : The above PSS-14 is for the baseline data before the intervention period. The cut-off times for the follow up 1 and 2 PSS-14 are the last month and the past 2 weeks.

Appendix 7.3 The Measure Yourself Medical Outcome profile (MYMOP)

Measure Yourself Medical Outcome Profile (MYMOP)

ID: _____

Date: _____

Choose one or two symptoms (physical or mental) which bother you the most. Write them on the lines. Now, consider how bad each symptom is, **over the LAST week**, and score it by circling your chosen number.

SYMPTOM1:	0	1	2	3	4	5	6
.....	As good as it could be						As bad as it could be
SYMPTOM2:	0	1	2	3	4	5	6
.....	As good as it could be						As bad as it could be

Now choose one activity (physical, social or mental) that is important to you, and that your problem makes difficult or prevent you doing. Score how bad it has been in the last week.

ACTIVITY:	0	1	2	3	4	5	6
.....	As good as it could be						As bad as it could be

Lastly how would you rate your general feeling of wellbeing during the last week?

	0	1	2	3	4	5	6
	As good as it could be						As bad as it could be

How long have you had Symptom1, either all the time or on and off? Please circle:
 0-4 weeks 4-12 weeks 3 months-1 year 1-5 years over 5 years

Are you taking any medication *FOR THIS PROBLEM*? Please circle: YES/NO

IF YES:

1. Please write in name of medication, and how much a day/week

2. Is cutting down this medication: Please circle:
 Not important a bit important very important not applicable

IF NO:

Is avoiding medication for this problem:
 Not important a bit important very important not applicable

MYMOP -- Follow up 1

ID: _____

Date: _____

Please circle the number to show how severe your problem has been **IN THE LAST WEEK**. This should be YOUR opinion, no-one else's!

SYMPTOM1:	0	1	2	3	4	5	6
.....	As good as it could be						As bad as it could be
.....							

SYMPTOM2:	0	1	2	3	4	5	6
.....	As good as it could be						As bad as it could be
.....							

Now choose one activity (physical, social or mental) that is important to you, and that your problem makes difficult or prevent you doing. Score how bad it has been in the last week.

ACTIVITY:	0	1	2	3	4	5	6
.....	As good as it could be						As bad as it could be
.....							

WELLBEING:	0	1	2	3	4	5	6
How would you rate your general feeling of wellbeing?	As good as it could be						As bad as it could be

If an important new symptom has appeared please describe it and mark how bad it is below. Otherwise do not use the line.

SYMPTOM3:	0	1	2	3	4	5	6
.....	As good as it could be						As bad as it could be
.....							

The treatment you are receiving may not be the only thing affecting your problem. If there is anything else that you think is important, such as changes you have made yourself, or other things happening in your life, please write it here (write overleaf if you need more space):

Are you taking medication *FOR THIS PROBLEM*? Please circle: YES/NO

IF YES:

Please write in name of medication, and how much a day / week

.....

.....

Could you please give any comments about your experience over the last 5 weeks?

MYMOP -- Follow up 2

ID: _____

Date: _____

Please circle the number to show how severe your problem has been **IN THE LAST WEEK**. This should be **YOUR** opinion, no-one else's!

SYMPTOM1: 0 1 2 3 4 5 6
 As **good** as it As **bad** as it
 could be could be

SYMPTOM2: 0 1 2 3 4 5 6
 As **good** as it As **bad** as it
 could be could be

Now choose one activity (physical, social or mental) that is important to you, and that your problem makes difficult or prevent you doing. Score how bad it has been in the last week.

ACTIVITY: 0 1 2 3 4 5 6
 As **good** as it As **bad** as it
 could be could be

WELLBEING: 0 1 2 3 4 5 6
 How would you rate As **good** as it As **bad** as it
 your general feeling could be could be
 of wellbeing?

If an important new symptom has appeared please describe it and mark how bad it is below. Otherwise do not use the line.

SYMPTOM3: 0 1 2 3 4 5 6
 As **good** as it As **bad** as it
 could be could be

The treatment you are receiving may not be the only thing affecting your problem. If there is anything else that you think is important, such as changes you have made yourself, or other things happening in your life, please write it here (write overleaf if you need more space):

Are you taking medication *FOR THIS PROBLEM*? Please circle: YES/NO

IF YES:

Please write in name of medication, and how much a day / week

.....

Appendix 7.4 Demographic Questionnaire

Demographic Questionnaire (Confidential)

ID No: Today's Date:

1. Gender: 2. Date of Birth:

3. Marital Status: 4. Number of Children:

5. Height: 6. Weight:

7. Type of Job:

Health Details:

Any medication being currently taken:

History of operations:

History of road traffic or other accidents:

Do you smoke? Yes No If yes, how much?per day

Do you drink? Yes No If yes, how much? units per week

Have you received any other medical treatment recently? Yes / No

If yes, please give details:

Have you ever taken complementary medicine? Yes No

If yes, which kind of complementary medicine?

When? and how long?

Have you ever had acupuncture before? Yes No

If yes, which kind of acupuncture?

When? and how long?

Past and Family History – Have you or any family member suffered from the following:

	Self / Year	Immediate Family / Year
Liver / Kidney Problems		
Heart / Stroke Problems		
Lung / Breathing Problems		
Digestion Problems		
Bowel Problems		
Bladder Problems		
Reproduction Problems		
Circulation Problems		
Diabetes		
Cancer		
Epilepsy / Nervous Disorders		

Past and Family History – Cont’d

	Self / Year	Immediate Family / Year
Allergies and Skin Disorders.....		
Blood Pressure Problems.....		
Migraines / Headaches.....		
Dizziness.....		
Tinnitus.....		
Ears/Eyes/Nose/Throat problems.....		
Arthritis / Orthopaedic problems.....		
Back Pain.....		
Multiple Sclerosis.....		
And other problems.....		

Any Health Problems Currently:

History of Present Complaint : (e.g. cause, time)

Symptoms of Stress:

physical symptoms	mental signs	behavioural symptoms
tiredness	anxiety	restlessness
headache	panic	forgetfulness
Light-headedness	increased worrying	change in usual behaviour
muscle tension	depression	poor concentration
palpitations	fearfulness	changes in eating patterns
stomach upsets	negative outlook	loss of appetite
indigestion	feeling of unreality	eating more sweets
skin problems	feeling unable to cope	changes in sleep patterns
weight gain or less	feeling of depersonalization	loss of sex drive
tingling of the peripheries	low self-esteem	increased smoking or drinking
trembling	feeling helpless	making mistakes
sweating	lacking confidence	changes in bowel movements
frequent cold	not wanting to socialise	irritability
dry mouth	loss of interest in anything	anger
more infections	Others:	shouting
insomnia		aggression
disturbing dreams		violent outbursts
poor balance		pacing
hyperventilation		hand-wringing
Others:		indecision
		inability to cope
		increased substance use
		Others:

General Living Habits:

Appetite:

Sleep:

Energy Levels:

Body Temperature (inc. sweat):

Menstruation:

Mood:

Bowel Movements:

Urine:

Tongue:

Pulse:

Diagnosis in Chinese Medicine:

**Demographic Questionnaire – Follow up
(Confidential)**

ID No: Today's Date:

Any Health Problems Currently:

Symptoms of Stress:

physical symptoms	mental signs	behavioural symptoms
tiredness	anxiety	restlessness
headache	panic	forgetfulness
Light-headedness	increased worrying	change in usual behaviour
muscle tension	depression	poor concentration
palpitations	fearfulness	changes in eating patterns
stomach upsets	negative outlook	loss of appetite
indigestion	feeling of unreality	eating more sweets
skin problems	feeling unable to cope	changes in sleep patterns
weight gain or less	feeling of depersonalization	loss of sex drive
tingling of the peripheries	low self-esteem	increased smoking or drinking
trembling	feeling helpless	
sweating	lacking confidence	making mistakes
frequent cold	not wanting to socialise	changes in bowel movements
dry mouth	loss of interest in anything	irritability
more infections	Others:	anger
insomnia		shouting
disturbing dreams		aggression
poor balance		violent outbursts
hyperventilation		pacing
Others:		hand-wringing
		indecision
		inability to cope
		increased substance use
		Others:

General Living Habits:

Appetite:

Sleep:

Energy Levels:

Body Temperature (inc. sweat):

Menstruation:

Mood:

Bowel Movements:

Urine:

Tongue:

Pulse:

Diagnosis in Chinese Medicine:

Appendix 8 Clinical timetable

Clinical Time-table

Week	Date	Time	Place	ID No.	Group	ID No. in Group C	Sampling		
1	13/09/05 Tue	12:00-12:35	WH	2	B	1,5	1,2,3,(4)-1,5		
		12:35-13:25		3	A				
		13:25-14:00		(4)-1	B				
2	20/09/05 Tue	12:00-12:30	WH	2	B	1,5			
		12:30-13:15		3	A				
		13:15-13:45		(4)-1	B				
3	27/09/05 Tue	8:30-9:20	WH	7	A	1,5			
		12:00-12:30		2	B				
		12:30-13:15		3	A				
		13:15-13:45		(4)-1	B				
4	04/10/05 Tue	8:15-9:00	WH	7	A	1,5	6, 8, 9, 10		
		12:00-12:30		2	B				
		12:30-13:15		3	A				
		13:15-13:45		(4)-1	B				
5	10/10/05 Mon	11:00-11:50	SMR	6	A	1,5,9	11,(4)-2		
		12:00-12:35		8	B				
		12:35-13:25		10	A				
	11/10/05 Tue	8:15-9:00	WH	7	A				
		12:30-13:15		3	A				
		12:10/05 Wed		10:00-10:30	WH			2	B
6	17/10/05 Mon	11:00-11:45	SMR	6	A	9,11	1,2,3,5,12	Collect samples N1, 2, 3, 5, 7*2.	
		11:45-12:15		8	B				
		12:15-13:00		10	A				
		13:00-13:35		(4)-2	B				
7	24/10/05 Mon	8:30-9:15	WH	7	A	9,11	1,2,3,5	Collect 2 days samples from N3 12:00 Caron 1312 28/10 Fri PM No 1 follow-up2	
		11:45-12:30		SMR	10				A
	25/10/05 Tue	8:30-9:15	WH	7	A				
8	31/10/05 Mon	11:00-11:45	SMR	10	A	9,11	7	8:30 WH No7 follow-up1 No2,3,5 follow-up2 Collect 6*2	
		11:45-12:30		6	A				
		12:30-13:00		8	B				
9	07/11/05 Mon	12:00-12:45	SMR	10	A	9,11	7		11/11 N9 follow-up1
		12:45-13:15		8	B				
10	14/11/05 Mon		SMR			11	6,8,9,10	8:30 WH No7 follow-up2; Collect 6*2; No 6,8,10 follow-up1 Free 5	
	15/11/05 Tue		WH						
11	21/11/05 Mon		SMR				6,8,9,10,11	No11 follow-up1 Free 5	23/11 N9 Follow-up2
	22/11/05 Tue		WH						
12	28/11/05 Mon		SMR				11	No 6,8,10 follow-up2 Free 5	
	29/11/05 Tue		WH						
13	05/12/05 Mon		SMR					Free treatment 11; No11 follow-up2	
	06/12/05 Tue		WH					Free treatment 5, 9	
14	12/12/05 Mon		SMR					Free treatment 11	
	13/12/05 Tue		WH					Free treatment 5	
15	10/01/06 Tue		WH					Free treatment 9	
16	16/01/06 Mon		SMR				4	Free treatment 9, 11	
	23/01/06 Mon		SMR				12,13	Free treatment 9, 11	
17	24/01/06 Tue	17:30-18:05	WH	4	B				
	30/01/06 Mon	14:55-15:30	SMR	12	B	13	14,15,16	Free treatment 11	
18	31/01/06 Tue	17:30-18:00	WH	4	B			Free treatment 9	
	19	06/02/06 Mon	9:30-10:05	SMR	15	B	13	17	
13:00-13:50			SLO	14	A				
15:00-15:30			SMR	12	B				
07/02/06 Tue		15:30-16:05	WH	16	B				
	17:30-18:00	WH	4	B					
20	13/02/06 Mon	13:00-13:50	SLO	17	A	13	18		
		15:00-15:30	SMR	12	B				
		14/02/06 Tue	9:00-9:45	WH	14			A	
	10:00-10:30		WH	15	B				
	15:30-16:00		WH	16	B				
	16:00-16:30	WH	4	B					

21	20.02.06 Mon	9:30-10:00	SMR	15	B	13,18		
		11:00-11:45	SLO	17	A			
		12:15-13:00	SLO	14	A			
		15:00-15:30	SMR	12	B			
	21.02.06 Tue	9:00-9:30	WH	16	B			
		17:00-17:30	WH	4	B			
22	27.02.06 Mon	9:00-9:30	SMR	12	B	13,18	4	
		9:30-10:00	SMR	15	B			
		12:30-13:15	SLO	14	A			
	28.02.06 Tue	15:00-15:30	WH	16	B			
		15:30-16:15	WH	17	A			
23	06.03.06 Mon	12:15-13:00	SLO	14	A	18	4,12,13	
		13:00-13:45	SLO	17	A			
	07.03.06 Tue	9:00-9:00	WH	16	B			
		9:30-10:00	WH	15	B			
24	13.03.06 Mon	13:10-13:55	SLO	17	A	18	12,13,14,15,16	
25	20.03.06 Mon					18	14,15,16,17	Free13
26	27.03.06 Mon						17,18	Free4,12,13,16
27	03.04.06 Mon						18	Free4,12,13,16
28	10.04.06 Mon							Free4,12,13,16,18
29	17.04.06 Mon							Free4,12,13,16,18
30	24.04.06 Mon							Free4,12,16,18
31	08.05.06 Mon							Free15,18
32	15.05.06 Mon							Free15,18
33	22.05.06 Mon							Free15
34	29.05.06 Mon							Free15
35	05.06.06 Mon							Free15

⊗: Group A: acupuncture; Group B: attention only; Group C: control.

(): Drop out

WH: Westel House 1312

SMR: St Mary's Road Health Centre

SLO: Slough

Free: Free Treatment

Appendix 9 The number of reported symptoms of stress collected in the Demographic Questionnaire

The number of symptoms of stress of participants before and after intervention

TCA Group:								
ID	Before Intervention				After Intervention			
	Physical	Mental	Behavioural	Total	Physical	Mental	Behavioural	Total
3	5	5	1	11	4	3	5	12
6	6	7	7	20	0	0	0	0
7	3	1	2	6	1	2	3	6
10	5	3	5	13	2	0	1	3
14	7	9	8	24	4	6	3	13
17	4	4	5	13	3	3	5	11
Total	30	29	28	87	14	14	17	45
Attention Only Group:								
ID	Before Intervention				After Intervention			
	Physical	Mental	Behavioural	Total	Physical	Mental	Behavioural	Total
2	8	2	9	19	2	3	6	11
4	5	3	7	15	1	2	1	4
8	12	7	10	29	13	9	13	35
12	3	5	7	15	6	5	3	14
15	9	3	6	18	12	5	9	26
16	5	5	9	19	3	1	3	7
Total	42	25	48	115	37	25	35	97
Control Group:								
ID	Before Intervention				After Intervention			
	Physical	Mental	Behavioural	Total	Physical	Mental	Behavioural	Total
1	4	8	4	16	1	4	1	6
5	8	6	5	19	3	6	4	13
9	7	2	8	17	4	1	3	8
11	10	3	11	24	3	0	4	7
13	15	9	7	31	12	10	9	31
18	6	8	11	25	4	6	5	15
Total	50	36	46	132	27	27	26	80

Appendix 10 The method sheet for Expanded Range High Sensitivity Salivary Cortisol Enzyme Immunoassay Kit from Salimetrics



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 800-790-2258 (USA & Canada only)
www.salimetrics.com
techservices@salimetrics.com

**EXPANDED RANGE
 High Sensitivity
 SALIVARY CORTISOL
 ENZYME IMMUNOASSAY KIT**

Catalog No. 1-3002/1-3012, 96 Well Kit
 For Research Use

Intended Use

Salimetrics cortisol kit is a competitive immunoassay specifically designed for the quantitative measurement of salivary cortisol. It is not intended for use with serum/plasma or for diagnostic use. It is intended only for research use with saliva. Please read the complete kit insert before performing this assay. For further information about this kit, its application, or the procedures in this insert, please contact the technical service team at Salimetrics or your local sales representative.

