EFFECT OF ACUPRESSURE ON WOMEN

WITH

URODYNAMIC STRESS INCONTINENCE

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EFFECT OF ACUPRESSURE ON WOMEN WITH URODYNAMIC STRESS INCONTINENCE

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CERTIFICATE OF ORIGINALITY

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ABSTRACT

Objective: To assess the effectiveness of a standardized protocol of acupressure for women aged between 18 and 60 years with urodynamic stress incontinence (USI).

Design: A randomized, single-blinded, placebo-controlled trial using a computer-generated table to allocate the interventions was employed. All of the participants were recruited in an urogynecology clinic in a local acute hospital.

Participants: Eighty-one women were randomly assigned to an intervention (acupressure) group (n = 27), sham (sham acupressure) group (n = 27), or control (usual care) group (n = 27). All of the participants were required to undergo pelvic floor training. The participants in the intervention group underwent a course of acupressure based on a validated standardized protocol.

Intervention: A validated standardized protocol of acupressure was developed. The intervention comprised three half-hour sessions per week for a total of thirty sessions.

Outcome measures: Outcome measures included pelvic floor muscle strength, one-hour pad test, number of episodes of urine leakage over four days, self-reported severity of urine leakage and quality of life as measured by the

Chinese version of the King's Health Questionnaire (CKHQ). Data was collected at baseline before intervention and at three months after intervention.

Five percent (n = 4) of the participants dropped out of the study. All of the analyzed data was randomized, and thus the condition of the withdrawing participants was assumed to be unchanged at the end point of the intervention.

Results: A Kruskal-Wallis test was used to conduct a three-group comparison, and a Mann-Whitney U test was used for an inter-group comparison. A Chi-square test of independence for the categorical variables was employed. The level of statistical significance was set at 0.05. The level of statistical significance gives no indication as to whether the intervention has clinical implications, and thus the relative change in the outcome measures was calculated.

There was a significant difference in pelvic floor muscle strength across the three groups (H = 7.05, p = 0.03), and between the intervention and sham groups (Z = -2.31, p = 0.02) and the intervention and control groups (Z = - 2.25, p = 0.02). There was a significant difference in self-reported severity of urine leakage between the intervention and control groups (Z = - 2.48, p = 0.01) after intervention.

Ancillary analyses were conducted to compare the relative change and mean

difference in pelvic floor muscle strength, number of episodes of urine leakage, and CKHQ scores among the three groups from baseline to the end of the intervention. In the intervention group, all of the selected outcome measures were found to have undergone a significant relative improvement after intervention. In contrast, there was relatively less improvement in pelvic floor muscle strength and number of episodes of urine leakage in the sham group and control group. A negative change was observed in four out of the eight CKHQ domains in the control group. There was a significant mean paired difference among the three groups in pelvic floor muscle strength (H = 9.92, p = 0.01) and number of episodes of urine leakage (H = 6.03, p = 0.01) before and after intervention. Similarly, there was a significant mean paired difference in all of the domains of the CKHQ among all three groups before and after intervention, with positive improvements in the group undergoing acupressure.

Conclusion: Acupressure is a simple and non-invasive intervention that appears to have positive physiological and psychological effects on women with USI. Nurses are in the best position to identify the needs of women with this distressing health problem. The findings point to the possibility of including acupressure as an intervention option for managing USI in women. As

acupressure is non-invasive in nature, nurses should consider extending its therapeutic use in existing healthcare services.

The physiological mechanisms of acupressure remain unknown, and the anatomical and electrophysiological changes induced by this intervention need to be further explored. As this study was conducted in a local clinic, the results require further validation from multicenter studies.

PUBLICATIONS AND CONFERENCE PRESENTATION ARISING FROM THE THESIS

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CHAPTER 1

INTRODUCTION

1.1 General introduction

Stress urinary incontinence (SUI) is one of the most commonly reported incontinence problems affecting women world-wide. The prevalence of women with symptoms of stress urinary incontinence is increasing. Although this health problem does not affect the mortality rate, it generates heavy psychological and emotional burdens. Many sufferers feel too embarrassed to seek medical advice until the symptoms of urine leakage worsen markedly, with a resulting negative impact on their quality of life.

SUI is treatable. In Western medicine, healthcare providers are constantly seeking better intervention for women with SUI. Common conventional interventions include surgery and pelvic floor training. Although positive outcomes of these interventions have been reported, surgical intervention can have adverse effects and the adherence rate of women to pelvic floor training is still controversial.

In Eastern medicine, acupoint interventions have been widely used for thousands of years. Of the various available interventions, acupressure is the least invasive, and is

used to manage problems related to the genito-urinary system with positive outcomes. In theory, urinary incontinence relates to a deficiency in kidney qi, which affects the bladder and causes urine leakage to occur. The principle in managing this problem is thus to strengthen kidney qi and the function of the bladder improves.

Acupressure is an acupoint intervention that is recognised across the world. However, scientific evidence on the effects of acupressure intervention in managing urodynamic stress incontinence is lacking. The purpose of this study is to examine the effects of acupressure intervention on the condition of urine leakage in younger women with urodynamic stress incontinence. This chapter introduces the background to the study, including the prevalence of SUI, the concerns of women with SUI in seeking healthcare management, and the integration of traditional Chinese medicine (TCM) with Western medicine as a global trend. The possibility of incorporating acupressure as a non-invasive intervention for SUI into existing healthcare systems is also explored. The significance of the study is discussed and the organization of the thesis is explained.

1.2 Prevalence of the problem of urinary incontinence

Urinary incontinence is a highly prevalent health problem that has physical, psychological, social, economical, and emotional effects on sufferers. There is increasing demand for healthcare services to manage urinary incontinence. Hunskaar, Lose, Sykes & Voss (2004) conducted a large-scale postal survey in Frances, Germany, Spain, and the United Kingdom on the prevalence of SUI and the

treatment-seeking behavior of women suffering from urinary incontinence. All women over the age of 18 were invited to participate in the survey, and 29,500 responded. The prevalence rate of urinary incontinence ranged from 23% in Spain to 42% in the United Kingdom. German women had the highest rate of seeking treatment for urinary incontinence.

Urinary incontinence affects women more than men (Song, 2004). Around two million women are affected by urinary incontinence at any one time (Sadler, 1996), and over half of all women experience urinary incontinence at some point in their life (Tomaselli, 2003; Herschorn, et al., 2008). The problem of urinary incontinence affects women in both Western and Eastern countries. In China, the prevalence of women with urinary incontinence ranges from 19% in Fuzhou (Song, Zhang, Song & Bo, 2005) to 30.2% in Wuhan (Chen, et al., 2004). A large survey conducted in six regional areas in China among 19,024 women (Zhu, Lang, Liu, Han, Huang & Li, 2009) reported a prevalence rate of 30.9%, and indicated the commonality of the problem among Chinese women from different provinces. In Hong Kong, the overall prevalence of women with urinary incontinence has increased from 13% (Brieger, Mongelli, Hin & Chung, 1997) to 52% (Pang et al., 2005) in recent years.

Stress urinary incontinence (SUI) is the most prevalent type of urinary incontinence affecting women in Western (Hunskaar, et al., 2004; Minassian, Drutz & Al-Badr, 2003; Kocak, Okyay, Dundar, Erol & Beser, 2005; Herschorn, et al., 2008) and Eastern countries (Chen et al., 2004; Song, 2005). The prevalence rate of SUI in

China has variously been reported to be 18.5% (Chen, 2004), 16.6% (Song, et al., 2005), and 18.9% (Lan, et al., 2009). In Hong Kong, the prevalence rate of SUI is even higher and has recently risen from 21% (Brieger et al., 1996) to 40.7% (Wong et al., 2006).

The reported prevalence of stress urinary incontinence may have been underestimated. Variation in the reported rates may be a result of the use of different definitions of SUI, different age groups, different rating systems to estimate the prevalence rate, and different methods of data collection. The underestimation of the prevalence rate may also be due to different cultures and beliefs. For example, Chinese women tend to be more conservative, especially in talking about embarrassing problems. Women who are younger may feel more embarrassed and avoid seeking advice about the problem. Women with SUI tend to have lower consultation rates than those with urge or mixed urinary incontinence (Burgio, Ives, Locher, Arena & Kuller, 1994; Seim, Sandvik, Hermstad & Hunskaar, 1995). Unlike other types of urinary incontinence, women with SUI tend to develop coping strategies to reduce the frequency of urine leakage.

Women suffering from SUI may also develop coping strategies. Fearing urine leaks, sufferers may avoid performing physical activities to minimize their occurrence (Radley, 2004). They may also minimize their social contact to avoid embarrassment from this uncontrollable problem. These factors affect the quality of life of SUI sufferers.

The problem may be particularly underestimated among older women. A local survey explored Hong Kong Chinese women's knowledge of urinary incontinence, and found that 60% of women thought that urine leaks were a part of the normal aging process (Wong et al., 2006). Nevertheless, SUI is a common concern for both women sufferers and healthcare providers.

1.3 Integration of traditional Chinese medicine (TCM) and Western medicine

Traditional medicine has been used in many countries, particularly in Asia and Africa, for thousands of years (WHO, 2008) and is increasingly being adopted in other countries. The term "traditional medicine" is interchangeable with the terms "complementary medicine" and "alternative medicine." According to the WHO Traditional Medicine Strategy 2002-2005, the term "traditional medicine" is mainly used in countries in southeast Asia, the western Pacific, Africa, and Latin America, whereas the term "complementary and alternative medicine" is used in countries in Europe, North America, and Australia. Different terms are used because "traditional medicine" is not integrated into the mainstream healthcare system in some countries (WHO, 2002). Given the increasing recognition of the therapeutic effects of traditional Chinese medicine (TCM) as a means of treating various health problems, there is a growing need to link TCM with Western medicine. The WHO (2007) defines this process as the "integration of traditional Chinese and Western medicine' (中西醫結合), and indicates that the relationship needs to be established in a scientific manner.

TCM is well known for its therapeutic effects not only on physical aspects, but on the human body as a whole. However, there is a need for scientific evidence to support its use alongside Western medicine. To promote the evidence-based practice of TCM, the WHO has set up working groups to generate general guidelines for the standardization of the common terms used and methodologies for the evaluation of the outcome effects of TCM treatment.

In general, TCM involves either medication or non-medication interventions. Medication interventions include the use of Chinese herbs, animal parts, and minerals, whereas non-medication interventions include the use of dietary and acupoint intervention. Acupoint interventions are perhaps the most popular nowadays (WHO, 2008). However, there is still a need to support the therapeutic effects of acupoint interventions with scientific evidence.

1.4 Development of evidence-based acupoint interventions

To generate scientific support for the effects of acupoint interventions, the standardization of acupoint locations across countries should be promoted. This will also involve the standardization of the terms used. There are many differences in the taxonomy of acupoints across countries, and some acupoints have several different names. In China, the Acupuncture and Moxibustion Society established a committee for the purpose of standardizing the taxonomy of acupoints. In 1965, the Japan Meridian and Points committee was established to discuss an international

numbering system for acupoints and the Japanese name for each point. Four regional meetings were set up by the WHO regional office for the western Pacific between 1982 and 1989 in Mania, Tokyo, Seoul, and Geneva, respectively, to standardize the taxonomy of acupuncture. In 1991, a Proposed Standard International Acupuncture Nomenclature was published that standardized the location of acupoints and the units used for measuring them. In 1993, a second edition of the Standard Acupuncture Nomenclature was proposed that included alphanumeric codes and the Pinyin and Han characters for acupoints and meridians.

In addition to the standardization of the terms used for acupuncture, general guidelines on clinical research on acupuncture were formulated in June 1994 for the western Pacific by the WHO Regional Office. To facilitate the accumulation of scientific evidence on acupoint interventions, the objective of the guidelines was to provide basic principles and criteria for researchers to monitor and evaluate the effectiveness of acupoint interventions. These clinical guidelines were published in 1995 to help policymakers to develop regulations and determine the allocation of funding for the development of acupoint interventions.

1.5 Integration of acupressure in conventional interventions for Urodynamic Stress Incontinence (USI)

According to the theory of TCM, qi is one of the fundamental substances that circulate round the human body (Ross, 1985). The functions of qi are to facilitate the circulation of air, nutrients, and blood and to serve as a nutritive substance to

maintain the functional activities of the human body (WHO, 2007). To maintain health, qi must remain balanced.

The kidneys are yin organs that store qi in the body (Rothfeld & Levert, 2002). Adequate kidney qi ensures good control of urination and the normal functioning of the bladder. The bladder is yang in nature, and relies on the proper functioning of kidney qi (Rothfeld & Levert, 2002). If kidney qi is unconsolidated, then numerous urinary problems may result, such as increased frequency of urination, dripping after urination, and urinary incontinence (Wu, 1999).

Most kidney syndromes are deficiency conditions (Wu, 1999). According to the theory of TCM, acupoint intervention can balance excesses or deficiencies in the organs (Stux, Berman & Pomeranz, 2003). The application of acupoint intervention can consolidate kidney qi and alleviate the problem of urinary incontinence. The concept of consolidation in TCM refers to the "lifting up" of qi. It is assumed that if the kidney qi is strengthened and the upward flow of qi is ensured, then the condition of descent of the pelvic organs will be alleviated. Continence is then maintained even in the presence of increased intra-abdominal pressure on the bladder.

Among the various acupoint interventions, acupressure is a commonly used intervention for the management of urinary problems (Forem & Shimer, 1999). As it is non-invasive in nature, acupressure intervention may contribute to improving the condition of urine leakage.

1.6 Significance of the study

USI is a distressing problem. The problem not only affects the physical condition but also the psychosocial well-being of women sufferers. With the limited choice of interventions available, more alternative and non-invasive interventions should be examined. The aim of this study is to suggest an alternative and non-invasive intervention for the management of urine leaking that improves the condition and has a positive impact on the quality of life of USI sufferers. Specifically, the study contributes scientific evidence on the effect of acupressure on women with urodynamic stress incontinence.

The findings are then used to examine the application of acupressure in nursing practice. Nurses, as core service providers, have a responsibility to provide effective and client-centred care.

1.7 Aim and objectives of the study

The aims of this study are to determine whether acupressure therapy improves the problem of urine leaking and the quality of life of women with urodynamic stress incontinence. The objectives are to investigate whether acupressure has an effect on (a) pelvic floor muscle strength, (b) urine leakage, and (c) quality of life.

1.8 Organization of the thesis

Chapter 1 is an introductory chapter that states the background, aim, objectives, and significance of the study. Chapter 2 provides a review the mechanism of urinary continence, the pathophysiology of stress urinary incontinence and the predisposing factors that affecting women with stress urinary incontinence. Various evidence-based outcome measures are proposed for the study. Chapter 3 introduces acupressure as a type of TCM intervention for managing problem of urine leakage. It also reviews the gaps in the knowledge about acupressure intervention and sets out the research framework for the study. Chapter 4 discusses the research methods and explains the study design, sample selection, types of instruments, and study protocol used. Chapter 5 reports a pilot study and estimations of effect size. Chapter 6 reports the main results obtained from the study. Chapter 7 presents a detailed discussion of the research findings, with further support from the literature. The limitations of the study are also addressed. Chapter 8 offers some conclusions and states the implications of the findings for nursing practice, the application of acupressure in clinical practice, and the education of women with stress urinary incontinence. Possible directions for future research in this area are also explored.

CHAPTER 2

LITERATURE REVIEW

WESTERN PERSPECTIVE OF STRESS URINARY INCONTINENCE

2.1 Introduction

This chapter tends to provide an overview on the functions of the lower urinary tract system and how the dysfunctions of the system affecting women in maintaining urinary continence. The understanding of the pathophysiology of stress urinary incontinence and the importance in confirming the diagnosis of urodynamic stress incontinence are essential. Studied on the predisposing factors that contribute to the systems of urine leakage and types of outcome measures help to guide the design of study variables in a scientific manner.

2.2 Mechanism of urinary continence in women

The mechanism for maintaining continence is complex. It involves nerves, muscles, supportive tissues, and various parts of the lower urinary tract systems to control the movement of urine in and out of the bladder. An understanding of the anatomy and physiology of the lower urinary tract system is essential to understand how urine is held in the bladder. The lower urinary tract system consists of kidneys, ureters, the bladder, and the urethra. The kidneys remove substances from the blood and excrete

them in the urine. The ureters transport urine from the kidneys to the bladder. The bladder is a hollow, muscular organ. It is located in the pelvis behind the pelvic bone, and consists of the detrusor muscle, which is a smooth muscle that allows the bladder to expand as it fills with urine. The bladder fills at a rate of between 0.5 and 5 milliliter per minute (Hilton, 1995), which results in only a minimal pressure increase. Urine is stored in the bladder before urination and drains out through the urethra, which functions to transport urine from the bladder to outside of the body. The urethra is guided by the urethral sphincter and the surrounding pelvic floor muscles. Urethral structures consist of internal and external urethral sphincters. The internal urethral sphincter is composed of involuntary smooth muscle fibers, whereas the external urethral sphincter is composed of voluntary skeletal muscle fibers. To maintain urine continence in the filling phase, the urethra must be closed by both urethral sphincters (Sand & Ostergard, 1995). Closure of the urethra is maintained by both the passive and active effects of the smooth muscle and skeletal muscle fibers, and by its elasticity and blood supply (Hilton, 1995).

The urethral sphincter also plays a vital role in maintaining urine inside the bladder, especially during increases in abdominal pressure. Pressure on the bladder can be increased through coughing, sneezing, or related physical exertion that compresses the bladder. When this occurs, the urethral closure pressure must be greater than the pressure inside the bladder to keep urine within the bladder (Chapple & Manassero, 2008).

2.2.1 The pelvic fascia

Urethral pressure relies on the interaction of ligaments, fascia, nerves, and the pelvic floor muscles (Hay-Smith et al., 2005). The cardinal and uterosacral ligaments are vertical in shape, and provide support for the pelvic organs. Pelvic organs such as the urethra, vagina, and rectum are also supported by the pelvic fascia. The pelvic fascia is located in the anterior part of the vaginal wall. It consists of parietal and visceral pelvic fascias that extend from the pelvic floor to the thoracic cavity (Koch & Marani, 2007). The parietal pelvic fascia covers the inside of the pelvic walls. The visceral pelvic fascia is formed by extra-peritoneal tissue, and is composed of smooth muscle, collagen, blood vessels, and elastin (Koch & Marani, 2007).

2.2.2 Neurophysiological control of the bladder

Neurological control of the urethra and the pelvic floor must be functional to maintain urinary continence, and the supporting structures of the pelvic floor must be stable (DeLancey, 1997). Neural control of the bladder and the urethral sphincters is also important for the storage of urine in the bladder. The nervous system of the human body comprises the central nervous system and the peripheral nervous system. The hypothalamus of the sympathetic nervous system and other parts of the brain are responsible for the timing of micturition or urination (Vodusek, 2007). The lower urinary tract system receives a message from the brain through the sympathetic and parasympathetic nerves of the autonomic nervous system (Newman, 1999). The main effect of sympathetic and parasympathetic activity in the urinary system is to

contract and relax the sphincter of the bladder. Micturition of urine is thus under the voluntary control of the brainstem in the central nervous system.

The peripheral nervous system consists of parasympathetic, sympathetic, and somatic nerve fibers. The sympathetic nervous system arises from the tenth vertebra of the thorax to the second lumbar vertebra of the thoracolumbar region, whereas the parasympathetic nervous system runs from the second sacral nerve to the fourth sacral nerve of the sacral cord (Fischer et al., 2008). Stimulation of the sympathetic nervous system increases the muscle tone of the urethral sphincters and inhibits urine micturition. Stimulation of the parasympathetic nervous system relaxes the sphincter of the internal urethra, causing the muscle of the bladder wall to contract and micturition to occur.

2.2.3 Neurotransmitters

The parasympathetic nerve fibers release acetylcholine, which stimulates the contraction of the smooth muscle fibers of the bladder through the action of the muscarinic receptors (Chai & Lehrfeld, 2008). The muscarinic receptors consist of M_2 receptors and M_3 receptors, and initiate bladder contraction. The sympathetic nerve fibers release alpha and beta-adrenergic chemical receptors to promote the relaxation of the smooth muscle of the bladder. The inhibition of the muscarinic receptors or stimulation of the beta-adrenergic chemical receptors governs the frequency, urge, and urgency of urinary incontinence (Chai & Lehrfeld, 2008).

2.2.4 Pelvic floor muscles

The pelvic cavity is funnel shaped. The female pelvis is wider than the male pelvis, and the wider diameter of the outlet may create a potential weakness in the pelvic floor (Herschorn, 2004). The anterior side of the pelvis is the pubic symphsis and the posterior side is the sacrum, which is joined to the sacroiliac joints. The lateral sides of the pelvis are the apices of the ischial spines (Fischer, Padmanabhan & Rosenblum, 2008). The pelvic floor is composed of the pelvic diaphragm and the perineal membrane. The perineal membrane is situated over the anterior part of the pelvic outlet, and the pelvic diaphragm is located superiorly to the pelvis (Koch & Marani, 2007). The pelvic diaphragm is composed of the pubococcygeal muscle, levator ani muscle, and coccygeus muscle (Walsh, 2007). The levator ani muscle consists of the puborectalis, pubococcygeus, and illococcygeus muscles. These branch out into the urinary tract and the intestinal tract of the rectum, and provide support to all of the pelvic organs (Bo, 2003). The pelvic floor muscles are controlled by the pudendal nerve in the somatic nervous system, and the sacral nerve roots (Newman, 1999; Fischer, et al., 2008). Damage to the pudendal nerve caused by vaginal delivery was observed in an animal study (Jiang et al., 2009). Other findings suggest that damage to the pudendal nerve during vaginal delivery may be irreversible if the nerve is transected.

Different pelvic floor muscles consist of different types of muscle fiber. The muscles are situated around the genitourinary and rectal canals, and are composed of either Type I or Type II striated muscle fibers. Type I muscle fibers are slow twitch

fibers that are capable of sustaining muscle contractions. Slow twitch fibers are only about half the diameter of fast twitch fibers, but can contract continuously for extended periods (Martini, 1995). Type II muscle fibers are fast twitch fibers that produce strong and quick muscle contractions for sudden changes in intra-abdominal pressure (Herbert, 1998). However, fast twitch fibers use large amounts of adenosine triphosphate (ATP) to produce strong and quick muscle contractions, and thus fatigue easily (Martini, 1995). Contraction of the muscle groups of the pelvic floor causes an inward lifting movement and the squeezing of the pelvic organs (Bo, 2003), which maintains continence.