Introduction

Historically, the immunodiagnostic community's approach to the application of immunoassay techniques in the measurement of biomarkers in saliva has been problematic. This assay kit was designed to address those problems.

First, prior to the late 1990s the majority of available immunoassays for saliva cortisol were modifications of protocols developed for the use with serum/plasma. The standards used in those assay kits were suspended in a human serum matrix. Given that the composition of serum is markedly different from saliva, those standards are likely to produce results that are influenced by matrix differences. To ensure the most accurate results, this salivary immunoassay uses a matrix that matches saliva. Second, the level of cortisol in saliva is significantly lower than levels in the general circulation. The use of a standard curve developed to capture the range of values expected in serum/plasma samples is often not sensitive enough to capture the complete range of individual differences in the level expected in saliva. This assay was designed to capture the full range of salivary cortisol levels (0.003 to 3.0 µg/dL) while using only 25 µL of saliva per test. Third, the pH of saliva is easily lowered or raised by the consumption of food or drink. Performance of immunoassays becomes compromised as the pH of samples to be tested drops below 4 (1). This results in artificially inflated levels. This assay system is designed to be resilient to the effects of interference caused by collection techniques that affect pH. In addition, a built-in pH indicator warns the user of acidic or basic samples.

Test Principle

A microtitre plate is coated with monoclonal antibodies to cortisol. Cortisol in standards and unknowns compete with cortisol linked to horseradish peroxidase for the antibody binding sites. After incubation, unbound components are washed away. Bound cortisol peroxidase is measured by the reaction of the peroxidase enzyme on the substrate tetramethylbenzidine (TMB). This reaction produces a blue color. A yellow color is formed after stopping the reaction with sulfuric acid. Optical density is read on a standard plate reader at 450 nm. The

amount of cortisol peroxidase detected is inversely proportional to the amount of cortisol present (2).

pH Indicator

A pH indicator in the assay diluent alerts the user to samples with high or low pH values. Acidic samples will turn the diluent yellow. Alkaline samples will turn the diluent purple. Dark yellow or purple wells indicate that a pH value for that sample should be obtained using pH strips. Cortisol values from samples with a pH < 3.5 or > 9.0 may be artificially inflated or lowered (1).

Precautions

1. Liquid stop solution is a 2-molar solution of sulfuric acid. This solution is caustic; use with care. Stop solution in powdered form is not sulphuric acid-based, and is mildly corrosive.
2. This kit uses break-apart microtitre strips. Unused wells must be stored at 2 - 8°C in the sealed foil pouch and used in the frame provided.
3. Do not mix components from different lots of kits.
4. When using a multichannel pipette, reagents should be added to duplicate wells at the same time. Follow the same sequence when adding additional reagents so that incubation time with reagents is the same for all wells.
5. See 'Material Safety Data' at the end of procedure.
6. As for all quantitative assays for salivary analytes, we recommend that samples be screened for possible blood contamination (3,4). This can be efficiently and economically accomplished using Salimetrics Blood Contamination EIA Kit (Cat. No.: 1-1302/1-1312). Do not use dipsticks, which result in false positive values due to salivary enzymes.
7. Routine calibration of pipettes is critical for the best possible assay performance.
8. Pipetting of samples and reagents must be done as quickly as possible (without interruption) across the plate.
9. When running multiple plates, or multiple sets of strips, a standard curve should be run with each individual plate and/or set of strips.
10. The temperature of the laboratory may affect assays. Salimetrics' kits have been validated at 68 - 74°F (20 - 23.3°C). Higher or lower temperatures will cause an increase or decrease in OD values, respectively. Salimetrics cannot guarantee test results outside of this temperature range.

Storage All components of this kit are stable at 2 - 8°C until the kit's expiration date.

Reagents and Reagent Preparation

1. **Anti-Cortisol Coated Plate:** A ready-to-use 96-well microtitre plate pre-coated with monoclonal anti-cortisol antibodies in a resealable foil pouch.
2. **Cortisol Standards:** Six vials, 500 µL each, labeled A-F, containing cortisol concentrations of 3.000, 1.000, 0.333, 0.111, 0.037, and 0.012 µg/dL, in a synthetic saliva matrix with a non-mercury preservative. (Values in nmol/L are 82.77, 27.59, 9.19, 3.06, 1.02, and 0.33 nmol/L respectively.) Standards are traceable to the NIST standard.
3. **Wash Buffer:** 100 mL of a 10X phosphate buffered solution containing detergents and a non-mercury preservative. Dilute only the amount needed for current day's use. Discard any leftover reagent. Dilute the wash buffer concentrate 10-fold with room temperature deionized water (100 mL of 10X wash buffer to 900 mL of deionized H₂O). (**Note:** *If precipitate has formed in the concentrated wash buffer, it may be heated to 60°C for 15 minutes. Cool to room temperature before use in assay.*)
4. **Assay Diluent:** 63 mL of a phosphate buffered solution containing a pH indicator and a non-mercury preservative.
5. **Enzyme Conjugate:** 50 µL of a solution of cortisol labeled with horseradish peroxidase. Dilute prior to use with assay diluent.
6. **Tetramethylbenzidine (TMB):** 25 mL of a non-toxic ready to use solution.
7. **Stop Solution:** 12.5 mL of a solution of sulfuric acid (USA customers only). Stop solution is provided in powdered form (not sulfuric acid-based) to customers outside the USA.

Reconstitute the powdered stop solution with 12.5 mL of deionized water. Let sit for 10 minutes before use.

8. Non-specific Binding Wells: These wells do not contain anti-cortisol antibody. In order to support multiple-use, a strip of NSB wells is included. They are located in the foil pouch. Wells may be broken off and inserted where needed.

Note: The quantity of reagent provided with break-apart kits is sufficient for three individual runs. The volume of diluent and conjugate used for assays using less than a full plate should be scaled down accordingly, keeping the same dilution ratio.

Materials Needed But Not Supplied

- Precision pipette to deliver 15 and 25 µL
- Precision multichannel pipette to deliver 50 µL, and 200 µl
- Vortex
- Plate rotator (if unavailable, tap to mix)
- Plate reader with a 450 nm filter
- Log-linear graph paper or computer software for data reduction
- Deionized water
- Reagent reservoirs
- One disposable tube capable of holding 24 mL
- Pipette tips
- Serological pipette to deliver up to 24 mL

Specimen Collection

The preferred saliva collection method is to collect saliva by passive drool allowing the saliva to pass through a short straw into a polypropylene vial. Samples may also be collected using Sorbettes, P/N 5029 (for infants) or cotton ropes, P/N 5016. For accurate results collection devices should be completely saturated before removal. **Do not** add sodium azide to saliva samples as a preservative. Samples visibly contaminated with blood should be recollected. Freeze at -200C or lower for long-term storage. Contact the technical service team at Salimetrics for more detailed information on specimen collection. Saliva samples should be frozen prior to assay to precipitate the mucins. On day of assay, thaw completely, vortex, and centrifuge at 1500 x g (@3000 rpm) for 15 minutes. Pipette clear sample into appropriate wells. Particulate matter may interfere with antibody binding, leading to falsely elevated results.

Procedure

Bring all reagents to room temperature.

Step 1: Determine your plate layout. Here is a suggested layout.

	1	2	3	4	5	6	7	8	9	10	11	12
A	3.000 Std	3.000 Std	C-H	C-H								
B	1.000 Std	1.000 Std	C-L	C-L								
C	0.333 Std	0.333 Std	Unk-1	Unk-1								
D	0.111 Std	0.111 Std	Unk-2	Unk-2								
E	0.037 Std	0.037 Std	Unk-3	Unk-3								
F	0.012 Std	0.012 Std	Unk-4	Unk-4								
G	Zero	Zero	Unk-5	Unk-5								
H	NSB	NSB	Unk-6	Unk-6								

Step 2: Keep the desired number of strips in the strip holder and place the remaining strips back in the foil pouch. If you choose to place non-specific binding wells in H-1, 2, remove strips 1 and 2 from the strip holder and break off the bottom wells. Place the strips back into the strip holder leaving H-1, 2 blank. Break off 2 NSB wells from the strip of NSBs included in the foil pouch. Place in H-1, 2. Alternatively, NSBs may be placed wherever you choose on the plate. Reseal the zip-lock and refrigerate the pouch at 2 - 8°C .

Caution: Extra NSB wells should not be used for determination of standards, controls or unknowns.

Step 3:

Pipette 24 mL of assay diluent into a disposable tube. Set aside for Step 5.

Step 4:

- Pipette 25 μL of standards, controls and unknowns into appropriate wells.
- Standards, controls and unknowns should be assayed in duplicate.
- Pipette 25 μL of assay diluent into 2 wells to serve as the zero.
- Pipette 25 μL of assay diluent into each NSB well.

Step 5: Make a 1:1600 dilution of the conjugate, by adding 15 μL of the conjugate to the 24 mL of assay diluent prepared in Step 3, (full plate only). Immediately mix the diluted conjugate solution and pipette 200 μL into each well using a multichannel pipette.

Step 6: Mix plate on rotator for 5 minutes at 500 rpm (or tap to mix) and incubate at room temperature for an additional 55 minutes.

Step 7: Wash the plate 4 times with 1X wash buffer. A plate washer is recommended. However, washing may be done by gently squirting wash buffer into each well with a squirt bottle or by pipetting 300 μL of wash buffer into each well, and then discarding the liquid by inverting the plate over a sink. After each wash, the plate should be thoroughly blotted on paper towels before being turned upright. *If using a plate washer, blotting is still recommended after the last wash.*

Step 8: Add 200 μL of TMB solution to each well with a multichannel pipette.

Step 9: Mix on a plate rotator for 5 minutes at 500 rpm (or tap to mix) and incubate the plate in the dark at room temperature for an additional 25 minutes.

Step 10: Add 50 μL of stop solution with a multichannel pipette.

Step 11:

- Mix on a plate rotator for 3 minutes at 500 rpm (or tap to mix).
Caution: *Do not mix at speeds over 600 rpm.*
- Wipe off bottom of plate with a water-moistened lint-free cloth and wipe dry.
- Read in a plate reader at 450 nm. Read plate within 10 minutes of adding stop solution (correction at 492 to 620 is desirable).

Calculations

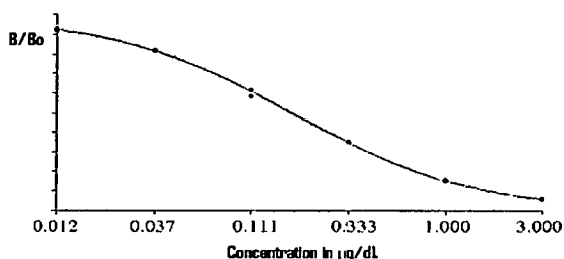
1. Compute the average optical density (OD) for all duplicate wells.
2. Subtract the average OD for the NSB wells from the average OD of the zero, standards controls and unknowns.
3. Calculate the percent bound (B/Bo) for each standard, control and unknown by dividing the average OD (B) by the average OD for the zero (Bo).
4. Determine the concentrations of the controls and unknowns by interpolation using software capable of logistics. We recommend using a 4-parameter sigmoid minus curve fit.

Typical Results

The following charts and graphs are for illustration only and should not be used to calculate results from another assay.

Well	Sample	Average OD	B	B/Bo	Cortisol (µg/dL)
A1,A2	S1	0.094	0.071	0.048	3.000
B1,B2	S2	0.236	0.213	0.145	1.000
C1,C2	S3	0.524	0.501	0.340	0.333
D1,D2	S4	0.897	0.874	0.593	0.111
E1,E2	S5	1.219	1.196	0.812	0.037
F1,F2	S6	1.379	1.356	0.921	0.012
G1,G2	Bo	1.496	1.473	NA	NA
H1,H2	NSB	0.023	NA	NA	NA

Example: Cortisol 4-Parameter Sigmoid Minus Curve Fit



Material Safety Data *

Hazardous Ingredients

Liquid stop solution is caustic; use with care. *Note: Stop solution in powdered form is not sulfuric acid-based and is mildly corrosive.*

We recommend the procedures listed below for all kit reagents.

Handling

Follow good laboratory procedures when handling kit reagents. Laboratory coats, gloves, and safety goggles are recommended. Wipe up spills using standard absorbent materials while wearing protective clothing. Follow local regulations for disposal.

Emergency Exposure Measures

In case of contact, immediately wash skin or flush eyes with water for 15 minutes. Remove contaminated clothing. If inhaled, remove individual to fresh air. If individual experiences difficulty breathing, give oxygen and call a physician.

*The above information is believed to be accurate but is not all-inclusive. This information should only be used as a guide. Salimetrics shall not be liable for accidents or damage resulting from contact with reagents.

HS Cortisol EIA Assay Performance Characteristics

Recovery: Six saliva samples containing different levels of endogenous cortisol were spiked with known quantities of cortisol and assayed.

Sample	Endogenous (µg/dL)	Added (µg/dL)	Expected (µg/dL)	Observed (µg/dL)	Recovery (%)
1	0.088	2.000	2.088	2.176	104.2
2	0.077	0.300	0.377	0.380	100.8
3	0.062	0.011	0.073	0.071	97.3
4	0.066	2.500	2.566	2.723	106.1
5	0.210	0.330	0.510	0.508	99.6
6	0.086	0.011	0.097	0.094	96.9

Precision:

1. The intra-assay precision was determined from the mean of 14 (low) and 18 (high) replicates each.

Sample	N	Mean (µg/dL)	Standard Deviation (µg/dL)	Coefficient of Variation (%)
Level 1	18	0.999	0.033	3.35
Level 2	14	0.097	0.004	3.65

2. The inter-assay precision was determined from the mean of average duplicates for 12 separate runs.

Sample	N	Mean (µg/dL)	Standard Deviation (µg/dL)	Coefficient of Variation (%)
Level 1	12	1.020	0.038	3.75
Level 2	12	0.101	0.006	6.41

Linearity of Dilution: Two saliva samples were diluted with assay diluent and assayed.

Sample	Dilution Factor	Expected (µg/dL)	Observed (µg/dL)	Recovery (%)
1			2.176	
	1:2	1.088	1.065	97.9
	1:4	0.544	0.503	92.5
	1:8	0.272	0.233	85.7
	1:16	0.136	0.109	80.1
2			0.508	
	1:2	0.254	0.247	97.2
	1:4	0.127	0.118	92.9
	1:8	0.064	0.058	90.6
	1:16	0.032	0.031	96.9

Sensitivity: The lower limit of sensitivity was determined by interpolating the mean minus 2 SD's for 10 sets of duplicates at 0 µg/dL standard. The minimal concentration of cortisol that can be distinguished from 0 is < 0.003 µg/dL.

Correlation with Serum: The correlation between serum and saliva cortisol was determined by assaying 49 matched samples using the Diagnostic Systems Laboratories' serum Cortisol EIA and the Salimetrics ER HS Salivary Cortisol EIA.

The correlation between saliva and serum was highly significant, $r(47) = 0.91$, $p < 0.0001$.