2.3 Western theories of stress urinary incontinence

2.3.1 Inadequate muscular support

According to Western medical theory, stress urinary incontinence (SUI) in women is due to inadequate muscular support of the pelvic floor. Kegal was the first to suggest in 1949 that symptoms of urine leakage can be decreased by improving the strength of the pelvic floor muscles. To avoid urine leaks under increased intra-abdominal pressure, the structure support in the pelvic must be built up. This can be achieved by strengthening the pelvic floor muscles by increasing the muscle size through exercises. A study by Lexell (1995) that compared the muscle mass of older people and younger people indicated that although the size of type I muscle fibers was more or less the same in the two age groups, type II muscle fibers were much smaller in the older group than in the younger group. A decrease in the size and volume of these fibers increases the accumulation of body fat and connective tissue.

Evans & Grimby (1995) explored muscle performance in the elderly, and found that muscle performance, especially of type II muscle fibers, in the biceps brachii could be maintained with regular physical activity. Hortobágyi et al. (2000) studied changes in muscle strength among 48 men and women who had their knees immobilized for three weeks and then underwent muscle retraining after 12 weeks. They found that immobilizing the muscle groups for three weeks decreased the strength of type I muscles by 13%, and of type IIa and type IIx muscles by 10%. After 12 weeks of muscle retraining, muscle strength increased, with the greatest enlargement being observed in the type IIa and IIx muscle fibers. Tannerstedt, Apro & Blomstrand (2009) studied possible increases in the size of muscles and found that, compared with type I muscle fibers, type II muscle fibers could be increased in size by performing regular resistance exercise. With the increase in muscle size of type II muscle fibers, the pelvic floor muscle can be strengthened.

DeLancey (1994) suggested that the pelvic floor muscles act like a hammock to maintain the position of the pelvic organs, such as the vagina and bladder, to avoid their compression against the urethra. If the avoidance of the compression of the pelvic organs against the urethra is promoted, then urine continence can be maintained despite a sudden increase in intra-abdominal pressure acting on the urethra. Hence, in recent years, the physiological feature of the pelvic floor in maintaining continence has been the main focus of research into urine incontinence (Olsen & Rao, 2001; Abrams, 2005).

2.3.2 Hypermobility of the urethra and deficiency of the intrinsic sphincter or urethral closure mechanism

It has also been suggested that SUI may occur due to the hypermobility of the urethra and deficiencies in the intrinsic sphincter or urethral closure mechanism (Agarwala & Liu, 2002). The major cause of loss of urethra support is the weakening of the pelvic floor muscles. This causes the bladder neck and proximal urethra to descend during increased intra-abdominal pressure, resulting in urine leaks. Another cause of SUI is the deficiency of the intrinsic sphincter, which is associated with a decrease in the innervation of the pudendal nerves (Chapple & Manassero, 2008).

2.4 Predisposing factors contributing to SUI

Various predisposing factors affect the anatomy and physiology of the lower urinary tract system of women that may result in SUI. The most common predisposing factors that have been linked to SUI are mode of delivery in childbirth, number of childbirths, and a high body mass index before pregnancy.

2.4.1 Mode of delivery

Vaginal delivery is the most common cause of nerve damage to the pelvic floor muscles. Up to 20% of women develop incontinence after vaginal delivery (Wilson, Herbison & Herbison, 1996), and 30% of women experience symptoms of SUI in the five years after giving birth to their first child (Viktrup & Lose, 2001). During the process of vaginal birth, damage can occur to structures such as the pudendal nerve, the caudal aspects of the levator ani muscle, the fascial pelvic organ supports, and

the internal and external anal sphincters (Dietz & Schierlitz, 2005). Compared with women who have a cesarean delivery, the bladder neck is significantly lower in women undergoing vaginal delivery (Peschers, Gingelmaire, Leib & Dimpfl, 2001).

2.4.2 Parity

The incidence of developing SUI in primiparous women is relatively higher than in nulliparous women (Groutz et al., 1999; Person, Wolner-Hanssen & Rydhstroem, 2000; Song, 2004, Minassian, Stewart & Wood, 2008). This may be due to an increase in intra-abdominal pressure during pregnancy, which induces urine leaks. However, other studies have found that urine leakage also occurs in healthy nulliparous women (Hagglund, Olsson & Lappert, 1999; Lightner & Itano, 1999) and before pregnancy (Wilson et al., 1996).

Another study by Rortveit, Hannestand, Daltveit & Hunskaar (2001) found that the association between SUI and parity was stronger among younger than older women. The results indicated that women who had given birth to their first baby between the ages of 20 to 34 years old were more likely to develop SUI later in life.

Other studies have explored the anatomical changes in women with and without pregnancy experience, but the findings are contradictory. DeLancey et al. (2007) investigated anatomical defects in 240 continent women before pregnancy and between 9 to 12 months postpartum. The results indicated that all of the nulliparous women had an intact levator ani muscle. The appearance of the levator ani muscle

and urethral closure pressure differed between primiparous women with and without SUI, with incontinent primiparous women having significantly lower urethral closure pressure and twice as many as visible defects in the levator ani muscle than continent primiparous women. This finding indicates that anatomical damage may be the risk factor for women, rather than parity in isolation. Further studies are, however, needed to explore the link between perineal trauma and the risk of SUI.

2.4.3 Body mass index

An increased body mass index (BMI) before pregnancy has been found to be associated with an increased risk of developing SUI in postpartum women (Wilson et al., 1996). A high BMI is also a common risk factor generally for women with urinary incontinence, including SUI (Brown, Grady, Ouslander, Herzog, Varner & Postner, 1999; Person et al., 2000; Huang et al., 2006, Minassian, Stewart & Wood, 2008).

Most studies define being overweight as a BMI of greater than or equal to 25 kg/m^2 and obesity as a BMI of more than or equal to 30 kg/m^2. A study (Huang et al., 2006) comparing Asian women with white women to identify the risk factors for stress and urge urinary incontinence used the same standard and scale to define BMI and being overweight for both ethnic groups. However, it may not be appropriate to use the same cut-off points for Western women and Asian women. According to the WHO (2000a), different standards and scales should be used to define being overweight in Asians.

2.5 Western diagnosis of USI

2.5.1 Clinical symptoms

The term "stress urinary incontinence" has been standardized by the International Continence Society (ICS) as referring to "the complaint of involuntary leakage on effort or exertion, or on sneezing or coughing" (Abrams et al., 2003, p. 38). Under normal circumstances, intra-abdominal pressure increases during physical exertion. As long as the pelvic floor muscles are strong and intact, urine will be retained inside the bladder. However, if these muscles are weak or defective, then urine leaks may occur during physical exertion.

SUI is often reported in terms of symptoms (Abrams et al., 2003). Women often self-report the occurrence of urine leaks when they cough or sneeze. However, SUI can also be reported in terms of signs observed by practitioners through examination, which include the "observation of involuntary leakage from the urethra, synchronous with exertion/effort, or sneezing of coughing" (Abrams et al., 2003, p. 42).

2.5.2 Urodynamic findings

SUI can also be reported in terms of urodynamic diagnosis, under which it is defined as the "involuntary leakage of urine during increased abdominal pressure, in the absence of a detrusor contraction" (Abrams et al., 2003, p. 45). In 2003, the ICS identified "urodynamic stress incontinence" as the preferred term to describe women who suffer involuntary urine leaks during increased abdominal pressure but with no contraction of the detrusor muscle during urodynamic observation.

Some women have mixed symptoms of urinary incontinence, and thus practitioners may not be able to make a correct diagnosis based solely on symptoms. On the other hand, some women report a mix of symptoms but are deemed after observation to have stress urinary incontinence only (Weidner, Myers, Visco, Cundiff & Bump, 2001). As USI is due to the hypermobility of the urethra with or without the present of intrinsic sphincter deficiency (Chapple & Manassero, 2008), urodynamic observations allow the diagnosis to be confirmed and appropriate interventions to be prescribed (Versi, Cardozo, Anand & Cooper, 1991). According to the ICS, abdominal leak point pressure refers to the "intravesical pressure at which urine leakage occurs due to increased abdominal pressure in the absence of a detrusor contraction" (Abrams et al., 2003, p. 45). During urodynamic observation, the intravesical pressure of women with USI should be higher than the maximum urethral pressure observed.

2.6 Conservative interventions for USI

2.6.1 Surgical intervention

Surgical intervention and lower urinary tract rehabilitation are the conventional interventions for managing urodynamic stress incontinence. Lower urinary tract rehabilitation refers mainly to pelvic floor training, biofeedback, and behavioral modification (Abrams et al., 2003).

Surgical interventions such as Burch colposuspension and the vaginal sling procedure are the most common types of surgery, and aim to elevate the bladder

neck and to improve anatomical deficient of urethral sphincter (Chapple & MacDiarmid, 2000). Although studies have reported the cure rates of these treatments to be about 78-84%, their complication rate is 20% (Sarkar & Ritch, 2000). About 30% of women receiving such surgery require another operation (DeLancey, 2005). Complications may arise due to the adverse effects of analgesic drugs or the nature of the surgery. Other potential complications, such as infection, obstruction of the urinary tract, and bladder perforation, may also occur, often resulting in the need for reoperation. Complications arising from these surgical procedures (Jarvis, 1994; Sarkar & Ritch, 2000, Holmgren, Nilsson, lanner & Hellberg, 2005) and the reoperation rate (Holmgren et al., 2005) are major concerns for women with SUI. A study in Hong Kong explored the treatment-seeking behavior of women with urinary incontinence and found that the majority of those interviewed were reluctant to seek surgery, and rated this as the last option (Wong et al., 2006). Clearly, the adverse effects of surgical intervention cause women to avoid surgery. This has lead to the search for less invasive interventions.

2.6.2 Lower urinary tract rehabilitation

Lower urinary tract rehabilitation is the collective name for non-invasive treatments such as behavioral modification, biofeedback, and pelvic floor training (Abrams et al., 2003). A systematic review by Berghmans et al. (1998) on randomized clinical trials of lower urinary tract rehabilitation among women with SUI concluded that, of the 24 studies meeting the criteria for their review, 22 focused on intervention trials and only two were prevention trials. Most of the lower urinary tract rehabilitation in

these trials focused on the efficacy of pelvic floor training with or without other interventions.

According to the ICS, pelvic floor training refers to the training of the pelvic floor muscles with a series of relax and contract movements (Abrams et al., 2003, p. 48). Other interventions included electrical stimulation, vaginal cones, and biofeedback. The review concluded that pelvic floor training alone may be an effective intervention for women with SUI, with an efficacy rate and satisfaction rate of between 60 and 70%. However, as there was no standardized program of pelvic floor training to compare among the studies reviewed, the results are inconclusive.

Another study by Wyman, Fantl, McClish & Bump (1998) compared three interventions among women with USI and detrusor instability. One group underwent bladder training, one group was assigned pelvic floor training along with a biofeedback device, and the third group underwent a combination of bladder training and pelvic floor training with a biofeedback device. Women with USI and detrusor instability in the third group experienced an immediate significant effect, and reported decreased distress from symptoms. A greater improvement in quality of life was observed in the women with USI. However, although there was a significant immediate effect of the adjunct interventions, no different was observed after three months. The efficacy of the intervention was not sustained. The results further indicated that pelvic floor training was better than no intervention or placebo intervention for women with SUI, but it was difficult to determine whether it was

better than the other interventions (Hay-Smith et al., 2003). Evidence on the efficacy and sustainability of the effect of conservative interventions thus remains inconclusive.

2.7 Types of outcome measures

Measurement of the effectiveness of an intervention should include both subjective and objective measures (Lalos, Berglund & Lalos, 2001). Both the physical and psychosocial well-being of women with urodynamic stress incontinence must be taken into consideration. Some clinical outcome measurements have been suggested based on the recommendations of the ICS, including severity and frequency of urine leaks, and impact on quality of life (Abrams et al., 2003). The ICS suggests measuring severity and frequency with frequency volume charts. Other objective outcome measurements can be obtained through a one-hour pad test. Pelvic floor muscle strength should also be measured.

2.7.1 Pelvic floor muscle strength

Two methods are commonly used to evaluate the strength of the pelvic floor muscles in a clinical setting: digital muscle testing (Miller, Ashton-Miller & DeLancey, 1998; Castro et al, 2008), and manual muscle testing (Bo et al., 1999; Yoon, Song, Ro, 2003). These have been employed to test changes in pelvic floor muscle strength before and after surgical interventions and lower urinary function rehabilitation. Both techniques can be performed on men and women. Pelvic floor muscle strength in men can be measured through the rectum and in women through the vagina.

Digital muscle testing scores pelvic floor muscle strength based on the six-point modified Oxford Scale (Laycock & Jerwood, 2000). Muscle strength is graded as no contraction, flicker, weak, moderate with lift, or good with lift. The scoring relies on the experience of practitioners during digital palpation. The second method is manual muscle testing, which scores pelvic floor muscle strength based on perineometric readings that allow the visualization of pressure through vaginal or rectal squeezing. Digital palpation requires no equipment except for the gloved finger of the practitioner, whereas the manual method requires a perineometer. Digital muscle testing is thus more convenient than manual muscle testing.

A study was conducted to compare the measurement of pelvic floor muscle strength by various techniques, including digital palpation, perineometer, perineal ultrasound, and intravaginal electromyography (EMG). Sixteen subjects aged between 27 and 33 years old performed the same set of pelvic floor muscle contractions. One subject was unable to contract her pelvic floor muscles and another could not activate the right muscle groups, and both were thus excluded from the study. The results indicated that intravaginal EMG and perineometer are the best methods for assessing pelvic floor muscle strength (Peschers et al., 2001). EMG can be used to record the bioelectrical activity produced by the pelvic floor muscle fibers with intra-vaginal probes (Hodges, Sapsford & Pengel, 2007). Compared with perineometer, intravaginal EMG requires sophisticated equipment. Perineometer is thus a more accessible means of evaluating pelvic floor muscle strength. As the measurement of

pelvic floor muscle strengths through the rectum may be confounded by the contraction of the anal sphincter and most women have a better sense of the contraction of the pelvic floor muscles through the vagina (Bo & Sherburn, 2007), vaginal squeeze pressure with the use of perineometer is the outcome measure of pelvic floor muscle strength used in this study.

2.7.2 One -hour pad test

Lack of consistency in the outcome measures for urinary incontinence was observed in the literature review. In terms of the primary outcomes of interest in this review, only four of the included trials (Joseph & Chang, 2000; Mathewson-Chapman, 1997; Moore, 1999; Moore, 2004) reported the results of the standardized pad test (grams of urine lost in a 1-, 4-, or 24-hour test). Two other authors (Franke et al, 1998; Opsomer, Castille, Abi Aad & van Cangh, 1994) reported using a pad test, but the data were not reported or were incomplete. Moore (1999) and van Kampen (1998) set different limits for incontinence (2 grams versus less than 1 gram). Bladder or voiding diaries recording patient-reported symptoms of incontinence (the second primary outcome of interest in this review) were used in seven of the trials (Bales, 2000; Franke et al., 1998; Mathewson-Chapman, 1997; Moore, 1999; Parekh et al., 2003; Porru e al., 2001; van Kampen, 1998).

Inconsistency in defining the effect of interventions by means of the one-hour pad test was observed. Different interpretations of one-hour pad weight gain were found in intervention studies on managing SUI in women. The major difference was in the

interpretation of the categories "cure" or "effective" based on pad weight in grams. Some studies interpreted the pad test as negative if the one-hour pad gain was less than or equal to two grams after surgical intervention (Andonian, 2005; Tseng, Wang, Lin, Li & Ko, 2005; Lord et al., 2006; Zhu & Lang, 2007) and pelvic floor muscle training (Versi & Harvey, 1998; Morkved et al., 2002; Dumoulin et al., 2004; Castro et al., 2008; de Oliveira Camargo et al., 2009). Other studies interpreted the pad test as negative if the one-hour pad gain was less than or equal to one gram (Glavind, Nohr & Walter, 1996; Glavind, Laursen & Jaquet, 1998; Yalcin, Hassa & Ozalp, 2000). This difference may have led to the over-estimation of the effect of interventions for SUI.

According to the recommendations of the ICS, the one-hour pad test can be considered an objective measurement to quantify urine lost (Abrams et al., 1988). As a loss of less than one gram over an hour may be due to potential experimental error, such as sweat, vaginal discharge, or even menstruation, the Society suggests that a pad gain of more than one gram only should be considered a positive result. If the pad gains less than or equal to one gram, then the result should be considered negative. A negative pad test indicates that the intervention has been effective.

2.7.3 Self-reported severity of urine leakage

A number of studies have reported an association between self-reported severity of urine leakage and quality of life impairment (Chiaffarino, Parazzini, Favezzari & Giambanco, 2003; Simeonova et al., 1999; Temml et al., 2000; Wong et al., 2006).

Women who suffer from SUI know themselves best. Abdel-fattah et al. (2004) suggested that the self-reported severity of urine leakage measured in their study was as good as the result obtained from a one-hour pad test with the participants scoring their quality of life. The sensitivity of the self-rated severity of incontinence measure was 95.65%, the specificity was 93.33%, the positive predictive value was 97.34%, and the negative predictive value was 89.36% (Abdel-fattah et al., 2004). The self-reported severity of urine leakage (continent/incontinent) measure was also strongly correlated with the result of the pad test (negative/positive). The self-reported severity of urine leakage was measured on a four-point Likert scale where 0 = total continent to urine; 1 = mild or occasional urinary incontinent (UI); 2 = moderate UI; and 3 = severe UI.

2.7.4 Number of episodes of urine leakage

Episodes of urine leakage are another parameter that can be used to assess the severity of urine leakage. Robinson et al. (2003) studied the perceptions of women of the meaning of "cure" in relation to their symptoms of urine leakage after intervention. The majority of women studied stated that frequent episodes of urine leakage were unacceptable. Forty-three percent expected a good improvement in their symptoms for the negative impact of SUI on their quality of life to be reduced. Episodes of urine leakage can be measured with a frequency volume chart. The duration of collecting records of episodes of urine leakage is an important issue. A minimum of three days is recommended for an effective outcome measure (Lose et al., 1998). However, there is some variation in the literature between three days (Bo,

Talseth & Holme, 1999), four days (Schick, Jolivet-tremblay, Dupont, Bertand & Tessier, 2003), and seven days (Dmochowski et al., 2005). A study examining the accuracy of the measurement of episodes of urine leakage over three days compared with measurement over seven days among men and women with urinary incontinence (Dmochowski et al., 2005) found that that the two durations gave equal accuracy. However, compliance with record keeping was better for the three-day measure. Another study suggested that the collection of four days of records was as reliable as the collection of seven days of records in accurately assessing the number of episodes of urine leakage (Schick et al., 2003). The mean number of episodes of urine leakage over four days is thus used in this study to assess the frequency of urine leakage.

2.7.5 Condition-specific quality of life

The impact of quality of life is an important outcome measure for evaluating the effects of interventions for SUI. The feelings of embarrassment caused by the health problem may induce emotional distress, which can result in depression (Dugan et al., 2000; Wong et al., 2006). Studies report that emotional responses to urinary incontinence include feeling anxious, lower self-esteem, and feeling socially isolated (Grimby, Milsom, Molander, Wiklund & Ekelund, 1993; Lin & Dougherty, 2003; Radley, 2004).

Improvement in quality of life is a good indicator of the effect of an intervention for urinary incontinence. A survey conducted by Tincello & Alfirevic (2002) on the

most important outcomes for surgical interventions for SUI suggested that the subjective ratings of both healthcare providers and patients of cure and improvement in quality of life are important indicators for evaluating the effects of an intervention.

A similar observation was made in a study in Hong Kong on the inadequacy of measuring the impact of urinary incontinence on quality of life (Leung, Pang &Yip, 2003). The study examined the impact of SUI on the quality of life of aging women with SUI and detrusor instability using Short-Form Health Survey (SF-36), a generic quality of life questionnaire that use to measure self-perceived of general health status. The results indicated that the items of the SF-36 were unable to detect differences in impact on quality of life between the two groups. Clearly, generic quality of life questionnaires are not sensitive enough for use among people with urinary incontinence.

There are several condition-specific questionnaires designed to measure the impact of urinary incontinence on quality of life. The Urogenital Distresses Inventory (UDI); Incontinence Impact Questionnaire (IIQ), Bristol Female Lower Urinary Tract System Questionnaire (BFLUTS), Quality of Life Measure Specific to Urinary Incontinence (I-QoL), and King's Health Questionnaire (KHQ) are the most commonly used self-administered questionnaires for women with urinary incontinence.

The UDI and the IIQ were designed to be used in conjunction with one another (Shumaker, Wyman, Uebersax, McClish & Fantl, 1994). The UDI consists of 19 items that measure the troublesomeness of symptoms of lower urinary tract dysfunction in women. The IIQ consists of 30 items that measure how urinary incontinence affects daily activities. Psychometric analysis indicates that the latter has a strong sensitivity. The questionnaire is designed for use among women with SUI and urge incontinence. The face validity, construct validity, and criterion validity are r = 0.54, with an effect size of 1.31 SD difference between the group means. In terms of internal consistency, the questionnaire has a Cronbach's alpha coefficient ranging from 0.48 to 0.90, and a test-retest reliability ranging from 0.52 to 0.70 with a total score of 0.71 (Wyman et al., 1998).

The BFLUTS was developed to measure symptoms in the lower urinary tract (Jackson et al., 1996). It comprises 33 questions. Twelve items address symptoms, eight items address urinary incontinence, nine items address the effect on quality of life, and four items are related to sexual function. The discriminant validity of the questionnaire was compared between women with no clinical symptoms of urinary incontinence and women with symptoms of urinary incontinence for 17 out of 20 items on symptoms. The internal consistency (Cronbach's alpha) of the overall instrument was 0.78, and the test-retest reliability ranged from 0.76 to 0.93 with a total score 0.86. Psychometric analysis confirmed the validity and reliability of the questionnaire.

The I-QoL was developed to measure all types of urinary incontinence in men and women (Wagner, Patrick, Bavendam, Martin & Buesching, 1996). It comprises 22 questions. The original questionnaire consisted of 28 items, but six were removed due to low correlation and ceiling effects. The discriminant validity of the instrument was confirmed by the severity of incontinence and number of medical visits to treat urinary incontinence in the previous year. The convergent validity of the I-QoL was confirmed against the SF-36 in the common domains. The internal consistency (Cronbach's alpha) was 0.95, and the test-retest reliability was 0.93. The questionnaire is thus a valid and reliable measure for different types of urinary incontinence.

The King's Health Questionnaire (KHQ) was first validated among women with urinary incontinence symptoms (Kelleher, Cardozo, Khullar & Salvatore, 1997). It comprises 21 questions in domains including general health, the impact of incontinence, personal relations, physical limitations, role limitations, emotional health, sleep and energy disturbance, and severity of urinary incontinence. The criterion validity of the KHQ was tested against the SF-36, and Spearman's rho nonparametric correlation coefficients were used to correlate the results of the two questionnaires in the common domains. The correlation coefficient ranged from 0.80 to 0.96 in all domains, indicating a significant correlation between the common domain scores for the two questionnaires. The internal consistency of the KHQ was measured by Cronbach's alpha coefficient, which ranged from 0.73 to 0.89 in all

domains. Psychometric analysis confirmed the validity and reliability of the questionnaire.

In summary, all of the aforementioned condition-specific questionnaires have been proved to be valid and reliable in measuring the quality of life of women with different types of urinary incontinence. However, the UDI and IIQ are too lengthy to use to evaluate the quality of life of women with urodynamic SUI. BFLUTS consists of a comprehensive list of symptoms. Of the 33 items, 19 items focus on the impact of urinary symptoms of all types of urinary incontinence, which should give an exhaustive list of symptoms for measuring USI. The KHQ is comparatively easy to use and the domains that are measured are correlated with those in other quality of life questionnaires. The KHQ has been used in different countries and has been translated into various languages. A study by Leung & Yip (2001) reported the use of the KHQ to measure the impact on the quality of life of women with urinary incontinence, but there is no mention in the literature on the psychometric testing of the Chinese version of the KHQ.

CHAPTER 3

LITERATURE REVIEW

EASTERN PERSPECTIVE OF STRESS URINARY INCONTINENCE

3.1 Introduction

This chapter introduce the theoretical and philosophical principles of TCM in restoring health in the body as a whole. TCM comprises of the theories of qi, yin and yang, viscera and bowels and meridians. These theories guide the principle of acupressure intervention in managing USI. The focus of the study is the effect of acupressure intervention on improving urine leakage, history of the development of acupressure, the basic principles of the application of acupressure are included. Gaps in the knowledge in this area are identified through a literature review of existing acupoint interventions for stress urinary incontinence. The process for researching the application of acupressure for women with urodynamic stress incontinence is then developed.

3.2 TCM view of SUI

In TCM, urinary incontinence is seen as a manifestation of a syndrome or pattern (證), rather than a disease. Deficiencies in kidney qi or spleen qi and sinking qi in the triple energizer are the ancient Chinese way of viewing urinary incontinence.

Poor reservation of kidney qi (Teeguarden, 1996; Wu, 1999 and Forem & Shimer, 1999) and dysfunction of the urinary bladder (Wu, 1999) may also lead to urinary incontinence. Weakened spleen qi may lead to a decrease in muscle tone (Forem & Shimer, 1999). To understand the manifestation of such syndromes, it is necessary to understand the philosophy behind TCM.

According to the philosophy of TCM, the restoration of health aims not only to alleviate physical symptoms, but also to restore the harmony of the whole body. The harmonization of the body rests on the balancing of yin and yang, the flow of qi, and the functional aspects of the viscera and bowels. If the harmonization of the body is disturbed, then syndromes such as SUI may result.

3.2.1 TCM theories

The basic theories of TCM include yin-yang theory (陰陽學說), the essential nature of qi (精氣學說), and the visceral manifestation theory (臟象學說). The terms used in this study are based on the terminology of tradition medicine as standardized by the WHO (2007).

3.2.2 Yin-yang (陰陽)

Yin and yang are the two opposites in nature (WHO, 2007). The main concept of the theory of yin-yang is the equilibrium of these two opposites. To maintain health, they must be in a balanced state. If yin and yang are not balanced, then the flow of

qi in the viscera may be affected, which may affect the functioning of the viscera. Syndromes of excess or deficiency may then occur.

3.2.3 Qi (氣)

Qi is the substance that maintains the functioning of the viscera and the activity of the body. It is a fundamental substance that circulates through the human body carrying air, nutrients, and blood (Ross, 1985). Qi is classified as either "innate qi" or "acquired qi" (WHO, 2007). We are born with qi that is stored in the kidney. This is "innate qi" (先天之氣). Qi can also be generated from fresh air and the food we eat after we are born. This is "acquired qi" (後天之氣). Qi can have a yin or yang aspect, known as yang qi (陽氣) and yin qi (陰氣). Qi is relatively more yang in nature (Wu, 1999). To main health, qi must be kept balanced and harmonious. The problems of the body can be eliminated if the circulation of qi is improved.

Qi circulates between the viscera and bowels through meridians in various directions: "upward, downward, inward, and outward" (升降出入) (WHO, 2007, p. 20). The balance between the viscera and bowels can be enhanced by the basic motions of qi. Meridians are related to particular parts of the viscera and bowels. There are fourteen meridians including twelve regular meridians and two extraordinary meridians (WHO, 2007). The twelve regular meridians are identical on both sides of the body, resulting in twenty-four separate pathways. Six pairs run over the arm and into the trunk, and another six pairs run up and down the legs and into the trunk

(Forem & Shimer, 1999). If the circulation of qi is disturbed, then the functions of the viscera and bowels may be affected (Li, 2007).

3.2.4 Viscera and bowels (臟腑)

Viscera and bowels refer to the internal organs of the body. There are five viscera (五臟) and six bowels (六腑) in the human body. The five viscera are the heart, liver, spleen, lungs, and kidneys. The bowels are the gallbladder, stomach, large intestine, small intestine, urinary bladder, and triple energizers. The viscera are yin in nature, and store vital substances such as qi, blood, essence, and body fluids from the bowels. The bowels are yang in nature, and are responsible for extracting the essences from food and drink (Su, 2005).

In TCM, the functions of the viscera and bowels are not considered to be the same as is in Western medicine. Qi is formed and stored in the viscera, whereas food is "received, digested and transported" in the bowel (WHO, 2007, p. 22). Triple energizer (三焦) is a general term used to describe the three portions of the body cavity, upper, middle and lower energizers. The upper energizer refers to the body cavity above the diaphragm, the middle energizer refers to the body cavity from the diaphragm to the umbilicus and the lower energizer refers to the lower part of the body cavity below the umbilicus (WHO, 2007). The main function of the triple energizer is to allow qi and body fluids circulate in the entire body (Xu, 2001).

The kidney is the partner organ of the urinary bladder. In TCM, the function of the kidney corresponds to the adrenal and endocrine glands, and influences the sexual organs of the human body (Omura, 2003). The function of the urinary bladder is to store and excrete urine from the body, and it corresponds to the genitourinary system as a whole (Omura, 2003). The genitourinary system encompasses the urinary bladder, urethra, ureter, and kidney. To maintain its function, the urinary bladder relies on the transformation of qi in the kidneys. This is called "bladder qi transformation" (膀胱氣化) (WHO, 2007).

Adequate kidney qi ensures good control of urination (Wu, 1999). If kidney qi is weakened, the functioning of the kidneys will be deficient. According to the standard terminology of the WHO (2007), kidney qi insecurity pattern/syndrome (腎氣不固證) is the term used to refer to the dysfunction of kidney qi. As the urinary bladder and the kidneys have a partner relationship, unconsolidated kidney qi may affect the urinary bladder, resulting in dysfunction. Pain in the lower back and weakness in the knees, frequent urination, and urinary incontinence are manifestations of urinary bladder problems caused by a deficiency in kidney qi (Xu, 2001).

3.3 Diagnosing SUI in TCM

In TCM, practitioners recommend intervention based on the identification of pattern/syndromes. The method of analysis used is known as "pattern identification/syndrome differentiation and treatment" (辨證論治) (WHO, 2007). A

pattern/syndrome is confirmed by the nature, cause, chief symptoms, and the pathogenic factors of the health problem (Wu, 1999). There are eight principles of identifying pattern/syndromes such as yin or yang, excess or deficiency, hot or cold, and internal or external.

Internal syndromes are problems that affect the viscera, skin, and muscles, whereas external syndromes are problems that involve the superficial muscles or connective tissue. Deficiencies are problems that exist because of a decrease in the movement of substances, and can be alleviated by applying heat or pressure. Excesses are problems that exist because of the constant movement of substances, and can be alleviated by decreasing this movement. Cold problems are caused by a cold constitution, whereas hot problems are caused by heat intolerance (Rothfeld & Levert, 2002).

The method of Cold-Heat Pattern Identification (寒熱辨證) is a strategy for differentiating pattern/syndromes proposed by Zhang Zhongjing in the Han dynasty. With this method, the symptoms of a disease are categorized as heat pattern (熱證) or cold pattern (寒證). Heat pattern/syndromes are caused by external heat pathogens or an excess of yang qi, whereas cold pattern/syndromes are caused by external cold pathogens or a deficiency of yang in the body (WHO, 2007).

Urinary incontinence is primarily due to kidney yang deficiency. A deficiency in qi can cause cold pattern. As one of the functions of qi is to warm up fluid in the body,

cold cannot be transformed to heat if there is insufficient yang qi. Cold pattern may then result, the clinical symptoms of which include clear, thin body fluids and clear, profuse urine. Loose stools may be observed if the spleen qi has also been affected (Xu, 2001).

3.4 Principles of intervention for managing SUI in TCM

According to TCM theory, urinary incontinence is primarily due to a deficiency in kidney qi (Forem & Shimer, 1999). Deficiency refers to a decrease in the movement of substances, which can be promoted by applying heat or pressure (Rothfeld & Levert, 2002). However, the hyper-functioning of qi can induce a deficiency in yin, which results in heat syndromes (Xu, 2001). Heat should not be applied in this circumstance. To ensure the appropriate method of acupressure for women with SUI, differentiation must be made between cold and heat patterns.

3.5 Clinical effect of the application of acupoint interventions for urinary incontinence

To understand the therapeutic effects of acupoint interventions to manage the symptoms of urinary incontinence, a literature review was conducted. Literature was searched using various computerized databases and manual searching. The databases searched included BIOMED (encompassing Medline from 1966 to 2009 and CINAHL from 1982 to 2009) and the Cochrane Central Register of Controlled Trials in the Cochrane Library Database. As this study examines TCM interventions, the literature search was extended to papers published in Chinese. Journals

published in Chinese were searched through the China Academic Journals full-text database. The keywords used for the database searches included: urinary incontinence, stress incontinence, acupressure, acupuncture, acupuncture points, electro-acupuncture.

Thirty-two publications were identified relating to urinary incontinence and acupoint interventions. One of these was a review of the use of acupuncture to treat urgency incontinence (O'Dell, 2006), and another briefly reported a pilot study conducted to evaluate the effects of a specially designed acupoint with magnets on specific acupoints instead of using needles to treat various types of urinary incontinence (O'Neill & Vines, 2004). However, there was no mention of the acupoints used, the course of the intervention, or its duration. The subjective improvement rate ranged from 95 to 100%, but three out of the 22 participants rated a less than 50% improvement. There was neither mention of the criteria for subjective measurement nor any objective outcome measurement to evaluate the acupoints.

3.5.1 Different conditions related to urinary incontinence

Most of the publications were written in Chinese. Different definitions were used to report acupoint interventions to treat urinary incontinence. Most of the studies were based on symptoms, but some were based on chronic conditions or age groups. Depending on the physiological causes, different clinical symptoms of urinary incontinence such as urge incontinence (Liu, et al., 2001; Ha, Chen, Fu, Zhou, Sun & Zhang, 2004; Liu, Peng & Ma, 2006), overflow (Lam, 1994; Cheng, Wong & Chang,

1998; Honjo, Naya, Ukimura, Kojima & Mik, 2000; Yang, Liu & Liu, 2003), functional incontinence (Bao, 1994; Choi, 2001), stress (Zheng et al., 1990; Zhang & Gao, 1999; Mi & Chen, 2003; Qin et al., 2004; Yang, 2004; Zhang & Yan, 2004; Kin et al., 2009), overactive bladder (Emmons & Otto, 2005), and nocturnal enuresis (Lu, 2002; Ellis, Briggs & Dowson, 1990; Ma, Li &Wang, 1998; Zhang & Lu, 2002) were treated with acupoint interventions. Several papers reported results based on age group, including children (Chow, 1994; Hao & Wang, 1994) and the elderly (Liu, Shao, Ye, Li, Huang, Zhang & Liu, 1998; Kang, 1994). Some of the papers reported results according to clinical condition, such as cerebral vascular accident (Liu & Li, 1995; Kao, 1996; Sun & Sun, 2007), cerebral apoplexy (Zhang, Xu & Dong, 1996), diabetes mellitus (Wang & Jie, 1994), and postpartum (Wu, 1994).

3.5.2 Types of acupoint intervention

There are different options of acupoint interventions for the management of urinary incontinence. Most of the interventions reported in the literature involve acupuncture (Ellis et al., 1990; Zheng et al., 1990; Bao, 1994; Chow, 1994; Lam, 1994; Wu, 1994; Kao, 1996; Zhang et al., 1996; Cheng, Wong & Chang, 1998; Honjo et al., 2000; Lu, 2002; Zhang & Lu, 2002; Mi & Chen, 2003; Emmons & Otto, 2005; Sun & Sun, 2007). Some of the studies used acupuncture with electrical stimulation (Liu et al., 1998; Liu et al., 2001; Yang et al., 2003; Ha et al., 2004; Liu et al., 2006), Teding Dianchibo Pu (TDP) lamp (Lau & Li, 1995); acupressure (Choi, 2001), moxibustion (Ma et al., 1998), TCM injection (Wang & Jie, 1994), or pelvic

floor training (Mi & Chen, 2003). Acupuncture was also used in combination with the use of moxibustion and TDP (Yang, 2004) or TCM (Qin et al., 2004). Other acupoint interventions reported included moxibustion only (Kang, 1994) or with acupressure (Hao & Wang, 1994), acupoint injection (Zhang & Gao, 1999), or acupoint thread-embedding with pelvic floor training (Zhang & Lu, 2004).

3.5.3 Acupoint interventions for SUI

Seven out of the 32 studies used acupoint interventions for stress urinary incontinence (Zheng et al., 1990; Zhang & Gao, 1999; Mi & Chen, 2003; Qin et al., 2004; Yang, 2004; Zhang & Yan, 2004; Kim, Nam, Park, Lee & Kim, 2008). One used hand acupuncture (Kim et al, 2009). As hand acupuncture is based on the Korean system of identifying acupoints on the hands, which is different from that used on acupoints on the body (Rothfeld & Levert, 2002) the study could not be compared with the other studies.

All of the studies recruited women as the target population, except for one (Zhang & Lu, 2004) that recruited two men. The age of the women studied ranged from 22 to 82 years old. In the uncontrolled studies, the sample size ranged from 24 to 36, whereas in the randomized control trials, the sample size ranged from 50 to 240. There was no mention of an estimation of effect size in any of the studies. Five of the studies reported the diagnostic methods used (Qin et al., 2004).

Four of the studies adopted acupuncture as an acupoint intervention for stress incontinence. Of these four studies, one adopted acupuncture only (Zheng, et al., 1990), one used acupuncture with pelvic floor training (Mi & Chen, 2003), one used acupuncture with moxibustion and TCM (Qin et al., 2004), and one used acupuncture with moxibustion and TDP (Yang, 2004). Another two studies used acupoints for injection (Zhang & Gao, 1999) or thread embedding and pelvic floor training (Zhang & Lu, 2004). However, as these studies used different intervention modalities, they could not be directly compared.

In terms of outcome measures, all of the studies reported the effects of the intervention in a subjective manner. Although some mentioned the use of objective outcome measures such as urodynamic studies (Zheng et al., 1990; Zhang & Lu, 2004) or pad tests (Mi & Chen, 2003), there was no description of the outcome measurement nor any protocol as to how the measurements were taken. It was thus impossible to compare the findings of the studies (see Table 3.1).

Table 3.1 Effects of acupoint interventions for SUI

Study	Study method	N	Age/gender	Intervention	Outcome measure	Effect rate		Result
						Immediate	Follow up	
Zheng et al (1990)	RCT	N = 60 study: 34 placebo:26	Age range: 22-75 mean: 55.6	acupuncture vs oral placebo	Subjective and objective	88 %	1 year (n=10) 75%	Markedly effective (n=10) effective (n=20); ineffective (n = 4) Control group: effective: (n= 6) ineffective (n = 20)
Zhang & Gao 1999)	Uncontrolled study	N = 24	Age range: 40-78 Mean: 54	Acupoint injection	Subjective	100%	1/2 year 100%	once (n = 10) two times (n = 8) three times (n = 6)
Mi & Chen (2003)	Uncontrolled study	N = 36	Age range: 28 – 60 Mean: 40.6	Acupuncture and pelvic floor training	Subjective and objective	80.6%	1 year (n =1) 100%	Cure (n = 8) Improved (n = 21) Ineffective (n = 7)
Yang (2004)	RCT	N = 50 Study: 30 Control: 20 Men (n =2)	Age range: 38 - 82	Acupuncture + moxibustion + TDP vs acupuncture + TDP	Subjective	Study: 93.3 % Control: 70%	1/2 year (n = 1) 100%	Study Cure (n = 9) Improvement (n = 19) No change (n =2) Placebo Cure (n = 3) Improvement (n= 11) No change (n = 6)
Zhang & Lu (2004)	RCT	N = 240 Study: 120 Control: 120	Age range: 25 - 75	Acupoint thread-embedding + pelvic floor training vs oral placebo + pelvic floor training	Subjective and objective	Study: 89.2% Control: 69.2%	1/2 year Study 89.2% Control: 69.2%	Study: Cure (n=114) Improvement (n = 4) No improvement (n = 2) Placebo Cure (91) Improvement (n = 17) No improvement (n= 12)
Qin et al (2004)	Uncontrolled study	N = 28	Age range: 62-81	Acupuncture and TCM	Subjective	75%	2 years (n = 1) 100%	Course of intervention: 15d – 70dCure: n = 21 Effective: n = 6 Improved: n = 1

3.5.4 Protocols for acupoint intervention

There was some variation in the protocols for intervention and the course of intervention among the studies. As different acupoint interventions were adopted,

the course of intervention may have been different. Multiple acupoints were used in all studies except one (Zheng & Gao, 1999). The number of acupoints used varied from one (Zhang & Gao, 1990) to thirteen (Zheng et al., 1990).

The selection of acupoints was based on the general principle of strengthening kidney yang qi and boosting the function of the bladder. Zheng et al (1990) studied the effect of acupuncture and moxibustion and compared it with the effects of an oral placebo among women with USI. The researchers classified the participants in the intervention group into three syndrome groups: deficiency in kidney qi, deficiency in qi in both the kidney and lung, and weak kidney yang. Three protocols for acupoint treatment were applied according to the syndrome shown by the participants. Explanations of the rationale of acupoints were provided, but no explanation was given for the reasons for the differentiation among the syndromes. There was also no comparison of the effect of different protocols for acupoint intervention based on the differentiation of syndromes before and after the intervention (Zheng et al., 1990).

Among the acupoints used, two could not be identified (Mi & Chen, 2003; Qin et al., 2004). The course of intervention also varied among the studies. Two studies did not specify the number of sessions in the intervention (Zhang & Gao, 1999; Qin et al., 2004) (see Table 3.2).

Table 3.2 Studies using acupoints to treat SUI

Study	Intervention	Acupoints	Course of intervention
Zheng et al. (1990)	Acupuncture + moxibustion vs oral placebo	Kidney qi deficiency, Bladder dysfunction: 1) Guanyuan (CV4), Qihai(CV6) Pangguangshu(BL28) 2) Shenshu(BL23), Zhonglushu(BL29) Huiyin(CV1), Weiyang(BL39) Yang deficiency, Deficiency of qi in both Kidney and Lung: Sanyinjiao (SP6) Lieque(LU7), Taixi(K13) Kidney yang deficiency: 1) moxibustion: Guanyuan (CV4) Qihai(CV 6), Lieque(LU 7) acupuncture: Pangguangshu(BL28) Sanyinjiao (SP6) 2) moxibustion: Shenshu(BL23) Mingmen(GV4) acupuncture: Zhonglushu(BL 29), Huiyin (CV1), Weiyang(BL39)	Study: once every other day, 30 times per course Placebo: 3 times per day; 2 tablets per time
Zhang & Gao (1999)	Acupoint injection	Zhongji (CV3)	One injection per week
Mi & Chen (2003)	Acupuncture + Pelvic floor training	Zhongji (CV3); Guanyuan (CV4) Zigu; Zusanli (ST36) Pangguangshu(BL28); Shenshu(BL23) Ciliao (BL32)	Once every other day, 10 times per course, 3 to 6 courses
Yang (2004)	Acupuncture + moxibustion + TDP vs acupuncture + TDP	Qihai (CV6) Guanyuan (CV4) Zusanli (ST36) Sanyinjiao (SP6)	Once every other day, 10 times per course for 3 courses Placebo: the same
Zhang & Lu (2004)	Acupoint thread-embedding + pelvic floor training vs oral placebo + pelvic floor training	Zusanli (ST36) Shenshu(BL23) Sanyinjiao (SP6) Guanyuan (CV4) Zhongji (CV3)	Once every 2 weeks, 4 times per course for 2 courses (20 resting days between courses) Placebo: 2 tabs, 3 times per day for 5 months
Qin et al. (2004)	Acupuncture + moxibustion + TCM	Guanyuan (CV4); Baihui (GV20) Zusanli (ST36) Tietok Sanyinjiao (SP6); Taixi(K13) Dadun(LR1); Taichong (LR3)	Acupuncture: 10 days per course TCM: 3 times per day; 10 days per course

3.5.5 Types of outcome measure

Both subjective and objective outcome measures were reported in three studies (Zheng et al., 1990; Zhang & Gao, 1999; Mi & Chen, 2003). Two studies evaluated the outcomes using imaging techniques (Zheng et al., 1990; Zhang & Lu, 2004), and the third confirmed the outcome with pad test (Mi & Chen, 2003).