Specificity of Antiserum

Compound	Spiked Concentration (ng/mL)	% Cross-reactivity in ER HS Salivary Cortisol EIA
Prednisolone	100	0.568
Prednisone	1000	ND
Cortisone	1000	0.130
11-Deoxycortisol	500	0.156
21-Deoxycortisol	1000	0.041
17 α-Hydroxyprogesterone	1000	ND
Dexamethasone	1000	19.2
Triamcinolone	1000	0.086
Corticosterone	10,000	0.214
Progesterone	1000	0.015
17β - Estradiol	10	ND
DHEA	10,000	ND
Testosterone	10,000	0.006
Transferrin	66,000	ND
Aldosterone	10,000	ND

ND = None detected (<0.004)

References

- Schwartz, E.B., Granger, D.A., Susman, E.J., Gunnar, M.R., & Laird, B. (1998). Assessing salivary cortisol in studies of child development. *Child Development*, 69, 1503-1513.
- Chard, T. (1990). *An introduction to radioimmunoassay and related techniques*. Amsterdam: Elsevier.
- Kivlighan, K. T., Granger, D. A., Schwartz, E. B., Nelson, V., & Curran, M. (2004). Quantifying blood leakage into the oral mucosa and its effects on the measurement of cortisol, dehydroepiandrosterone, and testosterone in saliva. *Hormones and Behaviour*, 46, 39-46.
- Schwartz, E., & Granger, D. A. (2004). Transferrin enzyme immunoassay for quantitative monitoring of blood contamination in saliva. *Clinical Chemistry*, 50, 654-656.

Seller's Limited Warranty

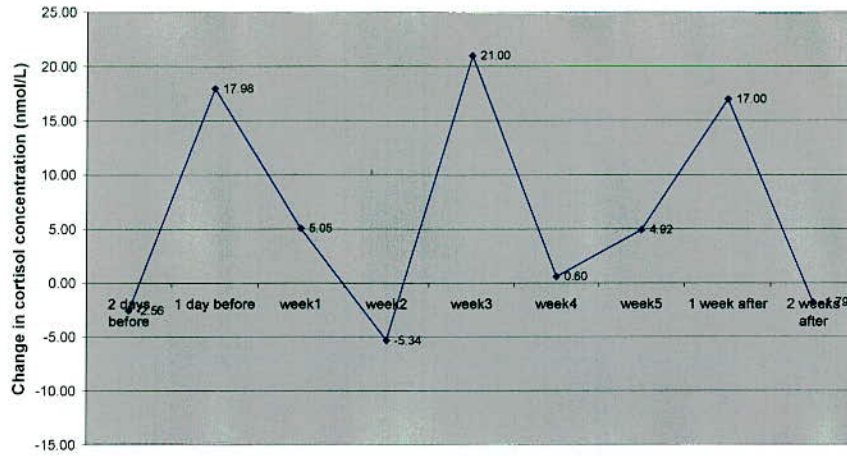
"Seller warrants that all goods sold hereunder will be free from defects in material and workmanship. Upon prompt notice by Buyer of any claimed defect, which notice must be sent within thirty (30) days from date such defect is first discovered and within three months from

the date of shipment, Seller shall, at its option, either repair or replace the product that is proved to Seller's satisfaction to be defective. All claims should be submitted in writing. This warranty does not cover any damage due to accident, misuse, negligence, or abnormal use. Liability in all cases, will be limited to the purchased cost of the kit.

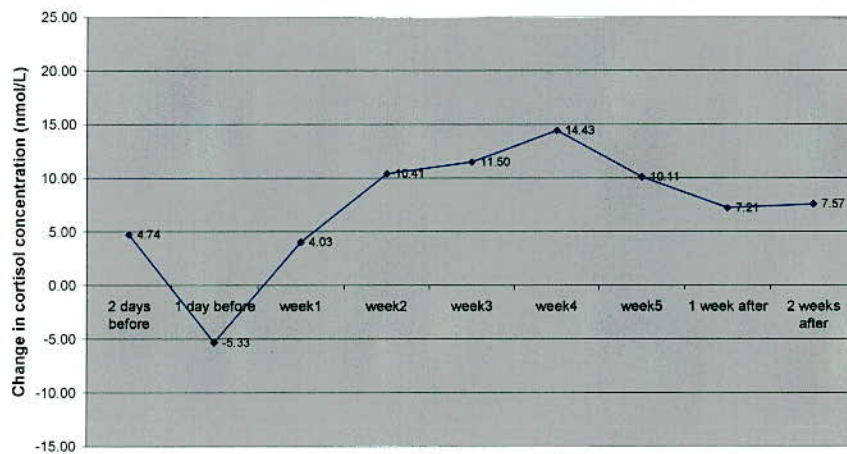
It is expressly agreed that this limited warranty shall be in lieu of all warranties of fitness and in lieu of the warranty of merchantability. Seller shall not be liable for any incidental or consequential damages that arise out of the installation, use or operation of Seller's product or out of the breach of any express or implied warranties."

Appendix 11 Individual morning rise of cortisol concentration in the 3 groups

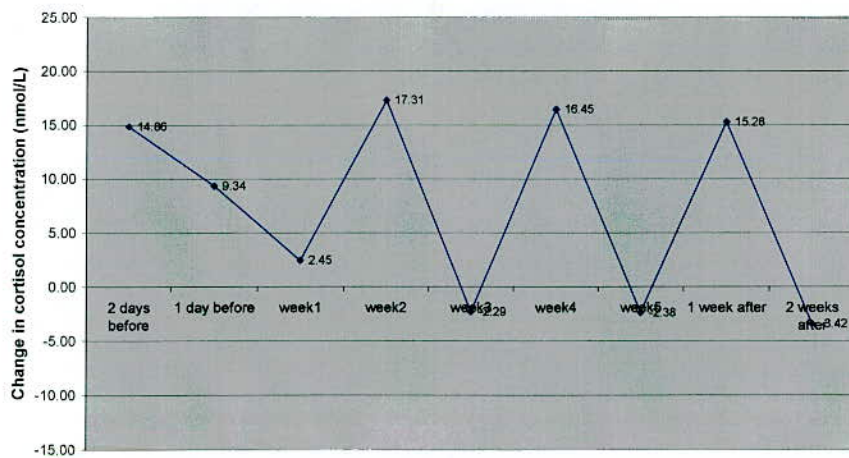
Morning rise of cortisol concentration for TCA3



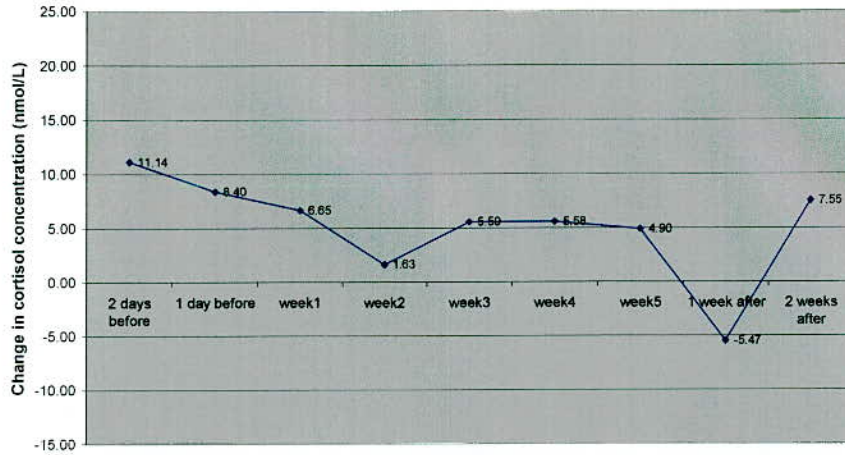
Morning rise of cortisol concentration for TCA6



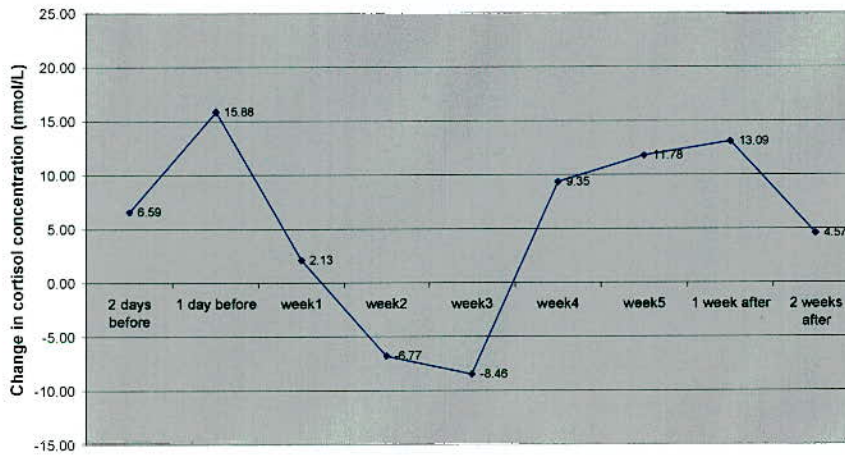
Morning rise of cortisol concentration for TCA10



Morning rise of cortisol concentration for TCA14

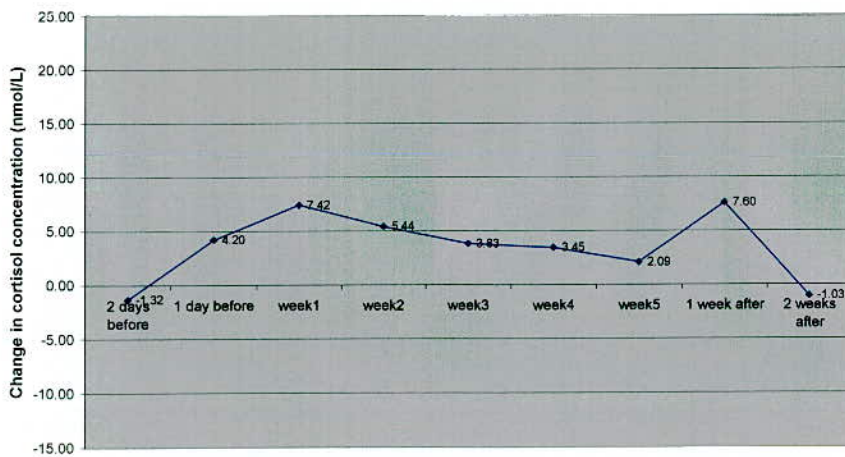


Morning rise of cortisol concentration for TCA17

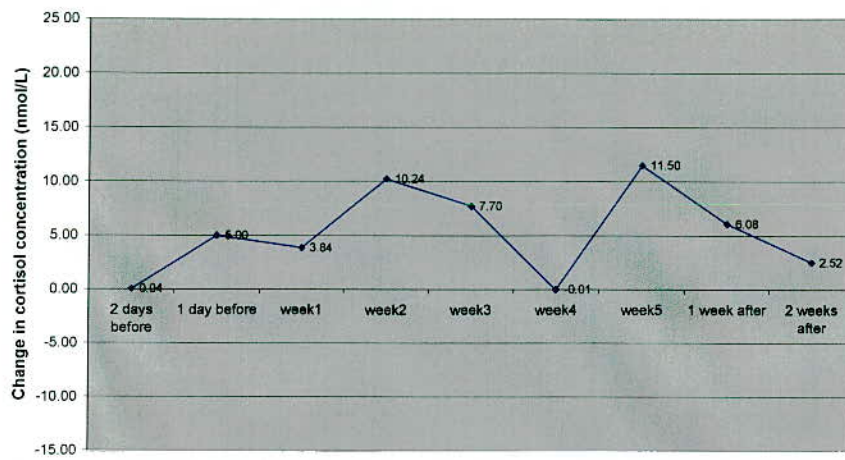


Appendix 11.2 Attention group

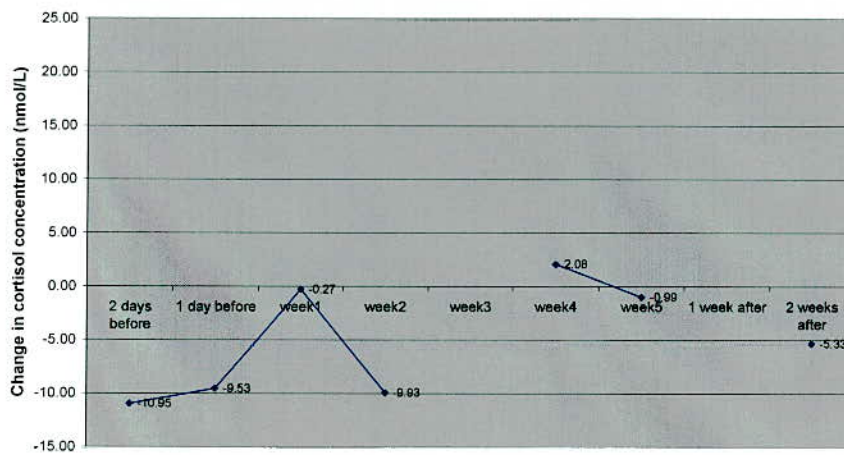
Morning rise of cortisol concentration for Attention2



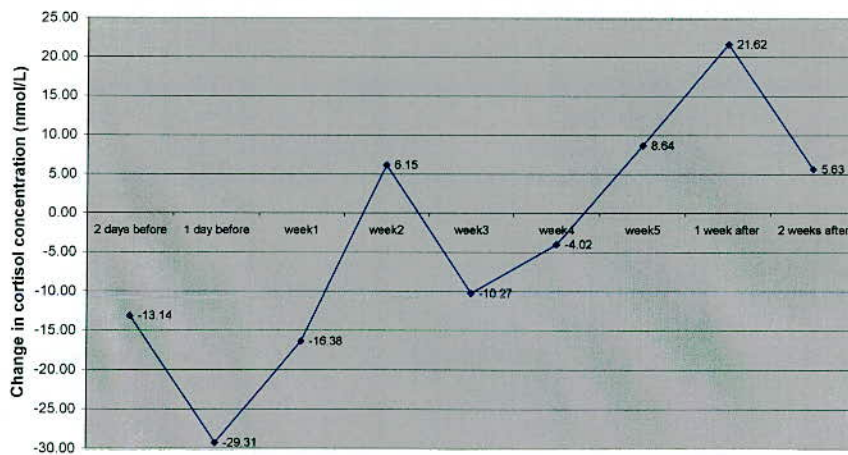
Morning rise of cortisol concentration for Attention4



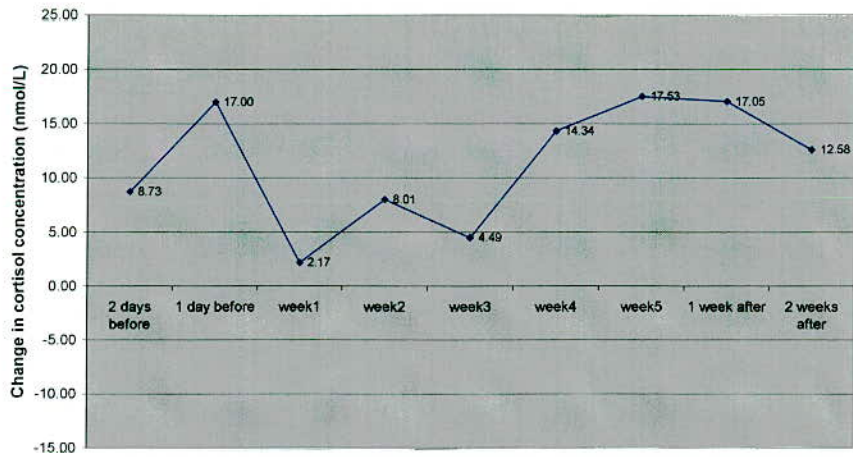
Morning rise of cortisol concentration for Attention8