None of the studies reporting objective outcome measures gave an explanation of the method or procedure adopted to conduct the measurements. Subjective outcomes were based on self-reports of cure, effect, or no effect. There was no standard criterion or instrument for evaluating subjective outcome measures across the studies. No adverse effects were reported: all of the studies reported high immediate effect rates ranging from 75% to 100%.

Three out of six studies were randomized control trials (Zheng et al., 1990; Yang, 2004; Zhang & Lu, 2004). Different methods of control were used, including oral placebo (Zheng et al., 1990), oral placebo with pelvic floor training (Zhang & Lu, 2004), and acupoint treatment with TDP but without moxibustion (Yang, 2004). None of the trials mentioned the qualification, training, or work experience of the practitioners who performed the interventions. Neither was the method of randomization or blinding method detailed. There was also a lack of information on the calculation of the effect size in the studies. Thus, the sample size in these studies may not have been sufficient to detect the effect of acupoint interventions compared with the controls. Hence, current randomized control trials of acupoint interventions for stress urinary incontinence give poor evidence due to weak study designs and inadequate descriptions of the methods used.

3.5.6 Common acupoints identified for further study

Some common acupoints were identified in the studies as being suitable for treating women with stress urinary incontinence. These include Zhongji (CV3), Guanyuan (CV4), Qihai (CV6), Zusanli (ST36), Sanyinijiao (SP6), Shenshu (BL23), Pangguangshu (BL28), and Ciliao (BL32).

1. Qihai 氣海 (CV6): This is the acupoint where qi is regulated, and is used to treat problems with the urinary system (Ellis, Wiseman, Boss & Cleaver, 2004).

2. Guanyuan 關元 (CV4): This is the acupoint where qi is stored (Cross, 2000). One of the functions of this acupoint is to eliminate the cold by warming the genital region.

3. Zhongji 中極 (CV3): This is the acupoint where the bladder can be restricted (Ellis et al, 2004). The transformation of qi can be promoted at this point if the reinforcing method is used (Li, 2007). The reinforcing method is a manipulation method used to tone yang or qi (Maciocia, 2005).

4. Shenshu 腎俞 (BL23): This is the acupoint where the kidney qi infuses into the back (WHO 1993). It controls the bladder and can supplement kidney qi if the reinforcing method is used (Li, 2007).

5. Pangguangshu 膀胱俞 (BL28): This is the acupoint where bladder qi infuses into the back (WHO, 1993). It regulates the bladder (Ellis et al, 2004).

6. Ciliao 次髎 (BL32): This is the acupoint where the bladder is controlled and the kidneys can be warmed when combined with Shenshu (BL23) (Li, 2007).

7. Sanyinjiao 三陰交 (SP6): This is the acupoint where three channels meet: the spleen channel, the liver channel, and the kidney channel (WHO, 1993). Sp 6 can be selected to treat disorders related to the three channels, including the genitourinary system (Li, 2007).

8. Zusanli 足三里 (ST36): The major function of this acupoint is to tone qi and the blood when the body is experiencing a deficiency (Maciocia, 2005). It can also control the bladder when combined with Zhongji (CV3) (Li, 2007).

In principle, qi can be boosted at all of these acupoints. Yang can also be increased with the combined use of Zhongi (CV3), Guanyuan (CV4), and Qihai (CV6). These acupoints are all located along the conception vessel, one of the unpaired meridians that are linked to the digestive and reproductive systems of the body. Genito-urinary problems can be alleviated by promoting the circulation along the conception vessel (Li, 2007).

3.5.7 Lack of rigorous research

In the past, the practice of traditional Chinese medicine was largely based on the expert opinion and clinical experience of practitioners. Most of the studies published in Chinese are based on clinical observations or a case study approach. The effect of the interventions has not been studied in a rigorous systematic manner. However, with the increasing demand for alternative interventions such as TCM, scientific evidence to support the effect of interventions should be emphasized.

Some studies have been conducted on acupoint interventions to manage the symptoms of urinary incontinence. Most of the evidence to support clinical practice comes from different levels of evidence: case study and randomised controlled trial. It is also limited by small sample sizes and non-randomized and non-sham control trial designs. Several studies claim to have used randomized control trials as the research design. However, they give no detail of how the randomization was carried out or the criteria for sample selection. Other limitations relate to the intervention used, including the utilization of an appropriate, inert sham-control, possible placebo effects, and investigator bias, all of which may have exaggerated the findings. Other issues with studying the effect of acupoint interventions include generalization and investigator bias.

Studies often report the positive effects of acupuncture in managing urinary incontinence. However, there are some potential risks of complications due to the use of needles to stimulate acupoints, such as hemorrhage and infection and so on

(Campbell, 2001). Other non-invasive acupoint interventions such as acupressure may be an alternative intervention for managing SUI. The action of acupressure applies the same principles as acupuncture, but using different tools to stimulate the acupoints, and may thus produce similar effects.

3.6 History of acupressure

The development of acupressure as a manual therapy has a long history in China. The term tuina or massage was commonly used in the past (Jin, 2002). References to acupressure have been found on inscriptions on bones and tortoise shells from the Shang Dynasty (Hu, Yan & Fang, 2005). The earliest formal references to acupressure were in the *Ten Volumes on Tuina of Huangdi and Qibo*, and *Huangdi's Internal Classic*. However, the *Ten Volumes on Tuina of Huangdi and Qibo* was lost (Jin, 2002). *Huangdi's Internal Classic* is considered the oldest existing record to mention acupressure as a method for restoring health. It was used extensively in the Song, Jin and Yuan dynasties (Jing, 2002). Wang Weiyi was well-known for his preparation of the *Illustrated Manual of Acupuncture Points on the Bronze Figure* in the Northern Song Dynasty. *The A-B Classic of Acupuncture and Moxibustion* published by Huangfu Mi in the Yuan Dynasty was the most comprehensive book on the use of manual therapy. In the Ming and Qing Dynasties, the development of manual therapy was extended from adults to children (Jin, 2002). Different specialties such as point-pressing, one finger meditation, bone-setting, surgery, keep-fit and internal exercise were developed.

3.7 Manipulation methods of acupressure

The acting principles of acupressure are to balance yin and yang, restore the circulation of qi, dredge the meridians and regulate the viscera and bowels (Teeguarden, 1996). The manipulation of local areas nourishes the bones and muscles of the corresponding viscera. Acupressure can be applied through the use of hands or tools on the external parts of the body. The earliest and most ancient tool was Bianshi, a type of prepared stone. There were many kinds of Bianshi with different functions for acupuncture and acupressure (Jin, 2002). Among the nine classical needles mentioned in *Huangdi's Internal Classic*, a spoon needle was used for supplementation and a round-pointed needle was used for draining. Spoon needles and round-pointed needles can also be used as acupressure tools to achieve supplementation and draining purposes (Jin, 2002).

In the Han Dynasty, Zhang Zhongjing mentioned the use of ointment during massage in the *Synopsis of Prescriptions of the Golden Chamber*. In the Song, Jin, and Yuan Dynasties, Zhao Ji discussed the implications of rubbing and pressing methods in the *Complete Record of Sacred Benevolence* (Jin, 2002).

There are different methods for applying pressure with the finger, thumb or palm to stimulate the flow of qi in the meridians (Teeguarden, 1996). The therapeutic use of the acupoints was observed through experience in ancient times. The most commonly used methods include pressing, grasping, pinching, rubbing, kneading, pushing and so on (WHO, 2007). A stable pressure is commonly applied to the skin

at a vertical angle (Jarmey & Bouratinos, 2008). Acupressure should be applied with an even, mild and persistent acupressure should be performed (Jin, 2002).

Acupressure has a long history in the management of various syndromes/patterns, and may have therapeutic effects that can improve urinary incontinence. However, there is a lack of scientific evidence to support the effects of acupressure. With the increasing popularity of the integration of traditional Chinese and Western medicine worldwide, there is a need to better understand the different advantages of traditional Chinese medicine and Western medicine for managing various health problems.

3.8 Construction of the study

3.8.1 Conceptual framework

The philosophy of TCM emphasizes the management of the body as a whole rather than diseases of certain body parts. This concept can also be applied to the principle of managing women with USI. This health problem affects not only the physical but also the psychological functioning of women. Several studies have observed the development of avoidance behavior among women with stress urinary incontinence to minimize disturbance from symptoms that affects their daily life. This can have a negative psychosocial impact. According to the holistic view of TCM, interventions should restore the physical function of women with urodynamic stress incontinence to improve their quality of life. In TCM, health problems are deemed to be due to pathogenic changes in qi and an imbalance in yin and yang (Liu, 1988). Dysfunction

of the viscera and bowels is induced by a deficiency or excess of qi in the body. SUI may be due to a kidney qi deficiency.

3.8.2 Acupressure and meridian system

Meridians and collaterals (經絡) make up the system that circulates qi around the body. The concept of meridians and collaterals was first described by Pien Chueh, one of the famous traditional Chinese Practitioner (Omura, 2003). The meridians facilitate communication between the viscera and bowels to regulate or coordinate the two organs so that they support or restrain each other and distribute vital substances to all parts of the body (Liu, 1988). Acupoints have been mapped on the body, and through stimulation can maintain qi in a balanced and harmonious way (Xu, 2001). The WHO (2008) has standardized the locations of the acupoints on the fourteen meridians. The meridians start at the fingertips and connect to the brain, viscera, bowels, and all other parts of the body. A series of acupoints is located on each meridian (Xu, 2001). By applying pressure to certain acupoints, stagnant qi or overactive qi can be either stimulated or dispersed (Sandifer, 2002). Suitable acupoints for acupressure to manage USI are identified in this study based on a literature search and opinions from experts in traditional Chinese medicine.

Acupoint interventions have been used for more than two thousand years (WHO, 2008). Acupressure is an acupoint intervention often used to manage urinary problems (Forem & Shimer, 1999). The improvement in health resulting from the application of massage and touch is mentioned in *Huangdi's Internal Classic* before

Han" (Xu, 2001). Similar to acupuncture, acupressure uses pressure rather than needles to stimulate qi to balance excess or deficiency conditions. By balancing excesses or deficiencies of qi, the functioning of the viscera is improved (Stux et al., 2003). There is increasing study of the mechanism of the stimulation of acupoints and the benefits to the human body. Such stimulation can induce the nervous system to release endorphins and enkephalin and increase the level of the adrenocorticotrophic hormone (a stress-related hormone) and cortisol (Omura, 2003). Recent research suggests that the stimulation of acupoints may also suppress the number of c-Fos-positive cells in the pontine micturition center region, which may improve the symptoms of SUI (Chung et al., 2008).

3.8.3 Acupressure intervention for USI

The principle of managing urinary incontinence is to consolidate kidney qi (Wu, 1999). The consolidation of kidney qi allows it to circulate in an ascending movement. In addition to kidney qi, boosting qi in the lungs and spleen is also important in treating urinary incontinence (Zhao, 1987). The triple energizer is closely related to these three internal organs. The triple energizer functions to mobilize and penetrate qi (Maciocia, 2005). It also controls the transformation of fluids, thus maintaining the function of the bladder. The spleen is responsible for the ascending movement of qi. One of the syndromes of sinking of qi is bearing down in the abdomen (Xu, 2001). It may act on the bladder neck and urine leak occurs. The ascending movement of qi may improve the condition of bearing down in the abdomen.

3.8.4 Acupoints used to manage USI

Shenshu (BL23), Pangguangshu (BL28), and Ciliao (BL32) on the bladder meridian (足太陽膀胱經) were selected to treat urodynamic stress incontinence in this study. Shenshu (BL23) is the location where the kidney qi infuses into the back (WHO, 2003), and controls the bladder and boosts kidney qi if the reinforcing method is used (Li, 2007). A vivo study has been conducted on the functions of Shenshu (BL23). The stimulation of Shenshu (BL23) decreased the renal blood flow in rabbits, which may reduce the frequency of urine production (Xu et al., 1995). Panngguangshu (BL28) is where bladder qi infuses into the back (WHO, 2003), and pressure here may help to regulate the bladder (Ellis et al, 2004). Ciliao (BL32) tones the kidneys and essence (Maciocia, 2005), and can help regulate the bladder and warm the kidneys when combined with pressure applied to Shenshu (BL23) (Li, 2007).

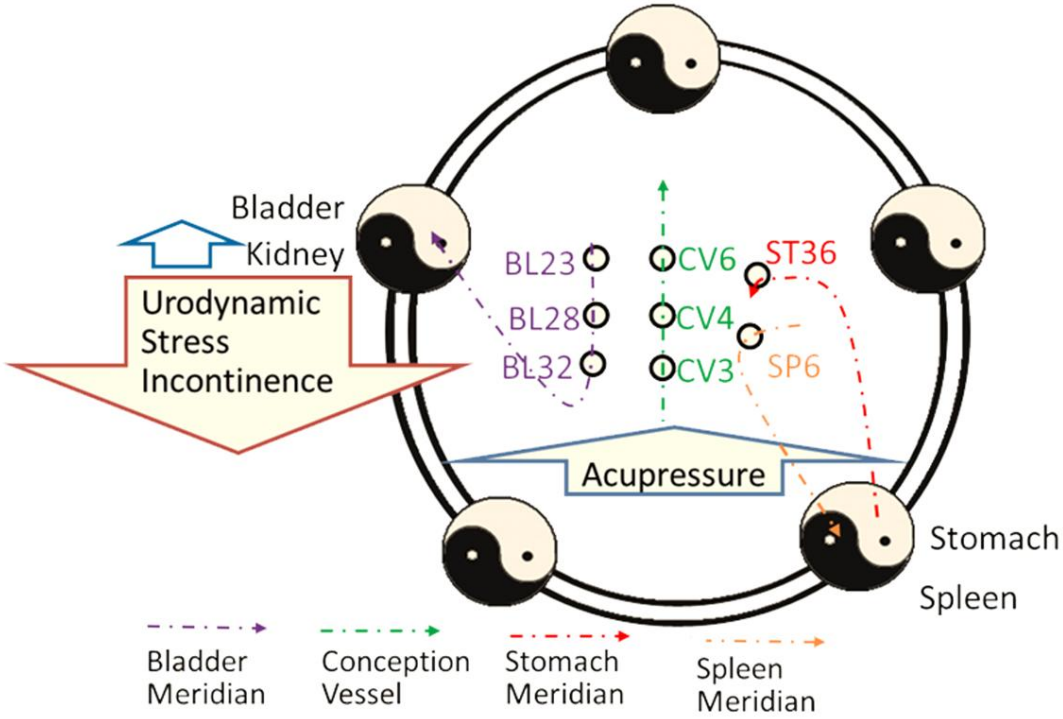
Zhongji(CV3), Guanyuan (CV4), and Qihai (CV6) are located along the conception vessel (任脈). According to the description in (Huangdi's) Internal Classic, the conception vessel is one of the most important extra meridians (Omura, 2003). It originates in the kidneys and circulate through the lower abdomen, the perineum and then forward and upward to the pubic bone and enter below each eye socket. The flow of menstruation and pregnancy in women should be normal if the circulation of qi flows smoothly in the conception vessel (Marchment, 2007).

Zhongji (CV3) is the acupoint where the bladder can be restricted (Ellis et al, 2004). The transformation of qi can be promoted here if the reinforcing method is used (Li, 2007). Qihai (CV6) is an important acupoint that promotes balance in the pelvis (Cross, 2000). Qi can be regulated and problems with the urinary system treated through this acupoint (Ellis et al, 2004). Guanyuan (CV4) is the acupoint that corresponds to where qi is stored (Cross, 2000). Another function of this acupoint is to eliminate cold by warming up the genital region.

Sanyinijiao (SP6) is located along the spleen meridian (足太陰脾經), and is the point at which the three meridians of the spleen, liver, and kidney meet (WHO, 1993). This acupoint can be used to treat disorders related to these three meridians, including the genitourinary system (Li, 2007). Chung et al. (2008) found that there was a significant decrease in abdominal leak point pressure in rats with SUI when this acupoint was treated.

Zusanli (ST36) is located along the stomach meridian (足陽明胃經). The main function of this acupoint is to tone qi and the blood when the body is in a state of deficiency (Maciocia, 2005). It can also control the bladder when combined with the treatment of Zhongji (CV3) (Li, 2007). Qi can be boosted and yang increased when this acupoint is used in combination with Guanyuan (CV4) and Qihai (CV6) (Li, 2007). Pressure applied to Zusanli (ST36) has been found to improve renal functioning in rats (Paterno et al., 2008). Conceptual framework of the study has been illustrated in figure 3.1.

Figure 3.1 Conceptual framework of the study



3.9 This study

SUI is commonly found in younger as well as older women, and affects both their physical and psychosocial condition. In view of the shortcomings of conventional management of USI in Western medicine, there is a need to explore more intervention options. Some studies have reported positive outcomes for acupoint interventions in managing urinary incontinence from the TCM perspective. However, the use of acupressure, which is one of the acupoint interventions used in TCM, to manage urodynamic stress incontinence has not yet been fully studied. As it is non-invasive, acupressure may be a suitable alternative intervention for improving urine leakage. This study evaluates the effects of acupressure on USI. As

SUI often presents with mixed symptoms (Fall, Geirsson & Lindström, 1995), an urodynamic study was employed to identify eligible participants for the study.

Objective and objective effects were used to evaluate the effect of acupressure before and after intervention. Objective effects were evaluated by measuring pelvic floor muscle strength and urine loss during a one-hour pad test. Subjective effects were evaluated from self-reported severity of urine leakage and condition-specific quality of life questionnaires. Pelvic floor muscle strength was the primary outcome and self-reported severity of urine leakage, one-hour pad test (negative/positive), and number of episodes of urine leakage and quality of life were the secondary outcomes.

3.10 Research questions

1. What are the physiological effects of acupressure on women with urodynamic stress incontinence?
2. What are the psychological impacts of acupressure on women with urodynamic stress incontinence?

3.11 Research hypotheses

The intervention group received the acupressure intervention, the sham group received a non-acupoint intervention and the control group practiced pelvic floor training.

1. There is no significant difference among the intervention group, sham group, and control group before and after intervention in terms of:
    a. pelvic floor muscle strength
    b. one-hour pad test
    c. number of episodes of urine leakage
    d. self-reported severity of urine leakage
    e. condition-specific quality of life

2. There is no significant difference between the intervention group and the sham group before and after intervention in terms of:
    a. pelvic floor muscle strength
    b. one-hour pad test
    c. number of episodes of urine leakage
    d. self-reported severity of urine leakage
    e. condition-specific quality of life

3. There is no significant difference between the intervention group and the control group before and after intervention in terms of:
    a. pelvic floor muscle strength
    b. one hour pad test
    c. episode of urine leakage
    d. self-reported severity of urine leakage
    e. condition-specific quality of life

4. There is no significant difference between the sham group and the control group before and after intervention in terms of:

    a. pelvic floor muscle strength

    b. one-hour pad test

    c. number of episodes of urine leakage

    d. self-reported severity of urine leakage

    e. condition-specific quality of life

CHAPTER 4

METHODS

4.1 Introduction

This chapter explains the operational definitions of the study variables, the sampling method used, and the design and rationale of the sampling method. The research design and validity and reliability of the instruments adopted are addressed. The data collection and analysis are described, and the ethical considerations and delimitation steps are explained.

4.2 **Operational definitions**

Urodynamic stress incontinence (USI)

Urodynamic stress incontinence refers to involuntary urinary leakage during increased abdominal pressure in the absence of a detrusor contraction (Abrams et al., 2003, 45). It is noted during filling cystometry. Filling cystometry is the term to describe the filling phase of the micturition cycle.

Stress urinary incontinence (SUI)

Stress urinary incontinence is defined by the ICS as a "complaint of involuntary leakage on effort or exertion, or on sneezing or coughing" (Abrams et al., 2003, 38).

Acupressure

Acupressure in this study refers to intervention based on a protocol that is specifically designed for women with USI.

Body mass index (BMI)

Body mass index (BMI) refers to a ratio of weight to height as measured in indoor clothing but without shoes. The calculation is weight in kilograms divided by height in meters^2. The cut-off points used to define underweight, normal, and overweight in Asian adults were those proposed by the WHO. A BMI of less than 18.5 kg/m^2 is the cut-off for being underweight, 18.5 to 22.9 kg/m^2 is the cut-off for being normal, and equal to or more than 23 kg/m^2 is the cut-off for being overweight.

Condition-specific quality of life

Condition-specific quality of life refers to the effects of urinary incontinence on quality of life. The measurement used in this study was a Chinese version of the King's Health Questionnaire (CKHQ). The domains of quality of life in the CKHQ include incontinence impact, physical limitations, role limitations, social limitations, personal relationships, emotional problems, sleep and energy disturbance, and severity measures.

4.3 **Research design**

A pilot study was conducted to assess the feasibility of the main study (Poilt & Beck, 2006). A before-after study design was adopted. The efficacy of the intervention

was measured at two time points before and immediate after the intervention (Poilt & Beck, 2006).

4.3.1 **Randomized control trial**

The main study was a randomized single-blinded sham-controlled trial. The randomized control trial is a common quantitative approach used in research studies, and is the most scientific method of evaluating the efficacy of interventions (Jadad, 1998). In the main study, the participants were randomized into three groups: an intervention group, a sham group, and a control group. None of the participants were informed as to the group to which they belonged. However, as the investigator was also the practitioner who performed the intervention, the investigator could not be blinded.

4.3.2 **Framework of the study**

The study framework was designed to measure the real effect of the intervention. One intervention group and two control groups were set up. All of the participants were required to perform pelvic floor training during the period of intervention. The pelvic floor training was carried out by an Advanced Practice Nurse (APN) on the day of follow-up at her clinic. The APN taught with the help of a pamphlet on pelvic floor training that included an explanation of the anatomy of the pelvic floor and its function and the muscles to be activated during training (Appendix 1). The participants were asked to demonstrate the contraction of their pelvic floor muscles

to assure that they had sufficient knowledge of and skill in pelvic floor training before the intervention.

Before the commencement of the study, except for the pelvic floor training, the participants were asked not to undergo any other intervention for the treatment of USI during the study period. In addition, the intervention was stopped and participants deemed no longer eligible to participate if they became pregnant during the study.

4.4 Study sample

4.4.1 Participant recruitment

Eligible participants were recruited in an urogynecology clinic in a major acute hospital in Hong Kong. The hospital provides immediate care to patients in acute conditions. It also operates General Out-patient and Specialist Out-patient Clinics. The General Out-patient Clinic (GOPC) provides focused care for chronic disease patients, while the Specialist Out-patient Clinic (SOPC) provides timely assessment and consultation for patients who require specialized care. The urogynecology clinic is one of the hospital's specialist clinics. Women who are referred to the clinic can seek advice from doctors and the APN. A nurse-led clinic provides urogynecological counseling, which comprises nurse consultation, bladder drilling, pelvic floor exercise training, behavior intervention, self-catheterization training, and urodynamic observation in the hospital.

Eligible participants were recruited by the APN once they were confirmed as having USI or on the day of follow-up in the clinic. The APN is stationed in the clinic to offer urogynecological consultation. One of her roles is to train women with urinary incontinence to perform pelvic floor training.

Before the start of the study, the investigator explained the procedure of recruitment to the APN, including the inclusion and exclusion criteria for participants. A list of recruitment criteria and a list of random numbers were included in the recruitment book. Once a potential participant was identified, the APN invited her to participate in the study. The names and contact telephone numbers of the participants were recorded in the recruitment book. When an eligible participant was identified, the APN referred them to the investigator to arrange a time and date for baseline measurement. The allocation of the participants to groups was concealed. Further explanation of the purpose of the study was given and written consent obtained from the participants on the day of baseline measurements before the intervention commenced.

4.4.2 Screening procedure

Before recruitment, all of the potential participants were screened by urodynamic studies to confirm the diagnosis of USI according to the definition of the ICS (Abrams et al., 2003).

Urodynamic evaluation is the gold standard for differentiating the competency of urethral sphincter control and for identifying the right patients for bladder neck surgery (Versi et al., 1991). The evaluation involves physiological measurement of the functioning of the lower urinary tract to confirm the diagnosis of the type of urinary incontinence (Schäfer et al., 2002). The physiological measurements taken include intravesical pressure, intra-abdominal pressure, and intra-abdominal pressure. The ICS defines urine leakage as occurring when the intravesical pressure is higher than the intra-abdominal pressure (Abrams et al., 1990). This evaluation was used to screen and exclude women with mixed symptoms of urine leakage from the study.

The urodynamic evaluation was performed by doctors at the Urogynecology Unit of the hospital. The Ellipse Urodynamics System (ANDROMEDA) was employed to evaluate the lower urinary systems of the participants. The system has built-in analysis programs to facilitate the interpretation of the results of the investigations, including pressure flow, leak point pressure, and stress profile.

On the day of evaluation, the potential participants were asked to void their bladder before the procedure. The urinary bladder was then catheterized. A size 8 French pressure feeding tube was inserted into the bladder for bladder filling. A rectal balloon catheter was then inserted well beyond the anal sphincter to detect the intra-abdominal pressure.

Before starting, all of the infusion lines were flushed with normal saline to remove any air that might induce artifacts (Lai, Smith & Boone, 2008). The transducers were reset to zero for each participant to ensure that all of the readings started from the baseline. The p_{det} was around 0 ± 1. The bladder was then filled with 500 ml of normal saline solution at room temperature. The average rate of bladder filling is suggested to be between 10 to 100ml/min (Lai, Smith & Boone, 2008). In this study, the bladder filling rate was around 80 ml/min.

The ICS defined the terms used to describe bladder sensation during evaluation in 1988 (Abrams, Blaivas, Stanton & Andersen, 1990). The terms include "first desire to void," "normal desire to void," and "strong desire to void." The potential participants were instructed to inform the evaluator whenever a bladder sensation arose during bladder filling by coughing. The bladder filling procedure was stopped when the potential participant reported a strong desire to urinate. The maximum cystometric capacity was monitored to detect any instability in the detrusor muscle. Under normal circumstances, the pressure on the bladder should not exceed 15 cm of water from empty to cystometric capacity (Hilton, 1995).

After the potential participants had reported their "maximum bladder capacity," the pressure tubing was disconnected from the urinary catheter. The potential participants were asked to cough in the lithotomy position, and any urine leakage that occurred during coughing was recorded. The strength of the urethra and abdominal pressure was then measured. An abdominal leak-point pressure of greater

than 90 cm of water refers to urine leakage mainly due to the hypermobility of the urethra (Lai, Smith & Boone, 2008). Only potential participants who showed no sign of over-activity of the bladder and who displayed urine leakage during coughing in the evaluation were recruited to the study.

4.4.3 Inclusion and exclusion criteria

Inclusion criteria:

- female;
- aged between 18 to 60 years old;
- first diagnosed with USI;
- cognitively intact to provide consent.

Exclusion criteria:

- pregnant;
- undergoing active diuretic treatment;
- previous history of undergoing continence surgery;
- medical problems such as diabetic mellitus, urinary tract infection, cerebrovascular lesions, urogenital tumours, dementia, or parkinson's disease.

4.4.4 Sampling method

Eligible participants were randomly assigned to the intervention group, sham group, or control (usual care) group with the use of the Research Randomizer (2006), a random assignment software package. Three sets of numbers were generated by the

software to ensure that the same number of participants was allocated to each group. Three numbers were included in each set: "1" for the intervention group, "2" for the sham group, and "3" for the usual care group. Different sequences were generated by the software. For example, if the sequence of the first set was 1-3-2, then the first participant was assigned to the intervention group, the second to the usual care group, and the third to the sham group. An equal chance of entering each group through random assignment was thus assured (Polit & Beck, 2006).

4.4.5 Sample size

The sample size was based on the calculation of the effect size from the pilot study. The estimation of the sample size is described in Chapter 4, which reports the pilot study. It was estimated that 27 participants would be needed for each group, giving a total sample size of 81 participants. The dropout rate was considered.

4.5 Development of the intervention protocol

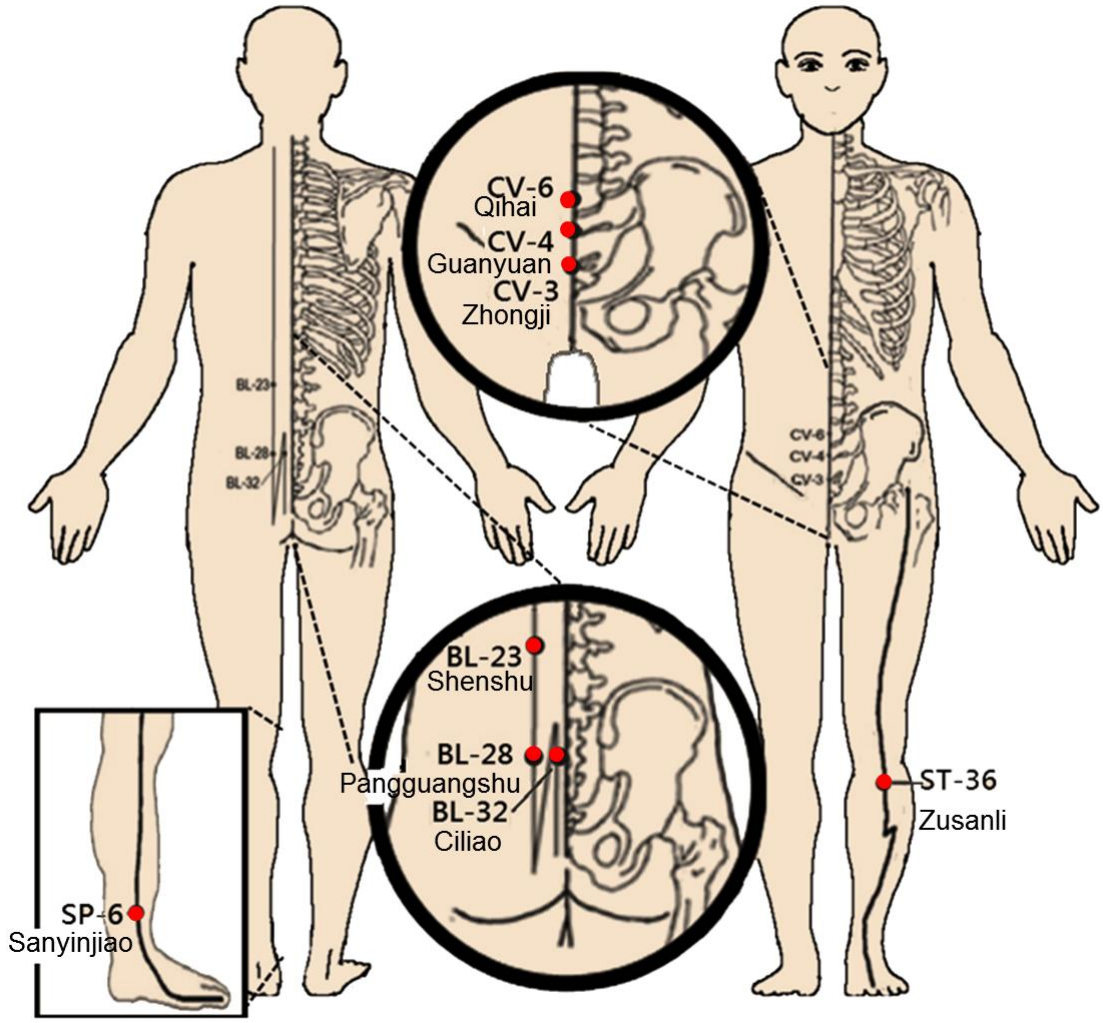
Following a review of previous studies and related TCM theories and further consultation with a group of TCM practitioners in a hospital in Guangzhou, eight acupoints were selected for this study (Figure 4.1). A protocol for the acupressure intervention was constructed accordingly, as follows.

1. Rub the lower abdomen gently three to five times to promote the movement of qi.
2. Press Qihai (CV6) for one minute.

3. Press Guanyuan (CV4) for one minute.
4. Press Zhongji (CV3) for one minute.
5. Press Zusanli (ST36) bilaterally for one minute.
6. Press Sanyinijiao (SP6) bilaterally for one minute.
7. Rub the sacral area three to five times to promote the movement of qi.
8. Press Shensu (BL23) bilaterally for one minute.
9. Press Pangguangshu (BL28) bilaterally for one minute.
10. Press Ciliao (BL32) bilaterally for one minute.

The appropriateness of the treatment of the acupoints for managing women with USI was further checked for content validity.

Figure 4.1 Location of the acupoints used in the intervention group



4.5.1 Validation of the intervention

A panel of six TCM experts was invited to validate the suitability of the protocol for the acupressure intervention. The experts included a vice-president and professor, an associate professor and section leader in TCM nursing studies, a professor and principal, a TCM practitioner and professor, and two TCM practitioners. The experts independently rated the various parts of the protocol on a four-point Likert

scale where 4 = very appropriate, 3 = appropriate, 2 = inappropriate, and 1 = very inappropriate. The calculation of the content validity index (CVI) was based on the total number of items rate either "very appropriate" or "appropriate" divided by the total number of items. The response rate of the experts was 100% (n = 6).

Most of the items were rated "very appropriate" or "appropriate," although the panel of experts did recommended that item 5 be replaced with a different acupoint. The overall content validity was 0.90, indicating that the protocol to be valid (Lynn, 1985) and suitable (see Table 4.1).

Table 4.1 Content validity of acupressure intervention protocol

Response index:
1=very relevent or quiet relevant
0= somewhat relevant or not relevant

Item	Expert 1	Expert 2	Expert 3	Expert 4	Expert 5	Expert 6	Agreement
1	1	1	1	1	1	1	Yes
2	1	1	1	1	1	1	Yes
3	1	1	1	1	1	1	Yes
4	1	1	1	1	1	1	Yes
5	1	0	1	0	1	1	No
6	1	1	1	1	1	1	Yes
7	1	1	1	1	1	1	Yes
8	1	1	1	1	1	1	Yes
9	1	1	1	1	1	1	Yes
10	1	1	1	1	1	1	Yes

Total numbers of agreement: 10
Total numbers of items: 9
CVI: 9/10 =0.9

4.5.2 Qualification and accuracy of acupoint selection

4.5.2.1 Training of the investigator

The investigator took a training course in Guangzhou specifically for the study. The training course lasted one month and covered the basic theories of TCM, methods of diagnosis and principles of treatment, techniques for locating acupoints, the different methods of performing acupressure, and special considerations in performing acupressure. In addition to the theoretical input, practical sessions were included in the course, and clinical placement was required at one of the hospitals in Guangzhou.

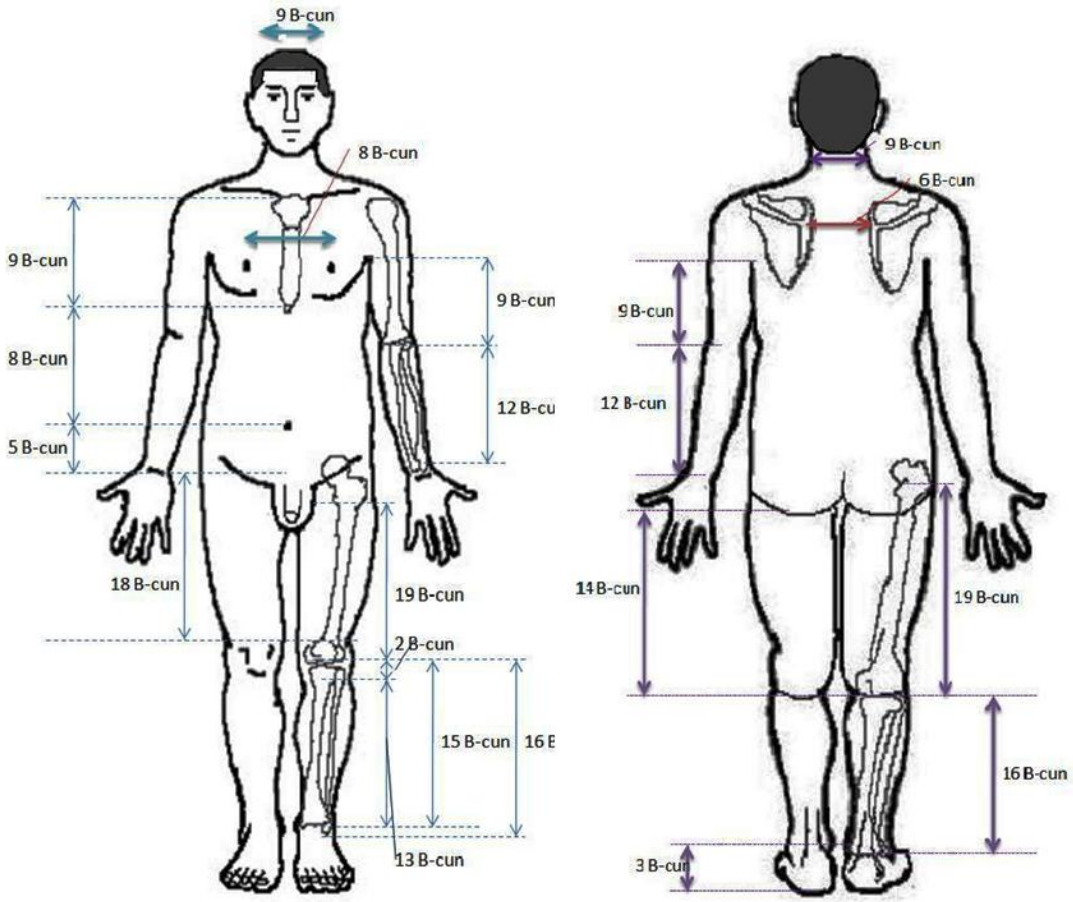
To ensure the accuracy of the acupoints chosen by the investigator, an assessment was conducted by an associate professor in TCM from Guangzhou. The associate professor checked the accuracy of the eight acupoints on three women with different body builds. A 95% level of accuracy was demonstrated.

4.5.2.2 Measurement and location of acupoints

i) Measurement of acupoints

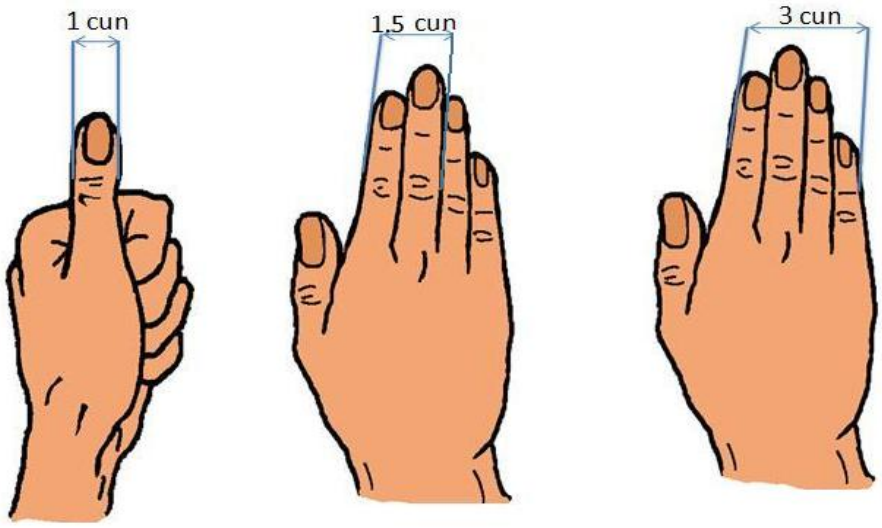
The unit of measurement of acupoints is called cun, the earliest record of which appears in Lingshu (WHO, 2007). Proportional bone measurement was used to locate the acupoints on the upper part of the body. The main focus of measurement in this study was the distance from the center of the umbilicus to the superior border of the pubic symphysis over the abdomen and between the bilateral medial borders of the scapula and the lumbar region, respectively (Figure 4.2).

Figure 4.2 Illustration of proportional bone measurement



Finger-cun measurement was employed to measuring method to locate the acupoints on the lower limbs. The finger-cun measurement is based on the proportional size of an individual participant's fingers. The measurement is obtained from the width of the thumb and fingers. The thumb measurement is taken at the interphalangeal joint, and is equivalent to one cun. The finger width measurement refers to the width of the four fingers (index, middle, ring, and little) when held together, and is measured on the dorsal side of the proximal interphalangeal joint of the middle finger. This is equivalent to three cun (Figure 4.3).

Figure 4.3 Illustration of the finger-cun measurement



ii) Location of the acupoints

The description of the acupoints used in this study is based on the WHO standard for acupuncture point locations developed in 2007. The acupoints used were distributed across the anterior, posterior, superior, and inferior aspects of the body (Figure 4.1).

Qilhai (CV6), Guanyuan (CV4), and Zhongji (CV3) are located along the anterior median line of the lower abdomen at 1.5 cun, 3 cun, and 4 cun inferior to the center of the umbilicus. Shenshu (BL23) is located in the lumbar region of the spine at 1.5 cun lateral to the posterior of the median line at the same level as the second lumbar vertebra. Pangguangshu (BL28) and Ciliao (BL32) are located in the sacral region. Pangguangshu (BL28) is found at 1.5 cun lateral to the median sacral crest and Ciliao (BL32) at the depression of the second posterior sacral foramen, midway between the superior iliac spine and the spinous process of the second sacral vertebra.

Pangguangshu (BL28) and Ciliao (BL32) are at the same level as the second sacral vertebra.

Zusanli (ST36) is located on the anterior aspect of the leg. It is measured at 3 cun inferior to the depression of the lateral and inferior to the patella. Sanyinjiao (SP6) is located on the tibial aspect of the leg at 3 cun superior to the prominence of the medial malleolus.

4.5.2.3 Sensation of true acupoint

Accuracy in locating the true acupoint was confirmed by reports of a sensation of obtaining qi by the participants. Such sensation is usually described as numbness, heaviness, or distension around the area of the acupoint (Chang, Liu, Li, Chen & Chou, 1994).

4.5.2.4 Measurement consistency

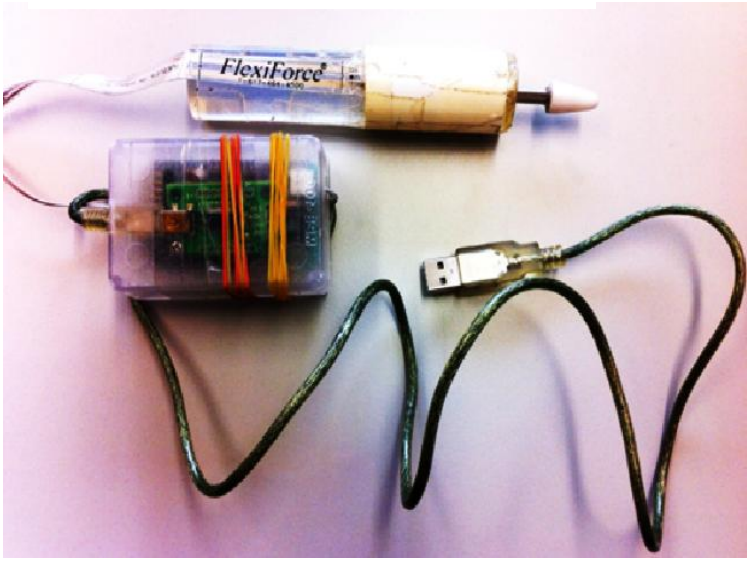
To ensure the consistency of the measurement of the acupoints during each acupressure session, the investigator marked down the individual measurements for each participant on a lolly stick. The identification of the acupoints was improved by using the same measurements each time.

4.5.2.5 Stability of the force exerted during acupressure

The stability of the force applied and the duration of each instance of acupressure applied for each participant were assured by the use of the Acupen during the study.

The Acupen was invented by Professor J. Chung and the Area for Strategic Development (ASD) team at the Hong Kong Polytechnic University in 2005 (Figure 4.4). A pressure sensor installed inside the Acupen is connected to a circuit board. When pressure is applied to the head end of the Acupen, the resistance of the pressure sensor changes. This change in resistance is converted into a change of voltage and amplified to a measurable level. The pressure is then calculated based on the measured voltage, and is output as a two-digit number to a computer through the USB port. The force of acupressure measured ranges from 0 to 50 Newtons. The Acupen is operated by a nine-volt battery, with an indicator to determine whether a low voltage remains. The sensor is changeable. As each sensor may behave slightly differently, calibration is performed whenever the sensor is changed. For consistency, the length of time spent on each acupoint was also standardized, and was set at one minute by the technical officer of the ASD team before the commencement of the study.