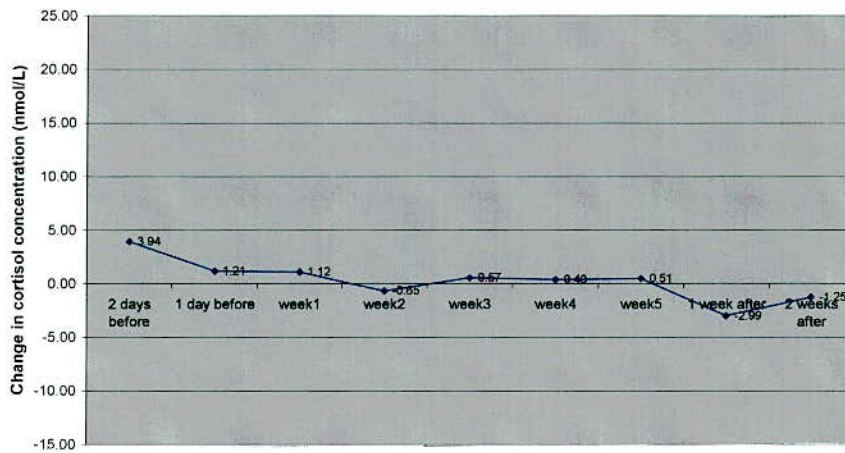
Morning rise of cortisol concentration for Attention12



Morning rise of cortisol concentration for Attention15

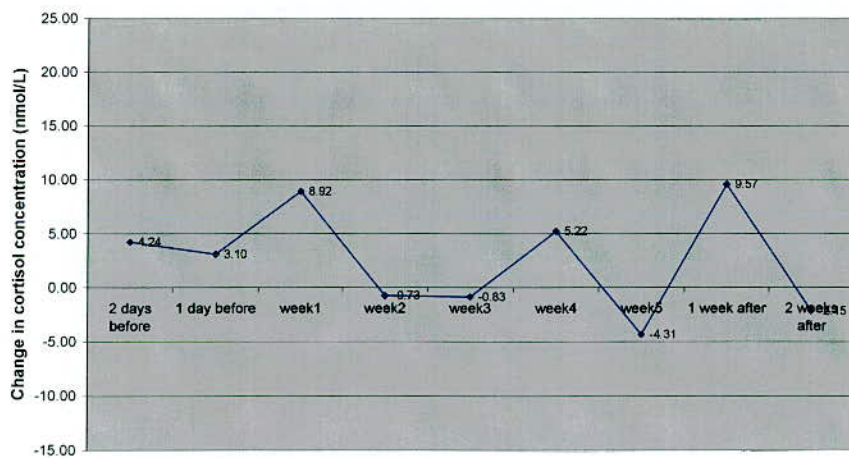


Morning rise of cortisol concentration for Attention16

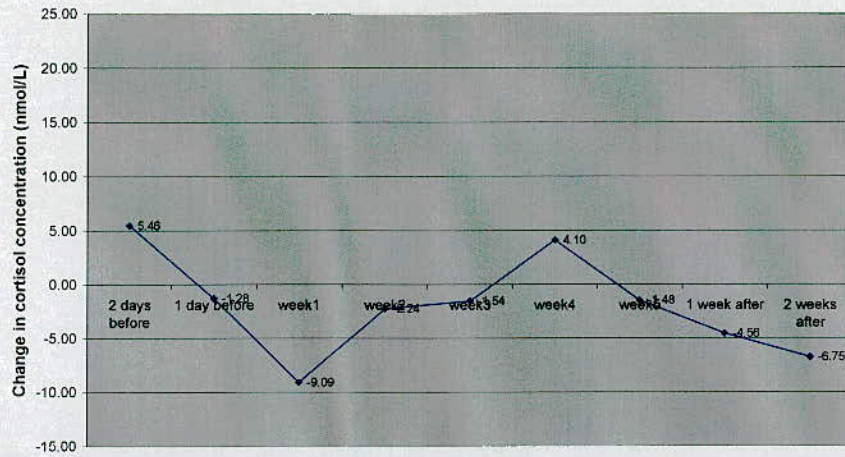


Appendix 11.3 Control group

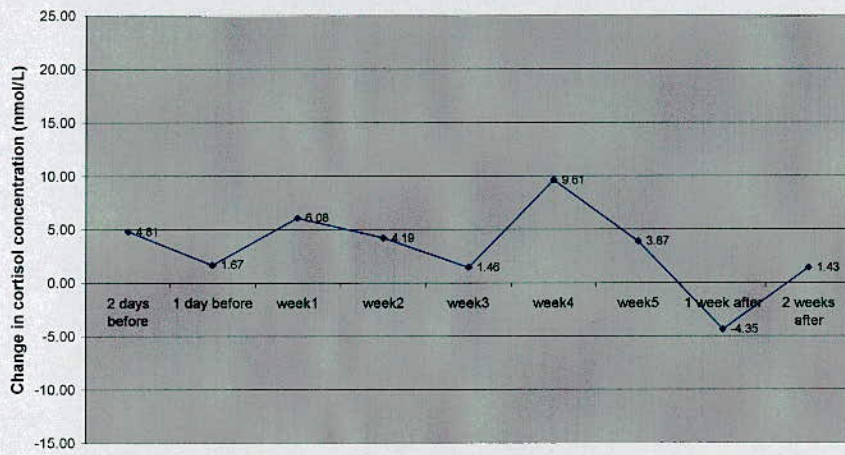
Morning rise of cortisol concentration for Contol1



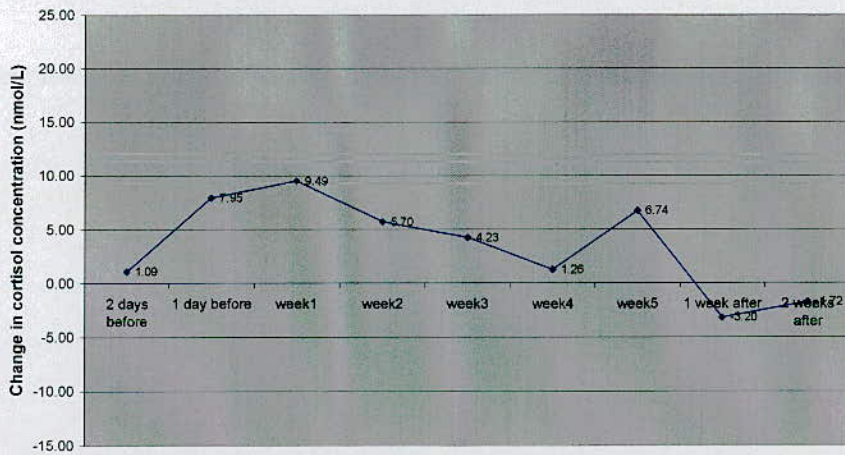
Morning rise of cortisol concentration for Control5



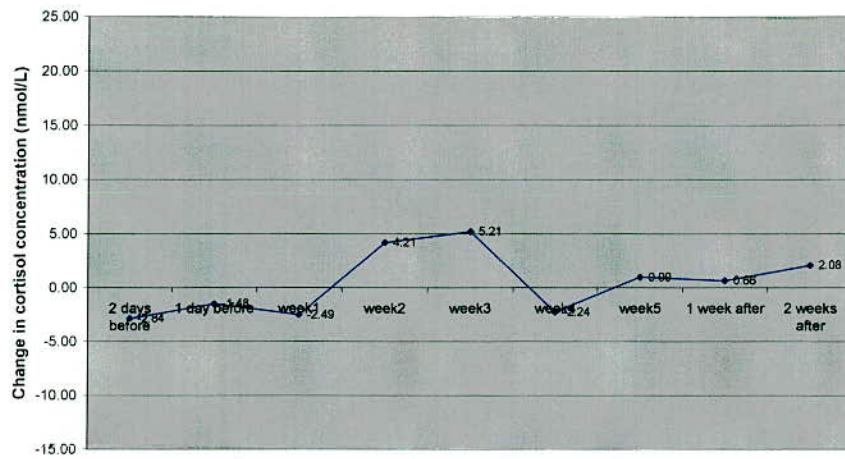
Morning rise of cortisol concentration for Control9



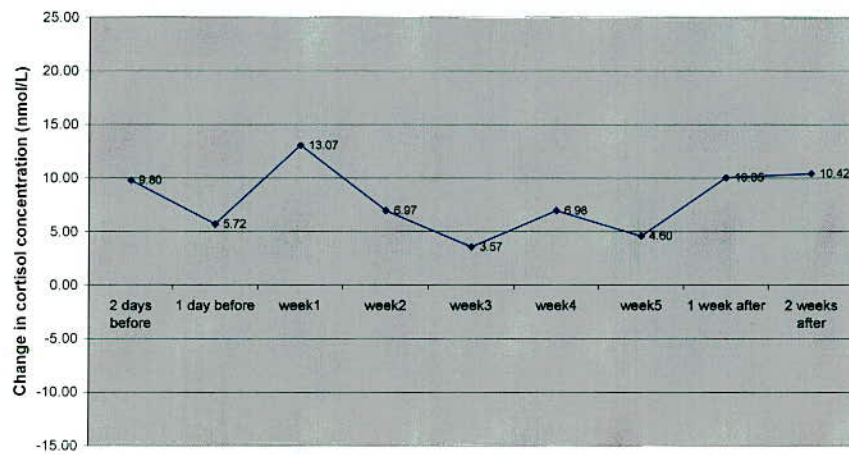
Morning rise of cortisol concentration for Control11



Morning rise of cortisol concentration for Control13



Morning rise of cortisol concentration for Control18



Appendix 12 Documents for focus groups

Appendix 12.1 Information sheet for the focus group

Research Study

Focus Group

A study to look at the traditional Chinese acupuncture for treating stress

Thank you for taking part in the research study. Now that you have completed the study you are invited to a discussion group (called a “focus group”) along with other participants to talk about your experience regarding the treatment you received. The discussion will be facilitated by _____, and will be assisted by _____.

Where and when will this group meet?

The date is _____.

The address is: _____.

Travel and cost

There are some parking spaces available on campus. Any additional costs incurred travelling to the discussion will be reimbursed when you attend this discussion group. Please bring receipts if you need to be reimbursed.

Confidentiality

All information collected during the discussion will be kept strictly confidential. As you arrive you will be given a number, and only by this number will you be identified during the discussion. A tape recorder and multi directional microphone will be used to record the session. This information will be transcribed and when the research study is published, no names of any persons taking part will be mentioned in the report.

Many thanks for your time.

Yours sincerely,

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Appendix 12.2 Focus group questions and prompts

Focus group questions and prompts – TCA group

1. Describe your experience of using acupuncture for stress.

- When you came to acupuncture treatment how did you feel?
- Did you notice any difference while having acupuncture?
- After how many sessions of acupuncture treatment did you notice any difference?
- What differences did you observe?
- How do you view this treatment?

2. Describe your experience how you feel about the research.

- How did you hear about the research study?
- Were the questionnaires appropriate?
- Was it easy for you to take part in the study and provide salivary samples?
- Was the venue / timing convenient?
- What were the drawbacks of the study?

3. Describe your expectations of traditional Chinese acupuncture.

- How do you feel about the acupuncture?
- Positive / negative aspects of acupuncture
- Will you continue to seek acupuncture?
- How do you think acupuncture should be promoted and or available through the hospital / NHS?

Focus group questions and prompts – Attention group

The following three questions will be put to the focus group. The bulleted points are prompts for the facilitator to ensure the required information is achieved from the responses.

Q1. Describe your experience of using relaxation for stress.

- When you came to relaxation treatment how did you feel?
- Did you notice any difference while having relaxation?
- After how many sessions of relaxation did you notice any difference?
- What differences did you observe?
- How do you view this treatment?

Q2. Describe your experience how you feel about the research.

- How did you hear about the research study?
- Were the questionnaires appropriate?
- Was it easy for you to take part in the study and provide salivary samples?
- Was the venue / timing convenient?
- What were the drawbacks of the study?

Q3. Describe your expectations of some provision for stress.

- How do you feel about some provision for stress?
- If that would affect your working performance?
- How do you think some therapies for stress should be promoted and or available through the hospital / NHS?

Appendix 12.3 Transcription of the TCA group

Transcription of recorded focus group discussion - 10 Jan 2006

Basically, in a focus group, there's no right or wrong answers. You're not supposed to actually come to any form of consensus. It's all just about your opinions, what you felt. Um, if there's something you don't want to say, then don't say it. If you're happy to start agreeing with each other, you do that. So it's just ... it's supposed to be like a conversation really and just to get a sort of a consensus view of what you've actually felt about what I'm going to ask you and the first thing that I'm going to sort of um ... I've got sort of three questions, if you like, about the experience that you've all had so they're very broad questions. So the first question is ... I'd sort of like ... like to find out a little bit about your experience and what you ... just describe the experience of having acupuncture for stress, the reduction of stress, because you were all sort of um recruited into the ... into the study because you felt under stress. So how did you feel about having acupuncture? I mean you might want to start about when you first came ... how you were feeling, you know, about acupuncture in general. I mean, why you got there in the first place or ...

Number 3

I'd never had acupuncture before, so um it was sort of ... for me it was something that would be quite interesting to see, you know, whether it would have any effect. And I thought ... I found it interesting in the sense that he was very good at explaining what he was doing and I asked quite a lot of questions because I was quite interested in what it would do and why. But every time I came back from a session, everybody said to me, oh, you look very pale. I often felt quite ill afterwards but apparently that was normal. Um, and I don't really know if it had any effect but, um, I think it was a useful experience to have gone through. Um, yes, so I think it ... it was interesting but I don't know that it had necessarily ... I couldn't see any, you know, definite benefit but then I was very stressed anyway and I think actually fitting it in was quite stressful, trying to find the time to fit it in and be involved in it was quite stressful but it was a regular commitment each week. I found that quite stressful, giving the time up for it.

Number 1

I actually found the fitting it in quite difficult and I came before classes so I started at a quarter past eight and, because I travelled from Reading to Ealing, sometimes I was a bit late and that made me quite stressful to begin with, if you know what I mean. Sort of ... and then not being able to get on with it ????? ????? up in Westel House, that's why I was ????? ????? So that part probably should have been reconsidered and maybe a later time in the day.

Yes, the scheduling was probably lacking.

It was good because it wouldn't interfere with any of my teaching because I don't start 'til 9 o'clock but in retrospect it was a little bit of a rush to fit it in before the first class at 9 o'clock if you know what I mean so I think the timing probably ... also, I hadn't had any acupuncture before but I'd worked on a ward where one of the doctors gave acupuncture as a form of relaxation therapy prior to surgery and he used it to lower blood pressure. That was primarily the aim. So I had seen it done before and ????? part of the experience, and seen how effective it can be with some of the patients. And, partly ... I'm not totally sure that I believe in the whole acupuncture effect but the calming effect of the person who's doing it and the way they speak to you and the whole, you know, experience ... I'm not sure about the actual theory behind it but ????? ...

I mean, did you notice any difference while you were having acupuncture?

I felt, um, less stressed afterwards but I was probably more stressed rushing to it to begin with so, on a day to day basis, it probably ... before and after treatment I felt better, immediately after, but, um, it depends on the traffic on the M4 sometimes for me on a morning how, you know ... if I'm going to be late or that sort of thing.

What about Number 2?