Figure 4.4 Acupen used in the study



4.6 Intervention group

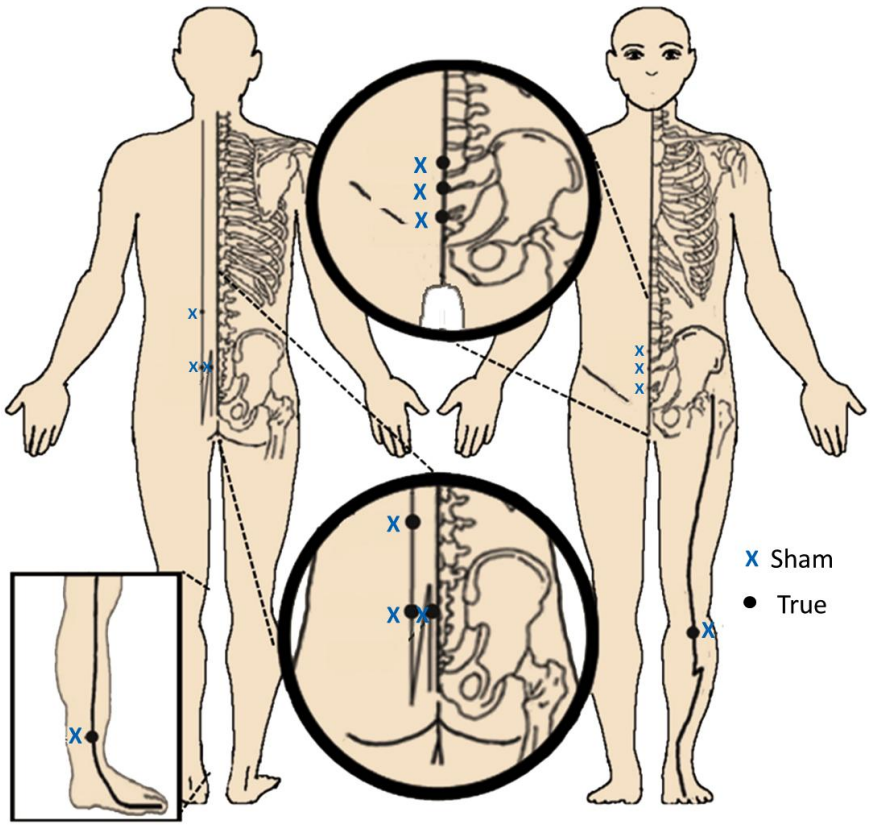
In accordance with a previous studies (Zheng, et al.,1990; Yang, 2004) and agreed by the TCM practitioners in Guangzhou, the intervention group participants received acupressure as per the intervention protocol three sessions a week for a total of thirty sessions. Each session lasted for about thirty minutes. The course of intervention was completed in three months.

4.7 Two control groups

i) Sham group

Non-acupoints was used as a placebo control in this study. The non-acupoints located not on single points but the area, which were mid-way between meridians (Figure 4.5). The sham acupoints did not correspond to known acupoints or meridians. Light pressure was applied only and no special sensation produced around the area of the non-acupoints. There was no non-specific effects associated with the non-acupoints. The length of time and number of non-acupoints treated were the same as in the intervention group (Harris et al., 2009). One minute was spent on each non-acupoint, and each session lasted around thirty minutes. The participants in the sham group also received the same number of sessions as the intervention group.

Figure 4.5 Location of the sham acupoints used in the sham group



ii) Control group (usual care)

The participants in the usual care group performed pelvic floor training only for three months. The participants received a telephone reminder at around one and a half months from the investigator about practicing the pelvic floor training taught by the APN. An appointment for post measurement was also made, and the participants were reminded to bring along the frequency volume chart.

4.8 Instrument and outcome measures

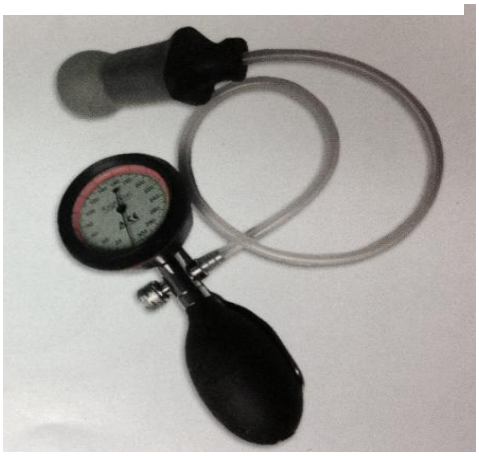
4.8.1 Demographic characteristics

The questionnaire consisted of sections on demographic data, general health status, and urine leakage profile. The demographic data solicited included age, educational background, marital status, occupation, body mass index, and parity. The general health status section included questions on general health status, menopausal status, smoking and drinking habits, bowel habits, and concomitant medical problems. The urine leakage profile data included the duration of urine leaks, the number of pads used per day, the coping strategies used, and activities that induced urine leakage (Appendix 2).

4.8.2 Primary outcome measure

Pelvic floor muscle strength was the primary outcome measure. The functioning of the pelvic floor muscles was evaluated by perineometer (Abrams, Blaivas, Stanton & Andersen, 1990) by measuring the vaginal squeeze pressure. The perineometer used in this study is called the Pelvexiser (Figure 4.6). It is a registered medical device designed for used in pelvic floor training. The device consists of a sensor to detect the increase in pressure produced by the pelvic floor muscles. The sensor is connected to an analog display. The highest difference of reading among the three was recorded.

Figure 4.6 Perineometer



4.8.3 Secondary outcome measures

4.8.3.1 One-hour pad test (negative/positive)

The one-hour pad test is an objective measurement of urine loss recommended by the ICS. The unit of measurement is grams (gm). As weight errors may occur due to sweating or vaginal discharge, a pad weight gain of more than one gram is considered a positive test result (Abrams, Blaivas, Stanton & Andersen, 1990), and a pad weight gain of less than one gram is considered a negative result (Figure 4.7).

Figure 4.7 An obstetric pad and an electronic scale

4.8.3.2 Episodes of urine leakage over four days

The number of episodes of urine leakage was obtained from a four-day frequency volume chart. The frequency volume chart is considered an accurate and consistent tool to evaluate bladder conditions (Palnaes & Klarskov, 1998; Tincello & Richmond, 1998), and number of episodes of urine leakage is one of the pieces of data that can be obtained from the chart (Abrams et al., 1990). In this study, the frequency of urine leakage over four days was recorded. A smaller the number of episodes denoted less severe incontinence.

4.8.3.3 Self-reported severity of urine leakage

A subjective assessment of urinary incontinence on a four-point scale was used to evaluate the subjective severity of urine leakage (Abdel-fattah, Barrington & Youssef, 2004). The four points on the scale were 0 = totally continent; 1 = mild or

occasional incontinence; 2 = moderate urinary incontinence; 3 = severe urinary incontinence. The lower the score, the less severe the incontinence as perceived by the participants.

Self-reports of the severity of urine leakage were compared with the results of pad tests among women who had undergone surgery for USI. The sensitivity was found to be 95.65% and the specificity 93.33 % with a positive predictive value of 97.34% and a negative predictive value of 89.36% (Abdel-fattah, Barrington & Youssef, 2004).

4.8.3.4 King's Health Questionnaire (Chinese version)

The quality of life of the participants was evaluated by using the Chinese version of the King's Health Questionnaire (CKHQ). The King's Health Questionnaire (KHQ) is a condition-specific quality of life instrument for measuring urinary incontinence developed by Kelleher and colleagues in 1997. The original questionnaire consists of two parts. Part I consists of two single items to measure general health and the impact of incontinence. Part II consists of six quality of life domains: role limitations, physical limitations, social limitations, personal limitations, emotional problems, sleep/energy disturbance, and severity measures, all rated on a four-point Likert scale. The domains for evaluation included the impact of incontinence (item 1); role limitations (item 2a, 2b), physical limitations (item 3a, 3b), social limitations (item 3c, 3d); personal relationships (item 4a, 4b, 4c), emotional problems (item 5a, 5b, 5c), sleep/energy disturbance (item 6a, 6b), and severity of incontinence (item 7a,

7b, 7c, 7d, 7e). A four-point Likert scale was used to measure each domain, with a five-point scale with an "inapplicable" option being used for "personal relationships." The total scores in each domain ranged from 0 to 100, with a lower score indicating less impairment of quality of life.

The criterion-related validity of the questionnaire was confirmed against the Short Form 36. A significant correlation of the scores was observed ranging from 0.80 to 0.96 for the common domains in the two questionnaires. The KHQ has been shown to have a good test retest reliability ranging from 0.8 to 0.96. Its internal consistency, as measured by the Cronbach's alpha coefficient, ranges from 0.73 to 0.89 across all domains, which is acceptable (Kelleher et al., 1997).

As no validated Chinese version of the questionnaire has been published, the questionnaire was translated into Chinese before use in this study. Permission was obtained from the developer to translate the questionnaire. A native speaker of Chinese with a nursing background who was fluent in English translated the questionnaire into Chinese. The Chinese version was then sent to two clinicians working with incontinent patients to review the wording. This process ensured that the wording was clearly understandable for Chinese patients with urinary incontinence (Wild et al. 2005). Minor discrepancies were observed and amended. A professional translator then translated the CKHQ back into English. The back-translated English version was then compared with the original version, and the two versions were judged to be equivalent.

4.8.3.4.1 Content validity of the CKHQ

To ensure that the content of the CKHQ was relevant and adequate for measuring the quality of life of Chinese women with urinary incontinence, a panel of eleven experts working in this area was invited to examine the questionnaire. The experts consisted of a consultant, senior medical officer, medical officers, advanced practice nurses, and registered nurses working in the areas of obstetrics and gynaecology, urogynaecology, and geriatric care.

The experts were asked to rate the relevancy of each item on a four-point rating scale where 4 = very relevant, 3 = quite relevant, 2 = somewhat relevant, 1 = not relevant. The calculation of the content validity was based on the total number of items rated either "very relevant" or "quite relevant" divided by the total number of items. The response rate was 100% (n = 11).

A few items were rated as being only "somewhat relevant." Three out of eleven experts rated item 1 as "somewhat relevant." This is a single item evaluating the general health status of people with urinary incontinence. The experts also commented that this item made little contribution compared with the other items. It was thus decided that the item should be removed from the questionnaire.

One of the experts rated "tiredness," "family life," and "feelings of depression" as only "somewhat relevant." However, according to Lynn (1985), this content can still

be considered valid if more than six experts are on the panel. As there were eleven experts on the panel, the content validity value was 0.76, which is acceptable. All of the remaining items in the domains had an acceptable content validity (see Table 4.2).

Table 4.2 Content validity of the King's Health Questionnaire (Chinese version)

Response index:

1=very relevent or quiet relevant

0= somewhat relevant or not relevant

Item	Expert 1	Expert 2	Expert 3	Expert 4	Expert 5	Expert 6	Expert 7	Expert 8	Expert 9	Expert 10	Expert 11	Agreement
1	0	1	1	1	0	0	1	1	1	1	1	No
2	1	1	1	1	1	1	1	1	1	1	1	yes
3a	1	0	1	1	1	1	1	1	1	1	1	No
3b	1	1	1	1	1	1	1	1	1	1	1	Yes
3c	1	1	1	1	1	1	1	1	1	1	1	Yes
4a	1	1	1	1	1	1	1	1	1	1	1	Yes
4b	1	1	1	1	1	1	1	1	1	1	1	Yes
4c	1	1	1	1	1	1	1	1	1	1	1	Yes
4d	1	1	1	1	1	1	1	1	1	1	1	Yes
5a	1	1	1	1	1	1	1	1	1	1	1	Yes
5b	1	1	1	1	1	1	1	1	1	1	1	Yes
5c	1	1	1	0	1	1	1	1	1	1	1	No
6a	1	1	0	1	1	1	1	1	1	1	1	No
6b	1	1	1	1	1	1	1	1	1	1	1	Yes
7a	1	1	1	1	1	1	1	1	1	1	1	Yes
7b	1	1	1	0	1	1	1	1	1	1	1	No
8a	1	1	1	1	1	1	1	1	1	1	1	Yes
8b	1	1	1	1	1	1	1	1	1	1	1	yes
8c	1	1	1	1	1	1	1	1	1	1	1	Yes
8d	1	1	1	1	1	1	1	1	1	1	1	Yes
8e	1	1	1	1	1	1	1	1	1	1	1	Yes

Total numbers of agreement: 16

Total numbers of items: 21

CVI: 16/21 =0.76

4.8.3.4.2 Internal consistency of the CKHQ

To ensure that the items in the questionnaire accurately measured the quality of life of women with urinary symptoms, the internal consistency was measured (Polit & Hungler, 1997). The Cronbach's alpha coefficient ranged from 0.76 to 0.95, which

is comparable with that of the original KHQ (Kelleher et al., 1997). The questionnaire can thus be deemed to have a high internal consistency (see Table 4.3).

Table 4.3 Internal Consistency for the King's Health Questionnaire (Chinese version)

Domain	Item #		internal consistency
Incontinence impact	2	impact	0.85
Role limitation	3a	household	0.79
	3b	job or daily living	
Physical limitations	4a	Physical activity	0.73
	4b	Travel	
Social limitation	4c	Social life	0.8
	4d	Friends	
	5c	Family	
Personal relationships	5a	Relation	0.52
	5b	Sex life	
Emotional problems	6a	Depress	0.83
	6b	Anxious	
	6c	feeling bad	
Sleep/energy disturbance	7a	Tired	0.5
	7b	Sleep	
Severity measures	8a	Pad	0.53
	8b	Fluid	
	8c	Clothes	
	8d	Smell	
	8e	Embarrass	

4.8.3.4.3 Stability of the CKHQ

The test-retest method was used to ensure the stability of the questionnaire across time (Polit & Beck, 2006). A sample of fifteen participants was recruited to test the questionnaire twice with a two-week interval. All of the participants were women with urinary symptoms. The Spearman's rank order correlation (rho) was used to calculate the coefficients of the domain scores at baseline and after two weeks (Pilot

& Beck, 2006). The values for the items ranged from 0.70 to 0.92, indicating that most of the items displayed a strong positive correlation (see Table 4.4).

Table 4.4 Test-retest reliability scores for the King's Health Questionnaire (Chinese version)

Domain	Item #		rho	Sig. (2-tailed)
Incontinence impact	2	impact	0.72	0.002*
Role limitations	3a	household	0.7	0.004*
	3b	job or daily living		
Physical limitations	4a	Physical activity	0.89	0.000*
	4b	Travel		
Social limitations	4c	Social life	0.75	0.001*
	4d	Friends		
	5c	Family		
Personal relationships	5a	Relation	0.71	0.003*
	5b	Sex life		
Emotional problems	6a	Depress	0.92	0.000*
	6b	Anxious		
	6c	feeling bad		
Sleep/energy disturbance	7a	Tired	0.85	0.000*
	7b	Sleep		
Severity measures	8a	Pad	0.75	0.001*
	8b	Fluid		
	8c	Clothes		
	8d	Smell		
	8e	Embarrass		

* Correlation is significant at the level 0.05 (2-tailed)

4.9 Data collection

4.9.1 Data collection before and after the intervention

Data were collected from the participants in each group at two time points. Both data collection sessions were carried out in a private single room at the Urogynecology Clinic of a Speciality Outpatient Department (SOPD) in Hong Kong to ensure privacy. The first session was the baseline, which was conducted before intervention. During this session, the participants were invited to fill in a questionnaire on

demographic data and a subjective assessment of urine leakage (Appendix 2) in which they were asked to assess the severity of their urine leakage and its impact on their quality of life (Appendix 3). Further objective tests of the participants' pelvic floor muscle strength and a one-hour pad test were then carried out by the investigator. Each participant was asked to record the number of episodes of urine leakage on a frequency volume chart over the next four days. The same procedure, except for the questions on demographic data and urine leakage profile, was repeated three months after intervention. A reminder was sent to participants before the post intervention assessment.

4.9.2 Procedure for measuring pelvic floor muscle strength and the one-hour pad test

The procedure for measuring urine lost during a one-hour pad test was based on the guidelines of the ICS and the Urogynecological Clinic. However, the standard activity of bending the knees to pick up small object five times was modified by the Clinic to stepping up and down two steps ten times, because some of the women who suffered from knee pain might not be able to perform the activity (Elder, Fantl & McClish, 1995). According to the ICS, the activities in the guidelines can be modified to suit the physical ability of whoever is performing the test (Abrams et al., 1990).

Before the test, each participant was asked to micturate once. They were then given an obstetric pad to wear that had been weighed beforehand in grams using an

electronic precision scale of 5 kg x 0.5g. Each participant was then asked to drink 500 ml of water in a standard paper cup within 15 minutes and to rest for half an hour before performing a series of standard activities.

The standard activities included (1) running on the spot for one minute, (2) stepping up and down two steps ten times, (3) standing up from a sitting position ten times, and (4) coughing vigorously ten times. At the end of the one-hour period, the obstetrical pad was removed and weighed again on the same scale. A pad weight gain of more than one gram was considered to be a positive test result (Abrams et al., 2002).

The strength of the pelvic floor muscles was assessed after micturition. Before the test, each participant was informed about the use of the device and the procedure. The participants were asked to demonstrate the correct technique for performing pelvic floor muscle contractions. As the contractions of other muscles such as the gluteal muscle can affect the measurement of intravaginal pressure, any use of the abdominal or gluteal muscles should be avoided during contractions (Bo & Sherburn, 2007). The investigator ensured that the analog display pointed to zero as the baseline reading before measuring the pelvic floor muscle strength of each participant.

The positioning and measurement procedure for the perineometer were based on the manufacturer's recommendations. During contractions, the participants were supine

position with the knees bent and feet flat against the bed. The deflated sensor was then inserted into the vagina. The participants were told to relax and breathe normally, and were then asked to squeeze the pelvic floor muscles as hard and as quickly as possible three times, with a rest period of three seconds between each squeeze. The highest reading among the three was recorded.

4.10 Data analysis with intention-to-treat analysis

To address the effect of data loss, all of the randomized participants were included in the analysis. Intention-to-treat analysis using the last observation carried forward technique was adopted (Wood, White & Thompson, 2004). The final outcome measures of participants who withdrew from the study were imputed from data measured at the baseline, based on the assumption that the intervention would have had no effect.

The data were analyzed using the Statistical Package for Social Sciences (SPSS Inc., Chicago) version 17.0 for Windows. Descriptive statistics were used to count the frequency of the categorical variables, include demographic characteristics, health status, profile of urine leakage, coping strategies used, and baseline data. Inferential statistics were used to examine the differences in the effect of the interventions among the three groups before and after intervention. As severity of urine leakage was not normally distributed, non-parametric statistics were used. The Kruskal-Wallis Test was used to conduct a three-group comparison. The Mann-Whitney U Test was used to conduct an intra-group comparison of changes and the Chi-square

test for independence was used to determine the association of data with categorical variables. The level of statistical significance was set at 0.05. The level of statistical significance gives no indication as to whether an intervention has clinical implications. The relative change in the outcome measures was also calculated (Kazis, Anderson & Meenan, 1989; Wyrwich et al., 2005).

4.11 Ethical considerations

The study and its protocol were approved by the Human Subjects Ethics Sub-committee of the Hong Kong Polytechnic University and the ethical committee of the cluster to which the study hospital belongs. An information sheet that set out the purpose and significance of the study was given to the eligible participants (Appendix 4).

The participants were informed of their right to withdraw at any time before or during the study. They were assured that all information relating to them would be kept confidential and identified by a code only, and would be accessible only to the investigator and the investigator's supervisors. The participants were told not to undergo any other intervention to manage USI during the study period, except for the pelvic floor muscle training, to avoid obscuring the real effects of the intervention. A consent form was signed by the participants on a voluntary basis (Appendix 5).

The participants in the intervention and sham groups were encouraged to inform the investigator immediately and to seek medical advice if they experienced any physical

discomfort during the study period, including a heavy period, fever or flu-like symptoms, and low back pain. If participants experienced a heavy period or felt sick on the day of an intervention session, then the session was postponed and rescheduled. A name and contact telephone number was given to each participant for any enquiries about the study. Any adverse reactions occurring during the study were recorded.

4.12 Delimitation

4.12.1 Bias control

To avoid selection bias, the participants were allocated to the groups according to the random number generated by the computer software (Jűni, Altman & Egger, 2001). The single-blinded approach was adopted whereby participants in the intervention or placebo groups were unaware of the group that they were in. As the investigator performed the intervention and assessed the outcomes, objective outcome measures were included to avoid investigator bias (Schulz & Grimes, 2002).

Placebo control was planned to avoid nonspecific effects (Birch, 2006). However, nonspecific effects might also have been induced by a placebo response toward the sham intervention and the natural course of urinary incontinence. To address this problem, a usual-care control group was included in the study. Usual care in this case refers to pelvic floor training. The participants in the control group performed pelvic floor training at home, and no patient-practitioner interaction was involved.

4.12.2 Patient-practitioner interaction

The diagnostic process in Western medicine and TCM is different. Western medical diagnosis takes place before the intervention, whereas TCM practitioners make an initial diagnosis at the first visit and continue to revisit the diagnosis and intervention at each subsequent visit. The interaction between practitioner and participant may thus have an impact on the effect of acupressure (Paterson & Dieppe, 2005). In this study, a western diagnosis was made before the potential participants were invited to participate in the study, and the acupressure protocol was based on a general principle of intervention, rather than an individual syndrome-identification approach. In this way, confounding effects arising from the interaction between practitioner and participant were avoided.

To further avoid any effects arising from the interaction between practitioner and participant, no questions were asked about the participants' belief about the group to which they had been assigned (Kaptchuk et al., 2008). As the investigator was the only person who performed the intervention, the attitude of the investigator had to be the same in managing both the intervention and the sham groups. The frequency and the duration of contact time during the intervention were set to be the same for groups (Vas et al., 2006).

4.12.3 Recruitment

The APN in charge of the nurse-led urogynecology clinic at the study hospital was responsible for the screening and recruitment of potential participants for the study. As her job is to follow-up women with urinary incontinence in her clinic, she was in the best position to recruit potential participants at the hospital, which enhanced the recruitment rate.

4.12.4 Attrition

Attrition is always a threat to the internal validity of a study (Polgar & Thomas, 2000). As the participants were comparatively younger, they were mostly employed or housewives. The times for the intervention sessions were thus mutually agreed to minimize the upset to the daily activities of the participants in the intervention and sham groups. The control group (usual care) may well have had knowledge of the intervention allocation, which could have increased the attrition rate (Schulz & Grimes, 2002). An option of undergoing acupressure after the intervention was thus offered as an incentive to increase the retention rate for this group.

CHAPTER 5

THE PILOT STUDY

5.1 Introduction

A pilot study was conducted to determine the feasibility of the main study. The objectives of the pilot study were to ensure the feasibility of the data collection procedure, confirm the intervention protocol, and identify the effect size for the intervention to determine the sample size for the main study. The pilot study adopted a pre-experimental, before-after without control group design.

5.2 Method

5.2.1 Sampling

A convenience sample of sixteen participants was recruited from the urogynecology clinic of a local hospital. The criteria for recruiting the eligible participants were the same as in the main study, as set out in Chapter 4.

5.2.2 Procedures

Eligible participants were informed of the aim of the pilot study, and their written consent was obtained. The eligible participants were asked not to undergo any other

intervention for USI except for pelvic floor training during the study period to avoid confounding the effects of the intervention.

Demographic data on age, educational background, marital status, occupation, parity, menopause, body mass index (BMI), general health history, history of urine leakage, conditions inducing urine leaks, pad consumption, and coping strategies were obtained from the participants. In addition, the nature of the urinary syndrome of reach participant was determined by Cold-Heat Pattern Identification separately by two TCM practitioners before the intervention. A case conference was held to reach a consensus on the diagnosis for each participant.

The effect of the intervention was evaluated with subjective and objective outcome measurements at two-time points, one before and one after intervention. The subjective data included self-reported severity of urine leakage and quality of life. The objective data was the strength of the pelvic floor muscles and the results of a one-hour pad test (negative/positive). The participants also recorded the number of episodes of urine leakage for four days before and after intervention on a frequency volume chart.

The intervention was performed by the investigator in a consultation room in the SOPD of the hospital. The participants received a 30-minute acupressure intervention three times a week for a total of 30 times. Each session lasted around 30

minutes. The intervention was performed according to the validated acupressure protocol detailed in Chapter 4.

5.3 Results

5.3.1 Demographic characteristics of the participants

A total of fifteen participants completed the intervention in the pilot study. One of the participants withdrew because she could not afford the time to come to the intervention sessions. This resulted in a dropout rate of 6%.

In terms of age, 13.3% (n = 2) of the participants were aged between 31 and 40, 40% (n = 6) were aged between 41 and 50, and 46.7% (n = 7) were aged between 51 and 60. In total, 66.7% (n = 10) had received a secondary school education and 86.7% (n = 13) were married. All of them (100%; n = 15) had given birth to children, with 26.7% (n = 4) having one child, 53.3% (n = 8) having two children, and 20% (n = 3) having three children. In terms of employment, 46.7% (n=7) were working women or housewives and 6.7% (n = 1) were retired (see Table 5.1).

Table 5.1 Demographic characteristics of the participants

n=15	n (%)
Age	
31 - 40	2(13.3)
41-50	6(40)
51 - 60	7(46.7)
Marital Status	
Married	13 (86.7)
Divorced	1(6.7)
Widowed	1(6.7)
Educational level	
Primary level	1(6.7)
Secondary level	10 (66.7)
Tertiary level or above	4(26.7)
Occupation	
Non-labour work	7(46.7)
Housewife	7(46.7)
Retired	1 (6.7)
No. of parity	
1	4(26.7)
2	8(53.3)
3	3 (20)

5.3.2 General health condition

In total, 66.7% (n = 10) of the participants reported good general health. In terms of BMI, none of the participants were underweight, 53.3% (n = 8) had a BMI of between 18.5 and 22.9 kg/m^2, and 46.7% (n = 7) had a BMI of greater than 23 kg/m^2. Among the participants, 26.7% (n = 4) were in a postmenopausal state. None of the participants reported constipation, and none smoked or drank. Twenty per cent (n = 3) reported a chronic cough, 13.3% (n = 2) had a history of allergic rhinitis, and 80% (n = 12) reported having low back pain (see Table 5.2).

5.3.3 History of urine leakage and pad consumption

In all, 6.7% (n = 1) of the participants reported experiencing urine leakage for less than

one year, 46.7% (n = 7) reported experiencing urine leakage for between one and than five years, and 46.7% (n = 7) reported experiencing urine leakage for more than five years. In terms of pad usage, 66.7% (n = 10) of the participants reported using pads due to urine leakage. Of these, 46.7% (n = 7) consumed two to three pads per day, 13.3% (n = 2) consumed three to four pads per day, and 6.7% (n = 1) consumed one to two pads per day (see Table 5.2).

Table 5.2 General health conditions of the participants

n=15	n (%)
Self-reported health	
good	10 (66.7)
fair	4 (26.7)
poor	1(6.7)
Body Mass Index (kg/m^2)	
<18.5	0
18.5 – 22.9	8 (53.3)
>23	7 (46.7)
Post menopause	
No	11 (73.3)
yes	4 (26.7)
Bowel habit	
Normal	15(100)
Constipation	0
Diarrhea	0
Smoking habit	
No	15 (100)
yes	0
Drinking habit	
No	15(100)
yes	0
Chronic cough	
No	12(80)
yes	3 (20)
Allergic Rhinitis	
No	13 (86.7)
yes	2 (13.3)
Low back pain	
No	3 (20)
yes	12(80)
History of urine leak (year)	
<1	1 (6.7)
1 to < 5	7 (46.7)
≥ 5	7 (46.7)
Pad used:	
No	5 (33.3)
yes	10 (66.7)
No. of pad used (per day)	
0	5 (33.3)
1-2	1 (6.7)
2-3	7 (46.7)
3-4	2 (13.3)

5.3.4 Activities inducing urine leakage

All of the participants reported experiencing urine leakage during one or more activities, with 86.7% (n = 13) reporting urine leaks when coughing, 80% (n = 12) reporting leaks when sneezing, 26.7% (n = 4) reporting leaks when laughing, 26.7% (n = 4) reporting leaks during heavy lifting, 20% (n = 3) reporting leaks when nervous, 53.3% (n = 8) of participants reporting leaks when in a rush. Further, 13.3% (n = 2) reported leaks when walking, 13.3% (n = 2) reported leaks when stooping, 6.7% (n = 1) reported leaks when squatting, 20% (n = 3) reported leaks when jumping, and 20% (n = 3) reported leaks when running. Twenty per cent reported leaks in other situations such as climbing upstairs (6.7%, n = 1), dish washing (6.7%, n = 1), and sexual intercourse (6.7%, n = 1). A total of 53.3% (n = 8) of participants reported using coping strategies to minimize urine leaks (see Table 5.3).

Table 5.3 Symptoms of urine leakage

	n (%)
Sneezing	
no	3 (20)
yes	12 (80)
Coughing	
no	2 (13.3)
yes	13 (86.7)
Laughing	
no	11 (73.3)
yes	4 (26.7)
Heavy lifting	
no	11 (73.3)
yes	4 (26.7)
Nervousness	
no	12 (80)
yes	3 (20)
Rushing	
no	7 (46.7)
yes	8 (53.3)
Walking	
no	13 (86.7)
yes	2 (13.3)
Stooping	
no	13 (86.7)
yes	2 (13.3)
Squatting	
no	14 (93.3)
yes	1 (6.7)
Getting up from a chair	
no	15 (100)
yes	0
Jumping	
no	12 (80)
yes	3 (20)
Running	
no	12 (80)
yes	3 (20)
Other symptom	
Climbing upstairs	1 (6.7)
After dish washing	1 (6.7)
During sexual intercourse	1 (6.7)

All of the participants in the pilot study underwent Cold – Heat Pattern Identification by two TCM practitioners before the intervention, and 93.3% (n = 14) showed symptoms in cold pattern and 6.7% (n = 1) showed symptoms in heat pattern (see Table 5.4).

Table 5.4 Cold-Heat Pattern Identification

Pattern	N (%)
Heat	1 (6.7)
Cold	14 (93.3)

5.3.5 Evaluation of the intervention effect

All of the participants performed pelvic floor training during the study period. Before the intervention, the participants were asked to rate the severity of their urine leakage. Eighty per cent (n = 12) reported the severity to be moderate before intervention, whereas 66.7% (n = 10) rated the severity to be mild/occasional after intervention. This difference in the self-reported severity of urine leakage before and after intervention was statistically significant (z = - 3.05, p = 0.002).

The participants underwent a one-hour pad test before and after intervention. Before intervention, 33.3% (n = 5) returned a negative pad test (a pad gain of less than one gram in one hour), whereas 60% (n = 9) returned a negative test after intervention, but the difference was not statistically significant. The participants were asked to record the number of episodes of urine leaks in the four days before and after intervention. The mean number of episodes over four days was 3.9 (SD = 3.1)

before intervention and 1.5 (SD = 1.8) after intervention, and the difference was statistically significant (z = -2.84, p = 0.004). The pelvic floor muscle strength was measured before and after intervention. The mean pelvic floor muscle strength was 3.9 (SD = 2.6) before intervention and 5.7 (SD = 1.3) after intervention, and the difference was statistically significant (z = - 2.44, p = 0.015).

The quality of life of the participants was measured using the CKHQ (Appendix 3). The mean score for the impact of incontinence was 71.3 (SD = 21.3) before intervention and 19.4 (SD = 35.4) after intervention, and the difference was significant (z = - 3.12, p = 0.02). The mean total score for role limitation was 48.8 (SD = 19.4) before intervention and 25.5 (SD = 20.7) after intervention, and the difference was again statistically significant (z = - 3.21, p = 0.001). The mean total score for physical limitations was 53.2 (SD = 26.9) before intervention and 20 (SD = 20.1) after intervention, and the difference was statistically significant (z = - 3.24, p = 0.001). The mean total score for social limitations was 28 (SD = 20.2) before intervention and 5.9 (SD = 10.9) after intervention, and the difference was statistically significant (z = - 2.95, p = 0.003). The mean score for personal relationships was 24.4 (SD = 16.4) before intervention and 3.9 (SD = 9.3) after intervention, and the difference was significantly significant (z = - 3.00, p = 0.003). The mean score for emotional problems was 37.8 (SD = 21.1) before intervention and 13.2 (SD = 13.3) after intervention. The difference was statistically significant (z = - 2.94, p = 0.003). The mean score for sleep/energy disturbance was 32.3 (SD = 21.3) before intervention and 5.53 (SD = 12) after intervention, and the difference

was statistically significant (z = - 3.14, p = 0.002). In sum, there was a statistically significant difference in the scores for all of the domains in the questionnaire (see Table 5.5).

Table 5.5 Comparison of outcome variables before and after intervention

	Before		After			
	Mean/SD	N (%)	Mean/SD	N (%)	*z*	*p-value*
Self-reported severity of urine leak					-3.05	0.002*
Mild/occasional		1(6.7)		10(66.7)		
Moderate		12(80)		5(33.3)		
Severe		2 (13.3)				
One-hour pad test						
Negative		5(33.3)		9(60)	2.14 #	0.143
Positive (>1 gm)		10 (66.7)		6(40)		
Episode of urine leaks (4 days)	3.9 (3.1)		1.5(1.8)		-2.84	0.004*
Pelvic floor muscle strength (mmHg)	3.9 (2.6)		5.7(1.3)		-2.44	0.015*
KHQ (Chinese version)						
Incontinence impact	71.3(21.3)		35.4(19.4)		-3.12	0.002*
Role limitations	48.8(19.4)		25.5(20.7)		-3.21	0.001*
Physical limitations	53.2(26.9)		20(20.1)		-3.24	0.001*
Social limitations	28(20.2)		5.9(10.9)		-2.95	0.003*
Personal relationships	24.4(16.4)		3.3(9.3)		-3	0.003*
Emotional problems	37.8(21.1)		13.2(13.3)		-2.94	0.003*
Sleep/energy disturbance	32.3(21.3)		5.53(12)		-3.14	0.002*

Chi-square Test
* $p \leq 0.05$ for Wilcoxon Signed RankTest

5.4 Implications of the pilot study

5.4.1 Feasibility of the data collection procedure

The pilot study showed that the questionnaires adopted in the study were appropriate, and that both the objective and subjective measurements of the effects of the

intervention were suitable. The recruitment of participants by an APN in the urogynecology clinic was also found to be effective. Most of the participants found the duration of the course of intervention to be suitable, and one or two even requested a second round of intervention.

Some of the participants were concerned about the venue for the intervention sessions, especially the working women. Most of the participants had to work in the daytime, and could not afford to take time off three times per week to attend the intervention sessions. It was decided that an alternative venue and time were needed, and the integrated health clinic at a local university was explored as a more convenient location for the intervention sessions for the main study.

5.4.2 Confirmation of the intervention protocol

Fifteen out of the 16 participants in the study presented similar clinical manifestations of cold pattern, including a comparatively white facial complexion, a pale tongue with a white coating, a tight or slow in pulse, intolerance to cold, cold limbs, the voiding of clear urine, and no complaint of constipation but loose stools. Cold pattern caused by deficiency of yang was confirmed to be the main syndrome of these women with USI. This indicated that the principle of the intervention of strengthening of kidney yang and the movement of qi should be promoted by the acupressure protocol.

5.4.3 Determination of the effect size and sample size for the main study

The pilot study was partly conducted to calculate the Pearson's r to determine the effect size for the main study (Bausell & Li, 2002). The equation used was as follows.

$$\text{Effect Size} = \frac{\text{Mean difference}}{\text{Pooled standard deviation}}$$

$$\text{Pooled Standard Deviation} = \sqrt{\frac{(n_1-1)S^2_1+(n_2-1)S^2_2}{(n_1+n_2+2)}}$$

where

n_1 = number of participants at pre-test,

n_2 = number of participants at post-test,

S^2_1 = variance in the outcome measures at pre-test, and

S^2_2 = variance in the outcome measures at post-test.

According to the preliminary results of the pilot study, the effect sizes of the outcome variables ranged from 0.92 to 1.74 (see Table 5.6). The effect size for pelvic floor muscle strength was used to determine the sample size of the main study. It was calculated that a sample size of n = 25 would detect an effect size of 0.92 with a power of 94% at an alpha level at 0.05, and a 6% of dropout rate should be considered. It was thus concluded that 27 participants would be needed in each group in the main study.

Table 5.6 Calculation of effect size by outcome variables

Outcome variable	Effect size	power	n
Pelvic floor muscle strength	0.92	94	25
Self-reported severity of urine leakage	1.5	90	8
One-hour pad test	NA	NA	NA
Episodes of urine leakage	0.97	90	15
Impact of incontinence	1.74	93	7
Role limitations	1.16	93	7
Physical limitations	1.4	90	8
Social limitations	1.37	92	11
Personal relationships	1.58	90	8
Emotional problems	1.39	92	11
Sleep/energy disturbance	1.55	90	8
Severity measures	1.50	90	8

NA = not applicable.

5.5 Summary

The preliminary findings from the pilot study were encouraging. The self-reported severity of urine leakage and number of episodes of urine leakage over four days were reduced, and the self-reported severity of urine leakage was improved. There was no statistically significant difference in the pad test before and after intervention,

but the strength of the pelvic floor muscles was found to have increased. Improvement was demonstrated in all of the domains in the CKHQ after intervention.

The pilot study examined one group of participants using a convenience sampling method, and the sample size was small. The results on the effects of the intervention were thus inconclusive. It was determined that the real effect of the intervention would need to be further explored in the main study, which would include a sham group and a control group and the random assignment of participants to the various groups. It was identified that an additional venue would be needed for the intervention sessions, and that the time of the sessions should be extended to non office hours. No further revision of the instruments was found to be necessary, and the feasibility of launching a larger scale study was confirmed.

CHAPTER 6

RESULTS OF THE MAIN STUDY

6.1 Introduction

This chapter reports the findings on the demographic characteristics, general health status, profile of urine leakage, and coping strategies of the participants in the main study. The effects of the intervention are compared among the intervention group, sham group, and control group both objectively and subjectively. The objective outcome measurements include pelvic floor muscle strength and the one-hour pad test, and the subjective outcome measurements included self-reported severity of urine leakage, number of episodes of urine leakage over four days, and impact on quality of life according to the validated Chinese version of the King's Health Questionnaire. Pelvic floor muscle strength was the primary outcome. The results for the primary outcome and secondary outcome are examined and compared.

6.2 Recruitment and response rate

Eighty-one participants were successfully recruited and randomized. All were recruited from the urogynecology clinic of a local acute hospital between March 2007 and January 2010. One hundred and sixty-one women were diagnosed as having USI at the clinic between 2006 and 2009. According to the selection criteria, sixty-five women were excluded from the study. Ninety-six eligible participants

diagnosed with USI were invited to participate in the main study. Fifteen women refused to participate, mostly because they were too busy with their job and family. Three women refused because of physical problems: one had just undergone major heart surgery and another two were experiencing knee pain and low back pain at the time of recruitment. Two women refused to take part in the test of pelvic floor muscle strength because they were virgins (see Table 6.1).

Table 6.1 Reasons for refusal to participate in the study

Reason	Number of refusal
Had to take care of young children at home	1
Worked during the day and took care of family members at night	1
Long working hours	2
Too busy to deal with a new job and the intervention at the same time	1
Busy	1
Physical problems	3
Did not want to take part in the test for pelvic floor muscle strengths	2
No need for treatment	1
No reason given	3
Total	15

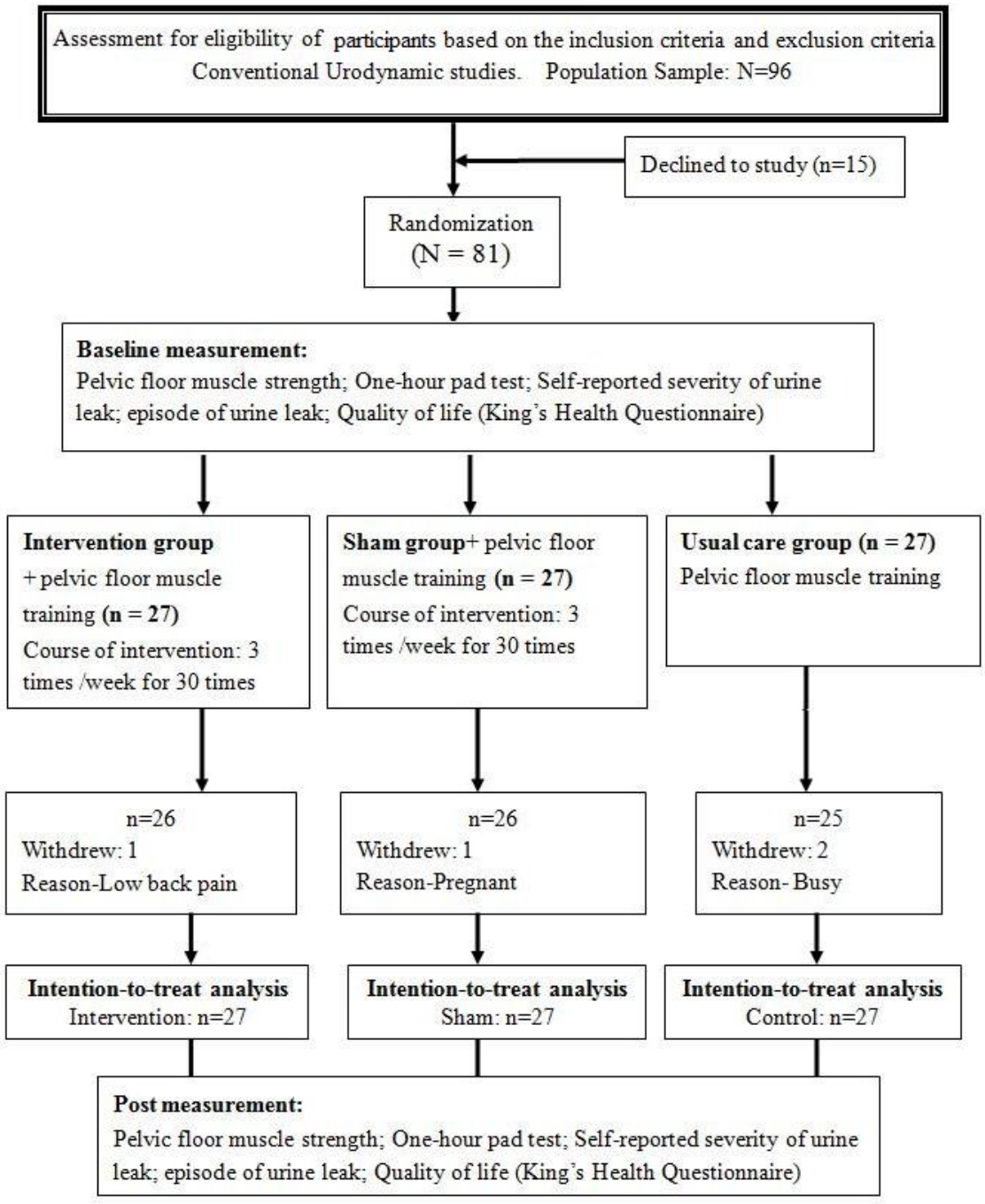
6.2.1 Reasons for withdrawal

Five participants withdrew during the study period, one from the intervention group, one from the sham group, and two from the control group. This gave a dropout rate of 4.9%. No adverse effects were reported during the intervention. The participant from the intervention group withdrew due to low back pain. The participant from the sham group withdrew due to suspected pregnancy. The two participants from the control group withdrew because they could not afford the time to undertake the pelvic floor training. As the estimated dropout rate in the pilot study was included in the calculation of the sample size for the main study, the estimated sample size was still achieved despite the withdrawals.

6.2.2 Intention-to-treat analysis

All of the randomized participants were included in the analysis of the results. The last observation carried forward technique was adopted to ensure complete case analysis (Wood, White & Thompson, 2004), based on the assumption that the intervention would have had no effect. The final observations of the participants who withdrew from the study were imputed from the data measured at the baseline before intervention (Figure 6.1).