Number 2

Right, I had just finished ... was coming to the end of the clearing period at TVU which is very stressful. I really hadn't had a lunch break for eight weeks and had worked some weekends from about eight in the morning, so I felt tired and I felt really, really stressed. And I didn't know a lot about acupuncture. Um, but, when my colleague and I ... we had our appointments one after the other ... when we came back from the session, er, our colleagues remarked how relaxed we looked. Now, whether that was because we had ... the week before had been virtually the end of this very busy time for us and here we were going for an hour and a half lying down, um, having someone, um, look after us in effect and say nice things, soothing things to us, or whether it was the effect of the acupuncture, I don't know, but I did feel more relaxed and my husband has remarked that I get less up-tight about things since then. And another thing, I forgot to mention it, I've had a longstanding problem with rhinitis which has left me virtually without a sense of smell. Now that has partially returned and I still can smell ... not all the time, but this is something that ... I'm talking about twenty years now and I spoke to Wei ????? about it and he said he wasn't treating anything ... any specific complaint, that it was purely for, um, stress, um but he said that he could have done something different. But still I did have that effect at the end of it and I feel that I was more relaxed, um, at the end but that was a...something ... a physical change.

Um, that's interesting. I mean, did you notice ... did anybody notice any difference as the sessions sort of ... what we're asking, number 4, is about describing the experience of having acupuncture for reduction of stress and I don't know if you have any comments on that.

Number 4

Well, I work with, um, do I just call you number 2?

Yes, number 2.

I work with number 2 and so I agree with the point that you raised about our colleagues noticing how relaxed we were when we came back from the sessions. I think ... and I agree with number 2 as well about it being difficult to judge how much was that and how much was the alleviation of some of the work stress. I'm not sure about long term effects although, today, having had a dreadful experience with public transport, um, I was thinking it would be nice to have ...

To have some acupuncture? Yes.

Maybe it's about, kind of strengthening you to deal with things and giving you a shot in the arm.

Did you have any ... did you notice any differences when you were having acupuncture? I mean actually lying there. Was there anything that you could ...

What, when you're ...

Yes, when you're physically having it. I mean, did you ...

Number 3

Um, no, I mean I think, um, when I was laying there ... I mean I found it quite interesting, sort of where he was putting things and I was asking him about why he was putting it there and there. ????? ????? to shut up.

????? ????? *not relaxing.*

But it ... to me, um, the machine and everything, the process of it I found very interesting and, you know, why he was doing certain bits, and ... I mean, I don't know if we were supposed to talk to people that were having it as well but I know several colleagues that were also having it and everybody was having different ...

... reactions

Well, and different needles in different places, which I found quite interesting. Um, and I mean ... I mean, as I said earlier, I often felt afterwards quite ill but he said that was perfectly normal, so ... I mean, while I was having it I was fine but then, you know, getting up afterwards, I'd have to sit down for a minute and then, you know, the rest of the day I was normally quite spaced and was quite sort of tired and feeling quite sort of stomach sick in the evenings. So it wasn't very relaxing for me. But I think, the actual ... when he was doing it I found quite relaxing. You know, laying there and ... I guess because it was just, you know, ... oh, this is quite interesting, what's happening now? But, yes, I mean I didn't ... I ... it was quite interesting feeling the needles going in and the pinging thing. You know, you put it in and ping it off. I thought that was all quite good fun.

Number 2

I found ... I know that everyone's got different thresholds for pain but, the first session, I did feel more relaxed and found quite pleasant. In the second session, I had quite ... I had quite bad bruising on my abdomen.

That can occur, yes.

And, I wouldn't say it was painful, but it was uncomfortable. And also some on my arm. And I think the sessions after that I was a bit anxious about whether the same thing was going to happen and, um, a slight discomfort on occasions. But, once the needles were in, then I could relax a bit more. But I wouldn't say it was a ...

...wasn't a relaxing experience.

...it wasn't a wholly pleasant experience and so ...

Number 4

I think it was ... it was always just this side of being unpleasant for me. It would ... there were occasions when you thought ... like when that little machine went on ... you thought, no, I'm not really sure about that and, just when you were getting to that point he would switch it off anyway, so ...

Number 2

That's right because he said, can ... you know, should I turn it up? No, that's fine. And also the massage. I don't know whether that was part of the whole process. The massage was ... I thought was beautiful. But again that was sometimes this side of being too much. But I looked forward to the end when he would give me a shoulder massage which I thought was

wonderful. I just really thought it was great. And the leg massage before you got up. I just loved that.

That's good. So, I mean, it's quite sort of interesting really but I mean, what you also had to do was ... you had to do the research didn't you. You had to do the saliva samples. I mean what was your experience about doing the actual research itself? Because you did have to do things in the ?????

Number 4

It was quite stressful wasn't it, remembering. I forgot on one occasion and I was late on the last one and I felt dreadful. And then I thought, do I say? I was, like, wrestling with my conscience. And I did admit to it.

And did you write down the right time?

I wrote the right time, yes.

Number 3

Yes, I don't think mine were all as they should have been but as long as I wrote down the time that was fair enough. I mean, ????? say that was OK.

Because it was more stressful than you think it would be just doing something four times a day
????? ?????

Number 1

I think not having to have anything to eat or drink beforehand and it was remembering that.

Number 2

That's right, you had to almost plan the day out before and think, what am I going to do tomorrow? Do I have to take the, what's it called, the little ... saliva ????? take it with me. Um, and...

????? ????? ?????

... thought I'd be able to rush up to Westel or something and get another one.

Number 3

I often had to do it when I was out and about. ????? ????? ????? discreetly when you're sort of out with people or something.

Number 1

People talk to you while you've got it in your mouth.

Number 3

I quite enjoyed all that because it felt like you were actually involved in it more and that you were ... there was some kind of science going on as well as having a session. I thought that was ... because a lot of people were saying ... were quite interested in it when you said you were doing it and were like, oh yes, you do this and this, and you were thinking, yes, I'm doing

this regularly and, you know, it's all being measured and monitored. I found it quite stressful keeping it in the freezer and bringing it in on certain days and all of that, because ...

Number ?

... what if I forget it.

Number 3

... and trying to hook up with him to give it over at the right times, and all of that was becoming a bit much.

So it's quite an arduous ????? What about the questionnaires. Did you think they were appropriate?

Number 2

I found it very difficult rating 1-5, um, and trying to find some sort of consistency really because, on a couple of occasions he said to me, but you put this last time. Um, and I found that ... I think there was one question about symptoms. You had to list symptoms and I felt that I didn't have enough guidance on what I should put for that because I listed two symptoms and then ... I think on a ... this was the questionnaire at the end, we had two. The next week when I did the questionnaire, I wasn't sure so I put two more symptoms and I think Wei Dong said to me, but you haven't mentioned these symptoms before. So I think there wasn't enough guidance.

... a bit of, OK, a bit of confusion.

Number 4

I felt you had to try and grovel around for a symptom if you were actually feeling OK almost.

Right, you must have been feeling very healthy at that point then. Oh dear. What... I mean, you talked a little bit, number 1, about the timing and the problem of you getting there. Was the venue where the treatments took place ... was that OK? Because we did have problems trying to locate somewhere, but ...

Number 3

I think it was quite a nice little room.

Did everyone have the same room? In Occupational Health was it?

In Westel, yes.

Number 2

Well, we went to the Health Centre in St Mary's Road. That was fine.

Number 4

I did both because one ... one I was ????? down on a Monday and there was a time when I had a day's leave so I had ... I arranged to meet him on a Tuesday, but, um, that was good that I could be fairly flexible within the ?????

So the timing was all adjusted to what you felt you could make as well, is that right? Yes. So the timing was all right. What do you think ... were there any particular drawbacks do you think. I mean, you've mentioned a few in terms of, you know, perhaps lack of guidance on some of the questionnaires. But I mean were there any other drawbacks you can see?

Number 3

I found it quite difficult that, um, if I'd have wanted to keep it private, I couldn't have because the people that I work with were coming in and out after and before me. We were all on the same day. So, um, it wasn't really confidential in the sense that ... I mean we all talk anyway so it wouldn't ... wasn't a problem but if I'd have wanted to say, you know, no, I want to keep this ... I couldn't have done that because, you know, I'd come out and there was somebody and, you know, when I went in somebody else was coming out. So it wasn't really... the way we had to fit it in. Because we all work in the same area and it's very busy and it so happened that we only had limited times we could ?????

So you had to negotiate anyway with colleagues for time.

So, I mean, that was a bit of a drawback for me, but, you know, it could have been more confidential maybe. I mean not ... I mean it was our own choice to talk about it separately but, um, I couldn't have said, oh no, I'm not doing it, you know, because they knew I was doing it anyway, so.

So it was sort of the peer situation really. What about your expectations, you know, when you went in for this study. What were your expectations and how do you feel about acupuncture now?

Number 2

Well I didn't really have any because I didn't feel as though I knew enough about it so I went in hoping that it would do something but I'm not quite sure what, um, I did actually start doing a little bit of research once I'd started but not very much. Um, and I ... I'm surprised at the outcome on my situation.

What about the others? Number 1?

Number 1

I was expecting better, can I say, better results. Maybe that's a bit unfair but I found possibly within the day that I had it some results, but that may have just been on lying down for the hour like I was saying. But for long term results I don't really ...

You haven't noticed anything particular.

No, and I feel sometimes it's more to do with the environment, you know, outside, external factors and what's inside, you know, goes along with what ...like you say ... if you miss the train or ... it's things that happen that make you feel stressed and you can't have the acupuncture there and then, can you? Like you were saying if you could come today and have it when you've had a stressful morning, it may help, kind of that way but I haven't found it helped in the long term so maybe I've been a little disappointed but I don't really want to, you know, knock it, and I went in with an open mind.

What about number 4?

Number 4

I found it very interesting and enjoyable and I suppose I would ... I would turn to it again although we didn't get any guidance did we on where we could continue with it if we wished. ?????? ??????

Yes, but there are services, you know, at St Mary's Road. They actually have an acupuncture service run by two of the midwives on a Wednesday and also I think there was an acupuncturist at Slough operating. So there is within the University some opportunities.

OK, I also felt I'd have liked to know a lot more about it but it probably would be... you know, I wanted a potted guide to acupuncture, whereas you wouldn't get a potted guide to Western medicine. It gave me a realisation that there's an awful lot behind it.

So how many of you would actually try acupuncture again? Say, for example, you had another ... a different type of problem or perhaps you developed some form of arthritis or more chronic health problems, would you ...

Number 4

Definitely.

OK, it would be two of you.

Number 3

I'm not sure.

Number 4 (but sounds more like number 1)

I'm not sure. I would like to actually compare it to other therapies now, you know. Like there was a relaxation group. I would kind of quite like to see if that helped me more.

Well, we'll feed back the results of the study as well which would be interesting.

... you know aromatherapy and everything just to see ...

Number 3

I think I felt that, um, I might do it again with him because I felt that I'd got to know him and he ... the way he talked about his background and what he'd been doing before, you know, because I asked him questions about that. I felt quite comfortable with him and that it actually was more scientific than I had anticipated it would be and I felt more comfortable with that, that there was, sort of ... you know, sometimes you hear complementary medicine and it all sounds a bit airy fairy but it actually ... the way he talked about it, he definitely believed in it and he could talk about the history of it and, you know, what benefit he thought it would be and, you know, there was a definite process, and I enjoyed all of that. But you know, where I live, there's some shops that offer it and I don't know that I'd feel comfortable walking in and getting it done by anybody because you kind of want to know ... it's really because it's inserting needles into you, you kind of want to know that it's going to be safe.

Number 2

That's right. You felt that he had a definite ... a background that you could discuss and there was some science behind it. That's how I felt, and especially as we were part of the research anyway, it wasn't, um, you know, someone else might feel completely different about complementary therapies who'd had ... who'd enjoyed other therapies and this wouldn't matter to them at all.

Yes, very different the touch therapies compared to homeopathy where you're taking things.

As I say, especially as he was sticking needles in.

Number 3?

Anyway, I don't think I'd go to necessarily anyone else and to have acupuncture unless it was through an organised ?????

Do you know how to obtain information on our practitioners for any complementary medicines?

Number 2

Well, I have sort of looked on the internet but then I think that would be my major misgiving. If I ever turn to it again, um, you know, OK, you'd go back to Wei Dong but what about someone else?

Are you aware of professional organisations for all the therapies. That there are umbrella groups and that there is a regulatory process? And for example acupuncture and herbal medicine will be going through a regulation so people will not be able to use the title acupuncturist unless they've actually got a specific standard of training. So I would always encourage you go to through the professional organisations, through the Foundation, The Prince of Wales Foundation for Integrated Health. So that's one route in rather than going to a high street shop or the Yellow Pages.

Number 4

I suppose I'd want to go via my GP, always supposing your GP ... that there's somebody in the practice who's sympathetic to it.

I mean, how do you think we should be promoting acupuncture? I mean, you know, do you think it should be available in hospitals and the NHS more widely. I mean, do you ... you've already mentioned the ...

Number 1

I've seen it used by one doctor who had a training in acupuncture and, um, he didn't use it on every patient, you know, it wasn't suitable for everyone but those who were, you know, more unduly stressed pre-operatively, it worked very well. And, as I say, they used blood pressure reading as a guide as to how well it worked and I thought that actually could be possibly used in some research that's done here. I don't know if that's ????? ?????

Well, interestingly enough, we are doing a study at Kings on post-operative anxiety for cataracts. There's a research study just started on that. It's very interesting.

Well this was for foot surgery at the Berkshire Hospital that ... and I don't know if he'd done any research into it but the doctor himself ran private acupuncturist clinics as well.

It's always quite complex because often medically qualified people may not have gone through the full training like somebody like Wei Dong will have done which would be a five year minimum and, in this country it's usually about 3-4 years.

Number 2

My GP offers acupuncture for, um, smoking addiction. She's been offering it for a number of years now.

I mean, do you think we should be looking to promote it within the NHS. I mean, if for example your GP or you're attending hospital as an outpatient say for pain or something like that, um, do you think it would be useful?

Number 2

If it has been found to reduce pain, especially for someone who's on long-term painkillers. I mean it could only be of benefit, even if it was a slight improvement.

Number 4

I found, having had the acupuncture treatment and telling people socially that's what was happening, I found there were unexpected people saying, oh I had that for such and such. And I think it would help me feel it was not some funny little shop in the high street. If it is through your GP it is an alternative or adjunct to regular treatment. I mentioned it to a friend and she said, oh I had that several years ago and I passed out. That was the first treatment.

That's interesting. Well there is quite good data on safety in acupuncture and actually the incidence of adverse events ... serious adverse events is extremely low compared to medical technologies and there's some very good literature on that so rest assured, um, that the effects that people do ... explain the feeling like spaced out, and perhaps some local pain ????? ????? perhaps the bruising that you experienced but in fact it is fairly rare. But I mean, if you're interested in any literature on this, I'm quite happy to photocopy it. I can give you a photocopy of the audit that we did on the acupuncture service at St Mary's Road. So do please let me know if you want that. Is there anything else that you'd like to say? Because I'm aware that people need to get off and I don't want to make you more stressed having got here and you need to get somewhere else. Are there any other points we've not covered or you've not said or ...

Number 2

Um, a little bit about feedback. I wanted ... at the end of every session I wanted to ask almost like, you know, how am I doing, compared with other people, you know, was there any change or was there any significant difference between last week. And I knew couldn't because I did touch on it once and I think Wei Dong explained that it was ... you know, he was having to have the samples, um, er, ... it was expensive the process and everything and he wouldn't have them analysed for a while. Um, but I felt that I wanted some sort of immediate feedback as to my progress, and also, within the group, that I didn't think was forthcoming and I'm not sure whether he quite understood what I wanted either because of the language problem.

Yes, I mean, did you find language a problem ... communication?

Number ?

There was a little

Number 3

... yes, in that you might have to explain ... I mean, sometimes you'd say things without realising that actually somebody else might not pick up on it straight away so you'd go round in a little circle trying to bring other words in, but I actually think he was very good at ... if he didn't know exactly what you meant, pressing you for it which meant that you did feel that he was getting, you know, what he needed from you. In terms of feedback, um, I mean, I felt that

he did give me feedback after each session because we moved on to, you know ... each session changed for me in terms of what he did and what he was explaining about ... what we needed to do next so I felt that it did change. You know, I did get feedback at each session but I did find that I would keep asking him questions and he ... he would, you know, give me information back and it was very much me asking me things rather than him giving an overview of where we were going. You know, sometimes you expect, oh you know, this is what happened and this is where you are now. And you kind of had to press for that a bit.

Number 4

I think that's what I meant when I said earlier about wanting to know how it was working. But that's impossible in a way. You can't say how brain surgery works too. I wanted to know why Number 2 got her needles in a different place to me, you know, which is like basic, um ... you can't answer on the back of a postcard type thing. So it's like a little knowledge being frustrating.

What about Number 1 about feedback? Was it something you wanted or ...

Number 1

I would like to have known what the cortisol levels were but perhaps ????? ?????

We don't know ourselves yet, no. I mean, all the analysis will be done at the end and it will all be done blind so we don't know who is in what group. And Wei Dong still needs more volunteers so ...

Number 1

I found on that score that most of the colleagues I work with and I'm not going to say why, but were quite unsupportive, I would say, as if, oh, what are you wasting time doing that for? Which was a bit ... I found, and trying to enrol anybody else to come was very difficult because people do just ... I don't think they want to open their mind to other alternatives.

Number 2

I was going to say, once it's been offered in a group ... and some people have accepted and some people haven't, then I think, whatever it was, the people who haven't accepted will be critical in some sort of way to almost justify why they ...

...why they're not doing it.

yes, I feel that's ...

Number 1

Yes, I felt a little ... because I wasn't using work time and I felt conscious that, if I was a bit late, I would be running past the 9 o'clock and people would be thinking, oh, you're using work time to lay down. And I'm sorry to be so basic but, um, people were like, oh, you know, where have you been, oh, you know, a little bit offhand about it. I mean I don't know if anyone else came across ... a little bit.

Number 4

I think our colleagues were very intrigued by it.

That's good.

Um, I think they enjoyed it vicariously really. I'm not sure they'd do it but they were very interested and supportive of us doing it.

Yes, yes. It probably just depends on the teams you work in.

Number 3

I did find a number of people that I thought should have done it said, oh no, I'm far too busy for that kind of thing ????? you'd have really benefited from, you know, maybe taking time out and recognising that you should stop at some point. And I was quite interested in the selection process as well because, um, somebody that I work with that is, in fact, very stressed, didn't get accepted and I think that was because of the way, you know ... that when you filled in the beginning questionnaire, depending what kind of person you are, you might ... the way you cope with stress might actually be to play it down and I don't think ... I think there could have been other ways to find out...

... the screening questionnaire then you feel might not have been appropriate?

Because in actual fact this person was very stressed at the time and I was completely amazed that they didn't get accepted because, like, I think, knowing the kind of person they are, they played down their answers just because ...

Number ?

'I'm not stressed.'

Number 3

Yes, exactly, that's just the kind of person they are and I think, you know, that actually meant, you know ... because then they weren't recognised as being stressed enough to attend. I think it actually made them feel worse, you know, that it wasn't being recognised.

It may have also depended on whether they'd had a serious event happen in their life within the last month and if that had happened then that would skew the results. So if they are ... if they did have that and they actually want to come back into the study, then that would be ... you could approach Wei Dong again because they were a group of people which, because they'd recently had something that was very very severe, they couldn't be included so that might partly explain that. But that's a good observation. That's an interesting one. That's the trouble with a research project. It's not necessarily for the people that it would suit the best but the people that meet certain criteria and you have to stick with those whether you want to or not, but, er ...

Yes, because I mean definitely some people that I know attended you can tell that they knew what answers to say in order to get that, kind of, you know, they thought, you know, just knowing some of the people that came, you think, oh, they're obviously not that stressed, they're ... you know, they've just decided that they're going to say that and get this free, kind of ... and I thought it wasn't fair, you know. There were some people that needed it more that couldn't have it.

Yes.

Number 1

I also thought, actually, to try it for free. I know that's a bad thing but, being quite honest ... because when do you get the chance to try something for free?

Yes, I mean if you go down to Harley Street, the amount you'd be charged for acupuncture would be pretty horrendous.

My husband had private acupuncture but he had private healthcare which covered it but it was ... ended up being, you know, would have been quite expensive.

Did he find it useful?

No, he didn't enjoy it. He didn't like the needles being put in but, yes he had 6 sessions - he had some shoulder pain and he had it for that.

Interesting. Had you had any experience of any complementary medicine before, any of you? Had any ... any treatment of anything else?

Number 3

I've had hypnotherapy, does that count?

Mm.

Yes, I've had that to give up smoking and that, like, that was really good. I had one session and it was good. It was quite traumatic but it was fantastic.

Number 2

I've had aromatherapy sessions which were very nice and I've dabbled a bit myself.

Number 3

I've had reflexology as well. I didn't like that.

Number 4

A bit of homeopathy.

OK, is that all? Has anybody got any more comments?

Number 2

Will we be... will anything else be required of us after this?

No, nothing will. I mean, obviously, if um ...

Number ?

And final questionnaires?

There might be a final questionnaire. Have you done a final questionnaire?

Number ?

We did do one ????? ????? did say there was a final one.

Yes, you might, yes. There may be one but there's no more ... no more salivary courses or testing or anything like that. It will just be something that, you know, ...you'll

Number ?

He's not doing the saliva ????? on the last ...?

I don't know. I can't quite ... there is a follow-up of something but I don't know. I can't remember if he's doing the saliva but it will be one more ... a gap, a follow-up questionnaire and he may or may not ask you to do another set of one day samples but I don't think he ... I think it's just a question of ...

Number ?

... and after he's written up his study ????? ?????

*Oh, gosh yes, yes. We anticipate that the analysis will probably be done late summer I would have thought because we need to complete the whole study ... **The recording stops abruptly here***

Appendix 12.4 Transcription of the attention group

Acupuncture & Relaxation Focus Group 2 - 22/3/06

This is 22nd March 2006, Focus Group 2. I have two participants here in the research project. What I'd like to do first of all, Number 1 is ask you just to describe your experience of the treatment you had.

Number 1

There wasn't any such treatment ... treatment in that way but there was relaxation once a week for about 20-25 minutes, which I found ... because I was doing this in the afternoon, because in the morning it was very busy for me, so I think at about 3 o'clock in the afternoon it was just right for me because after having like a very stressful working morning, just to kind of switch off for half an hour was very good for me so I found that very helpful.

And Number 2?

Number 2

I had the same treatment – relaxation therapy which ... I think again was useful, mainly because it was sort of the end of a working day. At that time ... things have eased off slightly but, with the work I was doing and sort of second and third jobs, just having that one break where I could switch off. And I found it helped sort of for a short while. I'm sure there was some sort of long term effect which, over a period of time could help. I just found it was good for about an hour or so afterwards, just sort of cleared my head a bit.

What about you, did you find that it was actually useful?

Number 1

I think in the long term it teaches you, if you can take that time out to just literally switch off. Here, because it's a treatment and it was part of a course, we were forced to so you had to make the appointment and you had to do it. Now, I don't know how good that would be in a normal working day. If I say, you know, most times... I don't know about Number 2, but most times I eat my lunch at the desk, answer the phones, keep watching, you know, the e-mails etc. so it's not like you can go away, just switch off somewhere and that's it. But previously we used to have what is known as the "leather room" on the third floor which was like a staff common room and I think a lot of people made use of that, including me, and that was what ... something of your relaxation if you like, where you took the paper, you took the food and you just went and you sat or you chatted and it was a nice thing. So, yes, in the long term if you can do that, that would be helpful. I found it helpful over seven weeks because my life is always busy – work. I don't have a peak time and a trough time so I found it helpful, yes. I don't know whether I can continue but I did find it helpful.

Do you think that, you know, if you had somewhere that you could do that that was made available ...

Number 1

Yes, that would be very good. Because we did this for half an hour. Normally your lunch break is for an hour so when the leather room was there I found it extremely helpful to just take the newspaper, take your food, sit in one corner, read the paper, completely switch off - no

telephones, no ... nothing. And then you came back and you felt better. But we don't have that opportunity now.

You don't have any where that you can go?

Number 1

We have nowhere to go now.

Do you tend to stay at the desk as well or ...?

Number 2

Yes, there just too much to be done at the moment so there's not really much of a chance to take a break.

How did it make you feel in terms of being aware that you had to come away from your desk and that you couldn't answer the phones and things during that time?

Number 1

Good, because it was forcing ... like I said, it forced you to take that break and, OK, you were ... maybe sometimes you were in the middle of something and maybe there was slight irritation to start off with but at the end of the time when you came back it was really worthwhile.

Did you not find that you were worrying at all that things weren't being done?

Number 1

No.

Number 2

I don't think I was worrying. It was, how can I describe it, a blessed relief to get away from it all for a short while because... I mean, I work outside of the University as well on two other jobs - a combination of teaching and performing around the place and ... so, wherever I am, I'm either here working on this or I'm, you know, at home practising because I'm a performer, and there's never really an escape from work as such. And actually ... just, I have to do this and I have to relax. It's not like you're forcing yourself but, once, you know, I was in the treatment room to relax, it was just right, ah. I think I actually fell asleep the first time, which was great.

Right. Did you fall asleep?

Number 1

Yes, very nearly. And I used to wake myself up because I thought, this is not a good idea but, towards the end, I got used to it and I would just ????? ????? if I go off to sleep just wake me up.

Yes, I mean, what did you find that you were doing during that relaxation period? If you weren't actually falling asleep, what else were you doing?

Number 1

I don't know, what do you mean? Just, basically just trying to wipe my mind off everything ... consciously. Because it was like - this is an opportunity, here's half an hour, nothing to do, just switch your mind off to everything and that's what I consciously tried to do.

Number 2

I think that's pretty much what I was aiming for. I don't know about you but I'd always find myself the first couple of minutes just lying there trying to relax and you just have so many feelings, probably ... oh, there's that and then that and I've got to write ????? for someone or I've got to get that sorted in the office. And then it would just sort of slowly go away and before you realised it, there was just no major thoughts. It was great.

And what about the end of the session? What tended to happen at the end of the session?

Number 1

My body was extremely sluggish at the end of the session so it was hard because it is going back to work. It's not like going off to sleep or going home or it's in a home environment where you can just continue to relax and sleep. So, for me, that first ten minutes, getting up, switching back on, getting on track, putting on your things, walking across, going back to the office. But by the time ... because from the treatment room to the office is quite a way with stairs and lifts and everything ... so by the time I was there I was back on. But of course there was the good effect. Like I said, you know, it lasts for about maybe half an hour, 45 minutes and then you're back in the stream of things.

Number 2

Yes, I certainly noticed that. I mean, I had the treatment over in ... is it Westel House? Yes. And, sort of, the walk from the treatment room, going down in the lift and still being in the street, it was like I was fuzzy in my head. It was really ... not in a bad way, that sounds terrible, but it was just nice. I managed to have a separation from all the traffic and ... yes, it was good to do, it was needed.

And, do you feel that, thinking back to the original symptoms and problems you had in terms of stress, do you think either in the short term or the long term that it's had any impact on those?

Number 1

No, I wouldn't say it's had an impact in so far as ... that, as I was explaining, stress varies from day to day, hour to hour. There are some things that cause stress, at least in my life, that are semi permanent and it'll take it's own time to go away. It's not like it was here today and it's gone tomorrow and somethings ????? be done and that's it. There are some things which are very much today, at work or whatever, like your car breaks ... whatever, and it's very temporary and then that goes away but the fact that you take the time to actually relax, that make an impact, the fact that, you know, I would make sure if ever I was in a situation where I am that stressed, is actually to try and switch off. Because that certainly made a difference in the day if you like.

Sorry, I just ... a third person

Number 3

????? interviews and they went on a bit longer.

... because we need to be finished fairly promptly so ... We've just been talking about the treatment you had and your experiences of it. You'll be Number 3. So perhaps if the other two don't mind if we catch up with you. Yes, about how you felt about the ... your experiences of the treatment that you had and what happened. How you felt before and after, those type of things.

Number 3

Yes, I was on control ... no, I was on the relaxation group so I had half an hour relaxation. I felt it was a bit ... not related to the work I'm doing because I'm all over the place with work. I work in the middle of London, I work at Reading, I work at Slough. I live in Hampshire so I travel 2 hours into work before I get ... and then I work all day and then I don't get home till late and I know that I'm stressed and I thought that, by having relaxation, or being part of the control, I would be able to get some pointers on really time management I think. The first three weeks of my five week session I worked extremely hard because I had deadlines to meet and the last two weeks I've met all the deadlines and I'm not stressed, which is ????? what I've put down to being very stressed at the beginning and not stressed at the end so how much the half hour just lying down actually helped I wasn't sure. Having said that, the first time I did the half hour lie down, I didn't think I really relaxed but by the fifth time I just got, you know, relaxed and I did find that of benefit. And I thought, yes, if I continue with this I can actually derive benefit from that half hour of just chilling out.

And I asked the other two, you now, what you were doing during that half hour and they both mentioned that at least one session they'd felt like they'd fallen asleep. I don't know if you fell asleep at all or ...

Number 3

The last two were more sleep-inducing but the first three times I spent the whole half hour lying down thinking, I've got to do this next, I've got to do that next - I didn't relax.

Were you worrying about things that you ...

... thinking how I can get it all done, how I can get a quart into a pint pot, but ...

But by the end...?

By the end I was actually thinking ... but then I had met all my deadlines and I just lay there and I could nearly have gone to sleep, yes.

Thank you. I'd just come round to Number 2 asking if you feel that, in terms of the symptoms that you put down on your questionnaires as the things that were causing you stress, whether, as a short or the long term, any of those had changed in any way or whether you felt any benefit in any way.

Number 2.

I'm not sure, say, if long term some of the symptoms I had, it's ... has much of a benefit because, I mean, that's something that will be going on and on and on, and in some respects is going to get worse before it gets better. I think just having that short break of the relaxation period, you know, and eventually actually not consciously thinking about things, in some ways helped. I certainly ... I think one of the symptoms is improved but that could be, like you said, just a part of some of the working patterns changing. A bit of a difficult one to really answer

because it was only, you know, a few short weeks. Maybe if the control went on longer I'd be able to give a better answer but at the moment it's a bit sort of ... we'll wait and see.

Do you feel at all any of you that you're ... even if the stress hasn't necessarily changed, whether you're coping with those stressful situations better. I mean it's something that you touched upon first of all.

Number 3

Yes, I think I can go and sit in a quiet room and derive benefit now, which is what I couldn't do five weeks ago because of the workload, because I didn't have time to take half an hour out. But, because I came in and two of those weeks I actually had some days off that I came, leaving at 7 o'clock in the morning to get to my half hour relaxation for half an hour to go off home again or do shopping or something, you know. So it was unrealistic because I thought, well, what's a typical week? I don't have a typical week. Sometimes I have a long weekend, sometimes I'm working till midnight, sometimes I don't go into work at all, I work from home so I'm not doing 4 hours travelling. So what's a typical week and when ... well you'd almost say, well, you can't do that, you know. I sort of felt, you know ... sometimes I do have a long weekend, go to Wales and work on the farm and, you know ... which is completely different. So I found it very difficult to attribute what I was feeling to the relaxation period.

This is the difficulty with working in real situations ... the importance of being in a real situation rather than putting in a very false situation that some research projects try and do. We're trying to work on real problems of real people and how we can address them really.

Yes, in terms of Number 1, ????? some of your difficulties that you've got are long term. Do you feel that you can cope any better with those than perhaps you could before?

Number 1

I can't answer that specifically but I can say categorically that, taking that half hour out of a busy day made a difference because, if I can do that, then obviously if you are more settled you can cope better with anything that's thrown at you. So, if ... what I've learnt is that you ... I mean, nobody here, at least people I know don't really do an eight hour day. I start at 6.30 and I don't finish till 5.00 - 5.30, OK. And it's on the go all the time. And because you go to meetings, you make up ... because there are other things that have to be done so as Number 3 was saying, we don't have a typical day. However, in such a long day, to take that half hour or forty-five minutes if I could, I think would help me cope, not just with personal problems but work problems. And I think it gives you that time to just switch off and then start again rather than ... because sometimes when you're on the go all the time, you ... it becomes fuzzy the edges. You can't see with clarity. So, yes, that's something that I have learnt, that if things get really on top, just walk away, go away, sit somewhere for half an hour - 45 minutes, switch off and come back and I think you will feel better. At least that's what I've learnt.

Number 3

I endorse that. And also I think the importance of eating, because I don't eat between ... you know, when I start in the morning, I just go all the way through there's just no time to stop, which isn't ... I know it's not good, I teach it's not good, but I do it, so ...

Thanks. I also want to ask you some questions about the research project itself and your experiences of that. First of all, how did you hear about the research study?

Number 1

It was on the broadcast e-mail. I actually ... I'm being very honest, I thought I'd be lucky enough to get the acupuncture because I've had acupuncture before and I found that very good. I found that both relaxing as well as it was a treatment, which actually helped, because I had a frozen shoulder and I have constant aches and pains anyway, so I thought, if somebody's going to do this as well as help, it's going to be wonderful. Unfortunately it didn't work, but I did come in for ... I'm being honest, I did come in for that but then, since I've decided ... he's a very earnest young man he ?????, you know and he's very sort of like you know, enthusiastic about his research. I said, well, never mind, it's just 7 weeks and I'll help. So basically I came in for that and when this was said that, no, you haven't got that but you've got the relaxation, I didn't ... I went in without the ????? but more to do a kindness if you like to say, you know, he hasn't got that many names and so I'm here for 7 weeks on the trot, which is unusual anyway because as of next week I'm moving so that's what made me go for it.

Number 2?

Number 2

Yes, no, I found it on the broadcast mail and thought, great, acupuncture and then, when I got the relaxation, thought mmm. But, no, it was good anyway but, yes, I found it from the broadcast mail.

Number 3?

Number 3

Yes, I thought, I don't want acupuncture, but if I had it it might do me some good. And I do do massage and reflexology and I believe very much in complementary and alternative therapies. And, yes, ?????

So were you pleased or disappointed to be in the relaxation group?

I think I was relieved but I would like some acupuncture because I do think it will help, but I think my main problem is time management. I ought to manage my time better, but I would if I wasn't given so many deadlines by managers.

What about the questionnaires? Did you think the things they were asking were appropriate? Did you find them easy or difficult to fill in? Did you manage to fill them all in?

Number 1

I managed to fill them all in but the questionnaires were very ... I ... because they're generic, they're very difficult sometimes to put your situation in it because they're saying things like ... somethings, they want to know if you've had any stress in the last month but like I was explaining, you don't know from month to month, week to week. Also, there are some parts of ... at least I'm one of the unlucky ones I think who have things in their life going on long term which will take time, so even though it's not happened last month, the repercussions from that are very much today and they will either get worse or better depending on how those things pan out on a day-to-day, week-to-week basis. So, for me to say, well it's only something that you can put in that happened last month, it just didn't seem relevant in many ways. But like I understand if you're doing a generic thing it's very hard to cover everything. And also some of the questions were fairly tedious but I suppose in research you have to be like that. No, it was OK. It's only that it was very hard for me personally to relate to some of the questions so I had to take help and say, well, can I go back a little bit longer and then put that in and whatever. So, yes.

What about the others?

Number 3

I'd say the same, yes. I couldn't decide what a week was and what a month was and whether I had the headache that week and the headache was actually due to sitting in the traffic and being late. It wasn't anything ... you know, it was what happened. And I'd also had palpitations on the fifth week and I ... oh, it's a new symptom. This is ... well actually that's what you said five weeks ago. And I hadn't realised that, actually, all this time I'd been having palpitations. But then also going on about the timing. One of my things is inability to concentrate or make decisions because I've got so stressed so, when it came to taking the swabs, I forgot. I mean, I managed the first three because they were relatively close together but each time I'd either eaten something at half past five and I thought, oh, I'm not supposed to eat for another half hour or I thought, oh dear, it's ... you know, the swab's not here. And then I couldn't put them in the freezer because they were all in the car. Because, you know, I leave at ????? so I'm thinking, oh I haven't taken the swab and ...

Actually, something that came up in my other focus group was that the stress involved in trying to remember ... Did you all find that you on the whole were managing to stick to the timescales?

Number 1

I was really chilled about this thing because that was the least of my problems. Because I get up at 5.30. So at 5.30 I get out of bed and straight put that in your mouth. Half an hour later I had to remember before I have a cup of tea I have to do that. So those two were fine. The bits that I forgot or couldn't specifically because I didn't go to a meeting with my little swab in my hand, so if the meeting lasted longer than say 10 o'clock, then I took it at 11, whenever I came back. And there was one evening when I didn't take the last one till about 8 when I was supposed to do it at 6. But like I said, that was ... the first two were perfect because that was at home and whatever but in a working week I didn't really get stressed out about that, I'm sorry.

Number 3

The first one I was usually sitting in the car waiting for the minutes to click round but I couldn't put it in the freezer and then it had to sit in the car all the time. And then the last one, six o'clock in the evening, I was still in the car. And then bringing them in today, I was 2½ hours coming so I think all the ice has melted so ...

What about you?

Number 2

Yes, it certainly makes you have to really think about everything just to fit it all in. There was the odd moment when I was sort of late on the last one or just quickly do this, quickly do that, and I had a ?????????????? there I am sort of about to go out of the house and I'm ... what's that? Oh, God, I've still got the swab in my mouth. You thought to yourself, right, I've got to give it another five minutes, I just need to. I'll do that, right. Pop that. And then you think, OK, I'm going to be nice ... and then you find yourself running to another rehearsal or there were moments when you think, oh God...

????? made you feel ??????

... well it's where I sort of got, oh, oh, yes. But on the whole I think I managed to get them all pretty much on time, I hope.

We shall see. What about the venue and the timing? You did mention at the beginning that you found the timing in the afternoon was quite suitable.

Number 1

Yes, for me it was.

Did you have yours in the afternoon?

Number 3

No, I had mine at half past nine in the morning but it ... again, just depends on the traffic. Sometimes I'm here at half past eight. And once I got there at quarter past nine. Oh, I'm going to be late, you know, it was to suit me. It was better to have it at half past nine in the morning than when I'm in the middle of lectures or when I'm doing something else, so •

And what about the venue itself. Was it conducive to relaxation? Did you find it all right? Was it handy for you to get to?

Number 1

Mine was St Mary's Road, just here, and the rooms are really nice so it was OK for me.

Number 3

We had to talk quietly because somebody was being counselled in the next room.

Number 2

I was in Westel House. The room itself was fine but there were a couple of times, because of its location, the room right next to it was a toilet so there would be occasions when you'd be halfway through relaxation and suddenly you'd get ding, shhhhhhh, fan with the light and then they'd flush the toilet and you were like ... I'm trying to relax. The moment I fell asleep it was absolutely fine, I just snored through it but after that there were moments when you sort of went oooh, carry on. But, yes, that one thing could be improved but, apart from that, no the room was fine. Actually laying down on that thing was great because it was more comfortable than the bed I've got in my flat at the moment. But, anyway ...

Were you on a couch or ...?

Number 1

No, mine was a bed which can go up and down and ...

Like a hospital bed...?

Like a hospital.

Number 2

Yes, mine was sort of like a doctor's surgery kind of ...

Some of these things we've actually covered in various points but I wonder if you could just go over again about your expectations and also whether you feel you would like to carry on or like to do something different to help your stressful situations. As I say, you have mentioned them in other parts but perhaps you could just go through again.

Number 1

I don't know whether ... I didn't actually go in with any expectations because the thing is it was a clinical research, that you were taking swabs and somethings so there wasn't much to expect and whatever. When I got the relaxation, I though, right, it's like, you know, just switching off for half an hour. And I expected that it would help, which it did, and I would be more interested actually to find out what the swabs actually told you because I would like to know what you actually get out of it and whether in any way it conforms to what I was going through at that time week by week. So I would be interested more in that, but as for expectations going in with it, I really didn't have any. I just knew that whatever I was going was going to help somebody and it was going to be ... whether it was the acupuncture or the relaxation it was going to be good for me in some form or the other. Because I also, like Number 3, believe in alternative medicine. I come from India so we do a lot of alternative therapies and things like that. So, yes, I didn't have expectations as such but I would like to know what the swabs actually tell you.

Yes, we will give you some information at the end. Because obviously the analysis hasn't been done yet. When the trial is finished we have to do all the analysis so we don't know what we're going to see.

Number 1

Because I didn't know how you would co-relate the saliva at different times of the day to what the body's actually going through. Because I haven't read anything more about it so I don't know. So it would be more like a knowledge thing for me.

Well, we're actually looking for a particular stress hormone that goes up and down during the day and ... to see if we can see any patterns of change in that and with the time, the before, and the after - that's what we're planning to see.

Number 3

Yes, I'd like to see a graph because I could say, on that day I was travelling back from Wales when I was taking it, on that day I was sitting in a traffic jam, on that day I'd passed all the portfolios across and I had nothing more to do. So I'm expecting you to see relaxation in the last fortnight as opposed to the first three ... so to see a graph that would actually show that would be interesting but, you know, to have them at the different time variables, especially when I wasn't very good at the last one, the twelve hour one, as to how much that actually affected ...

And, what about Number 2?

Number 2

It would be good to see sort of results of things, what's come out. I think going back to the question about what expectations we had of it, I think like the others I didn't really have any expectations because I thought, just lying down for half an hour, you know, gladly really. But I was in some ways surprised with what it did and I think, well I know, I would like to try out some acupuncture just to see what it can do. I think because of this as well I've been looking more into certain elements of yoga. I think that's mainly because of the performance side of things I do outside of working here. I think it will help me with my trumpet playing basically, that's the main thing. But, yes, No, I found myself looking into more sort of complementary

things, some of which before I was a bit cynical about to say the least. But, yes, no, definitely interested.

And do you think that some provision should be made for this type of treatment either within the workplace or available on the NHS, that kind of thing? Do you think that would affect your working performance?

Number 2

Yes

Number 1

Absolutely. I think a simple thing that they could do really, the University, which they've taken away is that they could have a staff room like they used to where you could really go and switch off. There is no place now because of the shortage of spacing. But this is important for the health of the people working because, like I said, I don't know many people that come in and do, literally, a seven hour day, take their full hour for lunch, go away somewhere and whatever. Most of us do way beyond what we're expected to do. So it would be nice for the University to have something in place where ... it's a simple thing, I'm not asking for treatment. All I'm saying is somewhere along the time, in my lunch hour or when I'm tired and I can't watch the computer any more, I have somewhere warm comfortable and nice, not standing outside in the cold, where I can just go and say, look, I'll be gone for half an hour, I'm just taking a break, and I'll be back. And I will be more effective for the University that way. So that, yes, that is something I would like to suggest if somebody could do that. And for the NHS, I think the NHS is slowly starting to realise complementary medicine actually does help. Because I know that, with the NHS for example, there are ... in Mattock Lane for example there's a medical health centre that does alternative medicine which you can get from your GP. The GP won't do it but he can actually suggest with a letter that you can go and get treatment done. So, yes, it's on the increase actually.

Number 3

Yes, I've worked, oh, ... since about 1980, I was doing the complementary therapies for West Berkshire writing protocols and we actually employed somebody who was doing aromatherapy in the ITU and it went on from there. But they do actually say I can go over for the gym any time and lie down at Slough, but I don't do it. I mean, unless it's actually on my doorstep ... I mean even walking from Westel here to lie down I probably wouldn't do it. If it was going from the ground floor to the fifteenth and there was a bed, I might actually lie on it for half an hour if it was there.

Do you think there's a problem with the culture of being able to relax as part of the working process?

Number 1

Managers tend to feel, particularly senior managers tend to feel if you're taking time out ... if you're caught staring outside the window, just taking a break, you're not doing the job. There is a culture definitely. There is a culture where, if you say, you know, occasionally you want to go home early, because ... then you're marked down as, you know ... here, it's always been in TVU hours equate to productivity. Not that you can do something in four hours and do a really good job but it's shuffling paper and if you stay eight hours then you're working very hard. You could have done absolutely nothing in those eight hours but it's mentally there that the longer stay, the harder you're working. You don't take time off, you don't relax, you don't go

away, you eat lunch at your desk. All these things are marked down as, you know ... so, yes there is a culture, definitely.

Number 2

I think it's a general thing happening throughout, not just necessarily in TVU. Because with the work I do outside, some people look worried that you're only doing a few extra hours on that day and you do the odd thing on that day. But then you take, you know, sort of ... you leave work a few hours early, so it's just that. But, you know, like you have with your travelling, where I'm teaching outside, you're travelling for that ????? concentrate, make sure you don't crash or anything, then get there and concentrate so you, even if you do sort of three hours ... say, for me three hours teaching, you end up sort of 6, 7, 8 hours of the day. Or, with some of the other work I do, people just look at you and go, oh, you're just, you know, you're relaxing, having fun on the stage doing whatever. But it's just concentration for an entire three hours doing one thing and, you know, for my ????? in the back of your head, one slip up tonight and I know I won't get any more work from these people or whatever. And you're only doing this for a few short hours there but you're travelling from London to Paignton in Devon and back in the one day. So you end up having an eighteen hour day because you're working in the morning, getting back at 2.00-3.00, this sort of thing. And it is generally throughout that you end up working more than you really should or probably need to just because of the general attitudes and the kind of climate that's going on around us. Horrendous personally but there we go.

Number 3

I think it's a bit deeper than that because bosses ... oh, yes, do take time off. She gives me lip service. But she doesn't ... yes, of course you can take the afternoon, yes, yes. But the pressure is there, whether it's inbuilt and it's only my fault and therefore if I need to take time out, I can take time out, I should take time out. And even after this, I think I will take time out.

I think that's a good point to finish on, OK. Thank you very much all of you.

Appendix 13 Published conferences abstracts

1. Huang, W., Robinson, N., Howie, J. and Taylor, A. (2005) Exploring the effectiveness of Traditional Chinese Acupuncture (TCA) for the reduction of stress in adults – a randomized, controlled, crossover pilot study. *Developing Research Strategies Conference*. University of Southampton, the UK 28 April 2005. *Complementary Therapies in Medicine*, 13, p.221-222.
2. Huang, W., Robinson, N., Howie, J. and Taylor-Vieira, A. (2008) An investigation into the effectiveness of Traditional Chinese Acupuncture (TCA) for chronic stress in adults – a randomised controlled pilot study. *3rd International Congress on Complementary Medicine Research*. Sydney, Australia 29-31 March 2008. *The Proceedings of the Third International Congress on Complementary Medicine Research*, p.15 (poster abstracts).
3. Huang, W., Robinson, N., Howie, J. and Taylor-Vieira, A. (2008) Is cortisol a useful marker for measuring reported stress in complementary medicine research? – a randomized controlled pilot study. *3rd International Congress on Complementary Medicine Research*. Sydney, Australia 29-31 March 2008. *The Proceedings of the Third International Congress on Complementary Medicine Research*, p.14 (printed abstracts).
4. Huang, W., Robinson, N., Howie, J. and Taylor-Vieira, A. (2008) The effectiveness of Traditional Chinese Acupuncture (TCA) for chronic stress adults – a randomised controlled pilot study. *Developing Research Strategies in CAM*. University of York, the UK 24 April 2008. To be published in *Complementary Therapies in Medicine*.



ELSEVIER

ABSTRACTS

Developing Research Strategies Conference, 28 April 2005

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This year the conference addressed issues and treatments that surround the menopause and included evaluating Herbal Medicine, Acupuncture and Bowen Technique as well as the underlying mechanisms that may underpin CAM interventions. Christine Barry encouraged us to be reflective and evaluate CAM in an ethnographic and anthropological context, emphasising the value of the patient perspective in increasing demand and subsequent patient perceived satisfaction with CAM. Removing the 'medicalised' emphasis of specific treatment efficacy and encouraging us to begin to look in a more holistic manner at treatment effects, patient satisfaction and indeed of course safety. This emphasised the observation that RCTs provide limited but important causal information in highly selected groups of individuals; how generalisable are they? An issue addressed by Paul Dieppe at our conference last year.

Harald Walach explored non-local quantum-based effects and questioned how they may impact on clinical trials. Lionel Milgrom suggested that these non-local effects might, through our understanding of the theory of quantum mechanics, underpin the effects within the homeopathic process. In a sense these perspectives make us consider whether we can separate specific treatment effect

from the process of receiving treatment within CAM. What is homeopathy without the homeopathic consultation? The sceptic might question whether the homeopathic consultation is any different from visiting a caring conventional GP but the ethnographers would disagree observing that the content and nature of CAM consultations offers a series of entirely different dimensions to those reported within conventional medicine.

Practitioners frequently wish to 'prove' their therapy, but the point of our strategies conference is not to prove or disprove anything. Its aim is to expand peoples understanding of research and how they may approach a research question in a logical, thoughtful, sympathetic and above all else, appropriate manner. The question is everything; the research methodology follows directly from the issues raised by the question. For instance, do we consider acupuncture to be solely about 'the insertion of needles in what is considered to be an appropriate acupuncture point' or do we consider acupuncture to be the whole process of going to see an acupuncturist, having your pulses taken and being quietly questioned for 10 or 15 min about how you feel and what changes there have been since the last consultation. The patients' perception would undoubtedly be that acupuncture represents the whole package; it is possible that the acupuncturist may consider that the critical bit of acupuncture simply relates to the insertion

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to cancer patients through support units. Patients and therapists report improvements in their condition and quality of life but this is not currently quantified or formally reported. Research is needed into the effects of NST (not to treat cancer, rather alleviate the side effects of treatment) and this pilot study aims to address this gap in knowledge and to inform the development of a larger study.

Methods: The pilot study design is pragmatic, investigating effects of NST of a therapist working in the community. Quantitative and qualitative methods will gather information on the patient's condition. Participants follow the following process: recruitment, baseline assessment, NST, interim assessment, NST and final assessment. The proposed study cohorts are patients accessing Cancer Support Centres in the North West Region. The pilot will recruit 20 participants experiencing health problems after being treated for cancer either post-operatively, post-chemotherapy, post-radiotherapy or a combination thereof. They will be randomised to receive immediate or delayed NST. The delayed group, therefore, act as controls. Traumas may include muscle pain, restricted movement, lymphoedema, neurological disruption, digestive trauma. **Recruitment**—Patients >18 years old, accessing a support centre, deemed suitable to receive NST will be eligible. Non-eligible patients are those with major pre-cancer health issues and those receiving palliative care. Written informed consent will be adopted and ethical approval sought. **Baseline assessment (30 min)**—Will provide information on the patient's current condition prior to receiving treatment. Consisting of a one-to-one discussion between the therapist and patient, the nature and severity of the trauma will be identified and quantified. Tools such as the quality of life questionnaire (SF36), pain intensity scores, depression and mobility scales will be used together with recording of verbal information. In some cases, physical measurements and/or photographs will be taken. **Bowen NST (1 session = 1 h)**—Although each session is tailored to the individual all patients will receive the same treatment structure, i.e., three sessions (1 per week), 2-week break followed by a further three sessions. The participant remains fully clothed during treatment. The moves used will be determined by the nature of the trauma and which part of the body is affected. A 2-week break is then taken and an *interim assessment* carried out using the same tools as the baseline. NST is then resumed for another three sessions. **Final assessment**—A repetition of the previous assessments.

Results: Each assessment will produce both qualitative and quantitative data. Quantitative

data will be analysed using appropriate statistics depending on whether the resulting cohort is parametric or not. Data will be dependent, e.g. numerical scores such as pain intensity will be compared before, during and after treatment. Qualitative information will be transcribed verbatim and thematic analysis carried out whereby common themes will be identified. Transcripts will be read and re-read by a third party to validate emerging themes. The study aims to elicit valuable information as to the effectiveness of NST for cancer-related traumas.

Reference

1. Nixon-Livy MJ. Neurostructural integration technique. *Positive Health* 1999;43:48–51.

Exploring the Effectiveness of Traditional Chinese Acupuncture (TCA) for the Reduction of Stress in Adults—A Randomised, Controlled, Crossover Pilot Study

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Aim: The pilot study forms the initial stage of a Ph.D. programme. This stage is exploratory and designed to inform the development of a future RCT.

Subjects: Eighteen volunteers with high self-reported stress levels as measured by the Perceived Stress Scale 14 (PSS-14), currently not receiving complementary or other treatment for stress and its related symptoms.

Methods: Participants will be randomised into three groups. In group 1, six participants will receive weekly sessions of Traditional Chinese Acupuncture (TCA) for a period of 5 weeks, and after a 2-week wash-out period they will receive five weekly sessions as an attention only control (i.e., TCA consultation and relaxation only). The six participants in group 2 will initially receive the five attention-control sessions followed by the five TCA sessions (after the 2-week wash-out). In group 3, six participants will act as a waiting list control. These subjects will be offered TCA once the study is finished.

Outcome measures: For groups 1 and 2, the Perceived Stress Scale 14 (PSS-14) and the Measure Yourself Medical Outcome Profile (MYMOP) will be completed on the day of commencement and com-

pletion of either the TCA or attention only phase for both arms of the study. Similarly, for group 3, the six participants will complete the two questionnaires at weeks 1, 5, 7 and 12.

A salivary cortisol sample will be taken at four points in time: (1) immediately upon waking in the morning; (2) 30 min after waking; (3) 3 h after waking; (4) 12 h after waking and the exact time will be recorded. These samples will be taken over a total 12-week time period: on the two consecutive days prior to commencement of the study, on the day following each TCA or control intervention and on the same day for each week of the 2-week wash-out. In group 3, the samples will be taken at the same time points. Salivary cortisol concentration will be measured by using a High Sensitivity Salivary Cortisol Enzyme Immunoassay.

Data collected for each participant will be anonymous and analysed at the end of the study to determine whether acupuncture has had a demonstrable effect in reducing stress, and whether the diurnal cortisol profile is a useful outcome measure for research into complementary medicine and the treatment of stress.

Investigating Complex Systems in Herbal Medicine: Reflections on the Black Box

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Finding suitable methodology to investigate a complex system is a challenge. Can treatment by herbal practitioners, a complex intervention, be evaluated within a randomised controlled trial?

"Changing with Herbs" is a randomised, controlled pilot study of the effectiveness of treatment of menopausal symptoms by medical herbalists. Currently nearing completion, this study investigates the effects of treatment by herbal practitioners, which is multi-faceted and develops over time within a therapeutic relationship. Forty-five menopausal women recruited from one GP practice in Bristol were block randomised between treatment and waiting list control groups, both completing outcomes measures at the same time points. The treatment consisted of a full 5-month individually tailored, holistic course of treatment from

one of three local members of the National Institute of Medical Herbalists with follow-up data collected after 6 months. Three outcome measures were used: a validated scale specific to the condition (the Greene Climacteric scale); a patient-centred instrument with a quality of life element (MYMOP2), and a qualitative feedback questionnaire. Challenges with this trial included: gaining ethical approval; funding; and finding a research sponsor when not working within academia or the NHS. Two issues extended the time taken and hence the cost: setting stringent exclusion criteria, which prolonged recruitment, and unexpected events in the participants' lives. Success of this methodology was indicated by a typical incidence of menopausal symptoms within the population, low drop out (2%), good patient compliance with treatment, substantial data collection (97%) and positive patient feedback. A waiting list randomised controlled trial with several outcomes measures proved a suitable methodology for investigating a complex intervention.

A Pragmatic Randomised Controlled Trial to Compare Usual Care Versus Usual Care Plus Acupuncture to Assess the Quality of Life of Patients Receiving Chemotherapy for Breast Cancer

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Aim: to determine the effect of traditional Chinese acupuncture on health-related quality of life measures for breast cancer patients undergoing chemotherapy.

Methods: 270 patients with breast cancer will be recruited for the study through the Oncology department at the Western General Hospital, Edinburgh. Participating patients will be randomised into one of two groups: (1) an acupuncture group and (2) a non-acupuncture usual care control group. Randomisation will be by stratified permuted blocks. Stratification will be by age/menopause and chemotherapy regime. Outcome measures will be Measure Yourself Medical Outcome Profile (MYMOP), global quality of life, functional scales and symptom scales (EORTC QLQ-C30 and QLQ-BR23) and a fatigue scale. A secondary analysis of data regarding use of adjuvant medication, plus neutrophil count and haemoglobin will also be undertaken.

Qualitative assessment will involve in-depth interviews with 20 patients to explore attitudes to acupuncture therapy, trial acceptability and themes that are important to the patient. These



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An Investigation Into The Effectiveness Of Traditional Chinese Acupuncture (TCA) For Chronic Stress In Adults – A Randomised Controlled Pilot Study

Weidong Huang, Nicola Robinson, Judith Howie, Alyx Taylor-Vieira

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INTRODUCTION: Stress is a physical and psychological response to perceived demands and pressures. Inability to cope can lead to a variety of symptoms of ill health which may eventually lead to serious chronic conditions. TCA has a holistic approach and can be used to reduce stress and its symptoms.

METHODS: 18 volunteers with high self-reported stress levels identified by the Perceived Stress Scale 14 (PSS-14) >20 were randomised into 3 groups. Group 1 received weekly sessions of TCA for 5 weeks; group 2 received attention only (practitioner present and subject supine) for 5 weeks and group 3 acted as a waiting list control. The PSS-14 and the Measure Yourself Medical Outcome Profile (MYMOP) were completed before and after 5 weeks of study. Case studies and focus groups were also conducted.

RESULTS: After 5 weeks, group1 had significant changes in MYMOP profile score and both MYMOP reported symptoms ($P<0.05$); group 2 had significant changes in MYMOP profile score and 1 symptom ($P<0.05$); group 3 showed no changes. Group1 also showed significant improvements on these scores compared to group 3, whereas group 2 did not. PSS-14 scores decreased in 3 groups, but the difference between pre- and post- study within and between the groups did not reach significance in this small study. Qualitative feedback confirmed the benefits.

DISCUSSION: This pilot study suggests that TCA is successful in treating the symptoms of stress, probably via a combination of specific and non-specific effects; but this may not relate directly to how a person perceives their stress.



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Is Cortisol A Useful Marker For Measuring Reported Stress in Complementary Medicine Research? A Randomised Controlled Pilot Study

Weidong Huang, Nicola Robinson, Judith Howie, Alyx Taylor-Vieira

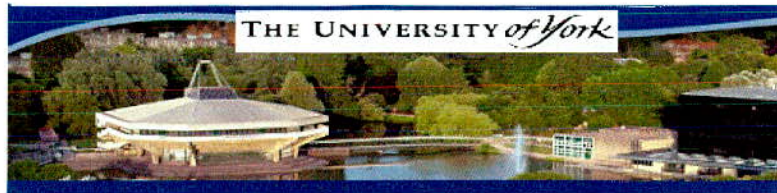
Thames Valley University, London, United Kingdom

INTRODUCTION: Previous research has suggested that salivary cortisol is a potential biochemical measure for quantifying psychological stress. This pilot study explored whether the diurnal salivary cortisol profile is a useful outcome measure when Traditional Chinese Acupuncture (TCA) is used to treat chronic stress.

METHODS: 18 adult volunteers with high self-reported stress levels were randomised into 3 groups. Group1 received weekly sessions of TCA for 5 weeks; Group2 received attention only (practitioner present and subject supine) for 5 weeks and group3 acted as a waiting list control. A diurnal cortisol profile was constructed for each individual at 9 data points: 2 at baseline, 5 during the intervention and 2 post-intervention. Salivary cortisol concentrations were measured using a High Sensitivity Salivary Cortisol Enzyme Immunoassay.

RESULTS: The initial rise in individual cortisol levels after waking (the morning rise) showed an average increase during the intervention which was greater for the TCA group than the attention only. This trend does not reach statistical significance due to individual variation in this small sample. The control group showed an overall decrease in the average morning rise over the same period.

DISCUSSION: Stress tends to decrease the morning rise in salivary cortisol. This pilot study suggests TCA could reduce stress and increase the morning rise of the cortisol profile. Thus the morning rise could be a useful outcome measure for monitoring the effects of treatment on perceived stress. A larger study is needed to confirm these observations.



**DEVELOPING RESEARCH
STRATEGIES IN CAM
Thurs 24th April 2008**

**THE EFFECTIVENESS OF TRADITIONAL CHINESE ACUPUNCTURE (TCA) FOR
CHRONIC STRESS IN ADULTS
– A RANDOMISED CONTROLLED PILOT STUDY**

Weidong Huang, Prof Nicola Robinson, Dr Judith Howie, Dr Alyx Taylor-Vieira
Centre for Complementary Healthcare & Integrated Medicine – CCHIM
Faculty of Health & Human Sciences
Thames Valley University

Purpose: 1. Investigate the effectiveness of the use of TCA to treat adults experiencing self reported chronic stress;
2. Explore whether the diurnal salivary cortisol profile is a useful outcome measure when TCA is used to treat chronic stress.

Method: 18 volunteers with high self-reported stress levels identified by the Perceived Stress Scale 14 (PSS-14) >20 were randomised into 3 groups.

Group1 received weekly sessions of TCA for 5 weeks; Group2 received attention only (practitioner present and subject supine) for 5 weeks and group3 acted as a waiting list control. The PSS-14 and the Measure Yourself Medical Outcome Profile (MYMOP) were completed at baseline, and after 5 weeks of study.

A diurnal cortisol profile was constructed for each individual at 9 data points: 2 at baseline, 5 during the intervention and 2 post-intervention. Salivary cortisol concentrations were measured using a High Sensitivity Salivary Cortisol Enzyme Immunoassay.

Results: After 5 weeks, group1 had significant changes in their total MYMOP profile score and for both reported symptoms ($P<0.05$); group2 also demonstrated significant changes in MYMOP profile score and for 1 symptom ($P<0.05$); group3 showed no change. Comparison between groups demonstrated significant improvements on these scores for Group 1 compared to Group3, whereas Group2 did not. PSS-14 scores decreased for all 3 groups, but the difference between pre- and post- study within and between the groups did not reach significance in this small study.

The initial rise in individual cortisol levels after waking (the morning rise) showed an average increase during the intervention which was greater for the TCA group than the attention only. This trend does not reach statistical significance due to individual variation in this small sample. The control group showed an overall decrease in the average morning rise over the same period.

Discussion: This pilot study suggests that TCA is successful in treating the symptoms of stress, probably via a combination of specific and non-specific effects; but this may not relate directly to how a person perceives their stress. It also suggests TCA could increase the morning rise of the cortisol profile. Thus the morning rise could be a useful outcome measure for monitoring the effects of treatment on perceived stress. A larger study is needed to confirm these observations.