Figure 6.1 Recruitment, Retention and Group Allocation of Participants during the study



6.3 Baseline information on the participants

6.3.1 Demographic characteristics

The participants were randomized into three groups, with 27 participants in each group. There were no significant differences in the demographic characteristics, general health status, or profile of urine leakage among the groups. Most of the participants were aged between 41 and 60 years old, but 48.1% (n = 13) of the intervention group, 70.4% (n = 19) of the sham group, and 40.7% (n = 11) of the control group were aged between 51 and 60 years. Most of the participants had attained at least a secondary school education: 48.1% (n = 13) in the intervention group, 53% (n = 17) in the sham group, and 59.3% (n = 16) in the control group. In terms of family size, 81.5% (n = 22) of the intervention group, 77.8% (n = 21) of the sham group, and 88.9% (n = 24) of the control group were married; and 59.3% (n = 16) of the intervention group, 55.6% (n = 15) of the sham group, and 40.7% (n = 11) of the control group had given birth to two children. The majority of the participants were either working women or housewives, with 44.4% (n = 12) of the intervention group, 40.7% (n = 11) of the sham group, and 51.9% (n = 14) of the control group being housewives. The majority of the participants were overweight, with 66.7% (n = 18) of the intervention group, 70.4% (n = 19) of the sham group, and 74.1% (n = 20) of the control group having a BMI of equal to or greater than 23 kg/m^2. None of the participants was underweight (BMI of less than 18.5 kg/m^2). Among the participants, 59.3% (n = 16) of the intervention group, 55.6% (n = 15) of the sham group, and 59.3% (n = 16) of the control group were not yet menopausal.

In total, 44.4% (n = 12) of the intervention group, 66.7% (n = 18) of the sham group, and 70.4% (n = 19) of the control group reported having a fair general health condition. Further, 7.4% (n = 2) of the control group reported a smoking habit and 7.4% (n = 2) of the sham group reported regular alcohol consumption. Otherwise, most of the participants did not smoke or drink alcohol. Most of the participants reported having normal bowel habits, but 3.7% (n = 1) of the intervention group, 11.1% (n = 3) of the sham group, and 3.7% (n = 1) of the control group reported having constipation.

In terms of concomitant medical problems, 14.8% (n = 4) of the intervention group, 22.2% (n = 6) of the sham group, and 18.5% (n = 5) of the control group reported having a chronic cough. Moreover, 14.8% (n = 4) of the intervention group, 7.4% (n = 2) of the sham group, and 25.9% (n = 7) of the control group reported having allergic rhinitis, with 3.7% (n = 1) of the sham group and control group reporting a history of sinusitis with surgery. A further 66.7% (n = 18) of the intervention group, 40.7% (n = 11) of the sham group, and 55.6% (n = 15) of the control group reported low back pain (see Table 6.2).

Table 6.2 Demographic characteristics of the participants

	Total	n=81	Intervention	n = 27	Sham	n=27	Control	n=27		
	Frequency	%	Frequency	%	Frequency	%	Frequency	%	*H*	*p*
Age (range of years)									3.95	0.14
21-30	1	1.2					1	3.7		
31-40	4	4.9	2	7.4	2	7.4				
41-50	33	40.7	12	44.4	6	22.2	15	55.6		
51-60	43	53.1	13	48.1	19	70.4	11	40.7		
Highest education level									4.91	0.09
No education	6	7.4	2	7.4	1	3.7	3	11.1		
No formal education	1	1.2					1	3.7		
Primary level	18	22.2	6	22.2	5	18.5	7	25.9		
Secondary level	46	56.8	13	48.1	17	63.0	16	59.3		
Tertiary level or above	10	12.3	6	22.2	4	14.8				
Classification of Occupation									0.77	0.68
Labour	8	9.9	2	7.4	2	7.4	4	14.8		
Non-labour	31	38.3	10	37.0	12	44.4	9	33.3		
Housewife	37	45.7	12	44.4	11	40.7	14	51.9		
Retired	4	4.9	2	7.4	2	7.4				
Unemployed	1	1.2	1	3.7						
Marital status									0.94	0.63
Single	2	2.5			2	7.4				
Married	67	82.7	22	81.5	21	77.8	24	88.9		
Divorced	9	11.1	4	14.8	3	11.1	2	7.4		
Widowed	3	3.7	1	3.7	1	3.7	1	3.7		
BMI range based on Asian									0.35	0.84
18.5 - 22.9	24	29.6	9	33.3	8	29.6	7	25.9		
>23	57	70.4	18	66.7	19	70.4	20	74.1		
Parity										
No child	4	4.9			4	14.8			1.24	0.54
One child	14	17.3	4	14.8	3	11.1	7	25.9		
Two children	42	51.9	16	59.3	15	55.6	11	40.7		
Three children	14	17.3	6	22.2	2	7.4	6	22.2		
Four children	6	7.4	1	3.7	3	11.1	2	7.4		
Five children	1	1.2					1	3.7		

H: Kruskal-Wallis Test

Table 6.2 cont'd

	Total	n=81	Intervention	n=27	Sham	n=27	Control	n=27		
	Frequency	%	Frequency	%	Frequency	%	Frequency	%	*H*	*p*
Menopause									0.10	0.95
No	47	58.0	16	59.3	15	55.6	16	59.3		
Yes	34	42.0	11	40.7	12	44.4	11	40.7		
Past health history									0.16	0.46
Good	23	28.4	11	40.7	7	25.9	5	18.5		
Fair	49	60.5	12	44.4	18	66.7	19	70.4		
Poor	9	11.1	4	14.8	2	7.4	3	11.1		
Habit of smoking									0.45	0.13
No	79	97.5	27	100.0	27	100.0	25	92.6		
Yes	2	2.5					2	7.4		
Alcohol consumption									0.49	0.13
No	79	97.5	27	100.0	25	92.6	27	100.0		
Yes	2	2.5			2	7.4				
Chronic cough									3.28	0.19
No	66	81.5	23	85.2	21	77.8	22	81.5		
Yes	15	18.5	4	14.8	6	22.2	5	18.5		
Allergic rhinitis									4.05	0.79
No	68	84.0	23	85.2	25	92.6	20	74.1		
Yes	13	16.0	4	14.8	2	7.4	7	25.9		
Sinusitis with operation done									3.44	0.18
No	79	97.5	27	100.0	26	96.3	26	96.3		
Yes	2	2.5			1	3.7	1	3.7		
Bowel habit									1.01	0.60
Normal	75	92.6	26	96.3	23	85.2	26	96.3		
Constipation	5	6.2	1	3.7	3	11.1	1	3.7		
Diarrhea	1	1.2			1	3.7				
Low back pain									3.64	0.16
No	37	45.7	9	33.3	16	59.3	12	44.4		
Yes	44	54.3	18	66.7	11	40.7	15	55.6		

H: Kruskal-Wallis Test

6.3.2 Urine leakage profile

Among the participants, 48.1% (n = 13) of the intervention group, 44.4% (n = 12) of the sham group, and 25.9% (n = 7) of the control group had a history of urine leakage of a duration of at least one year to more than five years.

In total, 74.1% (n = 20) of the participants in each group used a pad for urine leakage. Among them, 44.4% (n = 12) in the intervention group, 40.7% (n = 11) in the sham group, and 25.9% (n = 7) in the control group consumed two to three pads per day. Further, 51.9% (n = 14) of the intervention group, 51.9% (n = 14) of the sham group, and 63% (n = 17) of the control group had developed coping strategies to avoid episodes of urine leakage. Of the various activities that may induce urine leakage, coughing and sneezing were the most frequently reported (see Table 6.3).

Table 6.3 Urine leakage profile

	Total	n=81	Intervention	n=27	Sham	n=27	Control	n=27		
	Frequency	(%)	Frequency	(%)	Frequency	(%)	Frequency	(%)	*H*	*p*
History of leakage of urine									1.66	0.54
< 1 year	8	(9.9)	2	(7.4)	3	(11.1)	3	(11.1)		
1 and < 5 years	32	(39.5)	13	(48.1)	12	(44.4)	7	(25.9)		
5 or > 5 years	41	(50.6)	12	(44.4)	12	(44.4)	17	(63.0)		
Are pads used?									0	1.00
No	21	(25.9)	7	(25.9)	7	(25.9)	7	(25.9)		
Yes	60	(74.1)	20	(74.1)	20	(74.1)	20	(74.1)		
Number of pads used per day									1.89	0.39
0	21	(25.9)	7	(25.9)	7	(25.9)	7	(25.9)		
1-2	21	(25.9)	3	(11.1)	11	(40.7)	7	(25.9)		
2-3	25	(30.9)	12	(44.4)	6	(22.2)	7	(25.9)		
3-4	8	(9.9)	3	(11.1)	2	(7.4)	3	(11.1)		
4-5	4	(4.9)	2	(7.4)	1	(3.7)	1	(3.7)		
5-6	1	(1.2)					1	(3.7)		
6-7	1	(1.2)					1	(3.7)		
Activity induced urine leaks									NA	NA
Coughing	75	(92.6)	24	(88.9)	26	(96.3)	25	(92.6)		
Sneezing	70	(86.4)	22	(81.5)	24	(88.9)	24	(88.9)		
Laughing	37	(45.7)	10	(37.0)	12	(44.4)	15	(55.6)		
Lifting heavy objects	16	(19.8)	6	(22.2)	5	(18.5)	5	(18.5)		
Nervou	10	(12.3)	5	(18.5)	4	(14.8)	1	(3.7)		
Rushing	36	(44.4)	14	(51.9)	9	(33.3)	13	(48.1)		
Walking	6	(7.4)	3	(11.1)	1	(3.7)	2	(7.4)		
Stooping	7	(8.6)	4	(14.8)	1	(3.7)	2	(7.4)		
Squatting	9	(11.1)	3	(11.1)	1	(3.7)	5	(18.5)		
Getting up from a chair	5	(6.2)	2	(7.4)	3	(11.1)				
Jumping	32	(39.5)	5	(18.5)	11	(40.7)	16	(59.3)		
Running	33	(40.7)	8	(29.6)	12	(44.4)	13	(48.1)		
Other activities	12	(14.8)	3	(11.1)	4	(14.8)	5	(18.5)		
climbing stairs (down)	1	(1.2)	1	(3.7)						
during menstruation	2	(2.5)			1	(3.7)	1	(3.7)		
leakage after washing dishes	1	(1.2)	1	(3.7)						
nausea	1	(1.2)					1	(3.7)		
nausea during teeth brushing	2	(2.5)			1	(3.7)	1	(3.7)		
sexual intercourse	1	(1.2)	1	(3.7)						
swimming	1	(1.2)			1	(3.7)				
tracing bus	3	(3.7)			1	(3.7)	2	(7.4)		
Coping strategy									0.89	0.54
No	36	(44.4)	13	(48.1)	13	(48.1)	10	(37.0)		
Yes	45	(55.6)	14	(51.9)	14	(51.9)	17	(63.0)		

H: Kruskal-Wallis Test

6.3.3 Coping strategies

Among the participants who had developed a coping strategy, some had adopted more than one. The most frequently reported coping strategy was to avoid jumping and running activities. Some of the participants (n = 3) visited the toilet more frequently to avoid episodes of urine leakage (see Table 6.4).

Table 6.4 Coping strategies of the participants

NOT TO DO LIST	Frequency
Avoid jumping and related activities e.g. badminton, dancing, rubber band, skipping	22
Avoid running and related activities e.g. bus tracing	22
Avoid heavy lifting	2
Avoid swimming	2
Avoid wearing light colour trousers or bring along extra trousers	2
Control or avoid laughing	2
Avoid sexual activity	1
Avoid job seeking	1
Avoid bending knees	1
Avoid stooping	1
TO DO LIST	
Increase frequency of toileting	3
Wear pads whenever suffer from flu	2
Try to cross legs during coughing	1
Stand still before sneezing	1
Restrict fluid intake whenever going out	1

6.4 Comparison of the outcome measures for the three groups before and after intervention

After intervention, a single question of whether the participants practiced pelvic floor muscle training during the study period was included. 92.3 % (n = 24) of the intervention group, 84.6% (n = 22) of the sham group, and 92% (n = 23) of the control group reported of performing pelvic floor muscle training during the study.

As the data on severity of urine leakage were not normally distributed, non-parametric tests were employed to compare the outcomes for the three groups. Different statistical tests were used for different types of variables, such as nominal, rank, and interval variables. A comparison of the sham and control groups was conducted to identify the true effects of the intervention in terms of the various outcome measures.

6.4.1 Overall comparison of physiological outcomes

The Kruskal-Wallis Test was used to compare the difference in pelvic floor muscle strength, self-reported severity of urine leakage, and number of episodes of urine leakage among the intervention group, sham group, and control group before and after the intervention. There was no statistically significant difference in pelvic floor muscle strength, self-reported severity of urine leakage, and number of episodes of urine leakage over four days among the three groups before the intervention.

After the intervention, there was a statistically significant difference in pelvic floor muscle strength (H = 7.05, p = 0.03) in all three groups, but no significant difference in self-reported urine leakage or number of episodes of urine leakage. The intervention group had the highest overall ranking for pelvic floor muscle strength after the intervention and the lowest overall ranking for number of episodes of urine leakage. The sham group had the lowest ranking for self-reported severity of urine leakage (see Table 6.5).

Table 6.5 Comparison of the outcome measures for the three groups before and after intervention by Kruskal-Wallis test

		Before				After		
	group	N	Mean Rank	*H*	*p*	Mean Rank	*H*	*p*
Pelvic floor muscle strength (in mmHg)	intervention	27	38.02	0.739	0.69	50.48	7.053	0.03*
	sham	27	43.09			36.07		
	control	27	41.89			36.44		
Self-reported severity of urine leakage	intervention	27	46.30	3.717	0.16	33.11	5.450	0.07
	sham	27	41.35			44.67		
	control	27	35.35			45.22		
Numbers of episodes of urine leakage	intervention	27	42.81	0.489	0.78	36.72	3.314	0.19
	sham	27	41.63			38.87		
	control	27	38.56			47.41		

*significant at $p \leq 0.05$

6.4.2 Comparison of the one-hour pad test results

A Chi-square test for independence was used to compare the one-hour pad test results (negative/positive) of the three groups before and after intervention. Before the intervention, 40.7% (n = 11) of the intervention group, 59% (n = 16) of the sham group, and 70% (n = 19) of the control group returned a negative pad test. The

association was not significant. After the intervention, 70.4% (n = 19) of the intervention group, 59.3% (n = 16) of the sham group, and 66.7% (n = 18) of the control group returned a negative pad test. Again, the association was not significant (see Table 6.6).

Table 6.6 Comparison of the one-hour pad test results of the three groups before and after intervention by Chi-square test for independence

	Before								After							
	Intervention		Sham		Control				Intervention		Sham		Control			
	n	%	n	%	n	%	X^2	*p*	n	%	n	%	n	%	X^2	*p*
Pad test negative	11	40.7	16	59	19	70	4.93	0.08	19	70.4	16	59.3	18	66.7	0.764	0.68
positive	16	59.3	11	41	8	30			8	29.6	11	40.7	9	33.3		

6.4.3 Comparison of the King's Health Questionnaire (Chinese version) results

The Kruskal-Wallis test was used to compare the differences in the various domains of the CKHQ among the intervention group, sham group, and control group before and after the intervention. There were significance differences in the domains of role limitations (H = 7.29, p = 0.03), social limitations (H = 8.64, p = 0.01), personal limitations (H = 10.56, p = 0.01), emotional problems (H = 12.36, p = 0.00), and sleep/energy disturbance (H = 9.55, p = 0.01) among the groups before the intervention. The intervention group had the highest overall ranking for all of the domains before intervention, meaning that their symptoms had the most negative impact on quality of life. There was no significant difference in the impact of

incontinence, physical limitations, or severity measures among the groups before intervention. After intervention, there were significant differences in the physical limitations (H = 8.93, p = 0.01) and personal limitations (H = 7.85, p = 0.02) domains among the groups. The intervention group had the lowest overall ranking for physical limitations and personal limitations after intervention, corresponding to the least negative impact of their symptoms on quality of life. There was no significant difference in the impact of incontinence, role limitations, social limitations, emotional problems, sleep/energy disturbance, or severity measures among the groups after intervention (see Table 6.7).

Table 6.7 Comparison of the King's Health Questionnaire (Chinese version) results of the three groups before and after intervention by Kruakal-Wallis test

Domain		Before			After		
	Group	Mean Rank	*H*	*p*	Mean Rank	*H*	*p*
Incontinence impact	intervention	44.48	1.199	0.55	36.06	4..486	0.11
	sham	39.78			39.22		
	control	38.74			47.72		
Role limitations	intervention	49.81	7.287	0.03*	37.37	2.328	0.31
	sham	33.07			39.30		
	control	40.11			46.33		
Physical limitations	intervention	46.07	2.141	0.34	36.11	8.928	0.01*
	sham	37.07			35.33		
	control	39.85			51.56		
Social limitations	intervention	51.17	8.644	0.01*	35.52	3.641	0.16
	sham	38.44			40.96		
	control	33.39			46.52		
Personal relationships	intervention	51.33	10.557	0.01*	38.39	7.853	0.02*
	sham	35.70			36.85		
	control	35.96			47.76		
Emotional problems	intervention	52.70	12.364	0.00*	35.65	2.374	0.31
	sham	39.54			42.63		
	control	30.76			44.72		
Sleep/energy disturbance	intervention	50.98	9.551	0.01*	38.89	3.370	0.19
	sham	34.57			38.41		
	control	37.44			45.70		
Severity measures	intervention	46.15	2.286	0.32	34.30	5.095	0.08
	sham	36.65			40.17		
	control	40.20			48.54		

* significant at $P \leq 0.05$

6.5 Two-group comparison of the outcome measures before and after intervention

The statistical tests of the three-group comparison showed that the intervention had a definite effect on pelvic floor muscle strength in the intervention group. However, as there were significant differences in most of the domains of the CKHQ among the three groups before intervention, it was difficult to draw any conclusions on the

effect of the intervention on the CKHQ scores. The domain of physical limitations was the only domain to demonstrate no significant difference before but a significant difference after intervention across the groups. The sham group and control group were included in the study to decrease the chance of confounding effects. However, it was necessary to check the differences between these two groups to isolate the placebo effect.

6.5.1 Comparison of the intervention and sham groups before and after intervention

6.5.1.1 Comparison of physiological outcomes

The Mann-Whitney U test was used to compare the differences in outcome variables between the intervention group and sham group before and after intervention. There were no statistically significant differences in self-reported severity of urine leakage, pelvic floor muscle strength, one-hour pad test, or number of episodes of urine leakage between the two groups before intervention. However, there were significant differences in pelvic floor muscle strength (U = -2.31, p = 0.02) and self-reported severity of urine leakage (U = -2.06, p = 0.04) between the two groups after intervention, with the intervention group having the highest overall ranking for pelvic floor muscle strength.

The intervention group had a lower overall ranking for self-reported severity of urine leakage than the sham group after intervention. However, there was no significant

difference in the number of episodes of urine leakage between the two groups after intervention (see Table 6.8).

Table 6.8 Comparison of the outcome measures for the intervention and sham groups before and after intervention by Mann-Whitney U test

		Before				After			
	group	Mean Rank	Mann-Whitney U	Z	p	Mean Rank	Mann-Whitney U	Z	p
Pelvic floor muscle strength (mmHg)	Intervention	25.80	318.500	-.824	0.41	32.31	234.500	-2.310	0.02*
	sham	29.20				22.69			
Self-reported severity of urine leakage	Intervention	29.13	320.500	-.865	0.39	23.83	255.000	-2.064	0.04*
	sham	25.87				31.17			
Number of episodes of urine leakage	Intervention	27.94	352.500	-.210	0.83	26.91	348.500	-.289	0.77
	sham	27.06				28.09			

* significant at $P \leq 0.05$

6.5.1.2 Comparison of the one-hour pad test results

A Chi-square test for independence was used to compare the results of the one-hour pad test results of the intervention group and sham group before and after intervention. In total, 40.7% (n = 11) of the intervention group and 59% (n = 16) of the sham group returned a negative pad test before intervention. The difference was not significant. After intervention, 70.4% (n = 19) of the intervention group and 59.3% (n = 16) of the sham group returned a negative pad test, but again the difference was not significant (see Table 6.9).

Table 6.9 Comparison of the one-hour pad test results of the intervention and sham groups before and after intervention by Chi-square test for independence

		Before						After					
		Intervention		Sham				Intervention		Sham			
		n	%	n	%	X^2	*p*	n	%	n	%	X^2	*p*
Pad test	negative	11	40.7	16	59	1.82	0.17	19	70.4	16	59.3	0.73	0.39
	positive	16	59.3	11	41			8	29.6	11	40.7		

6.5.1.3 Comparison of the King's Health Questionnaire (Chinese version) results

The Mann-Whitney U test was used to compare the differences in the various domains of the CKHQ between the intervention group and sham group before and after intervention. Before intervention, there were no significant differences in the domains of impact of incontinence, physical limitations, social limitations, and severity between the two groups. However, there were significant differences in the domains of role limitations (U = -2.49, p = 0.01), personal relationships (U = -2.65, p = 0.01), emotional problems (U = -2.15, p = 0.03), and sleep/energy disturbance (U = -2.77, p = 0.01). Before intervention, the intervention group had the highest overall ranking for role limitations, personal relationships, emotional problems, and sleep/energy disturbance, corresponding to the most negative impact on quality of life before intervention. However, after intervention there were no significant differences in any of the domains of the CKHQ between the intervention group and the sham group (see Table 6.10).

Table 6.10 Comparison of the King's Health Questionnaire (Chinese version) results of the intervention and sham groups before and after intervention by Mann-Whitney U test

		Before				After			
Domain	group	Mean Rank	Mann-Whitney U	Z	*p*	Mean Rank	Mann-Whitney U	Z	*p*
Incontinence impact	Intervention	29.04	323.000	-0.799	0.42	26.41	335.000	-0.586	0.56
	sham	25.96				28.59			
Role limitations	Intervention	32.72	223.500	-2.493	0.01*	26.81	346.000	-0.335	0.74
	sham	22.28				28.19			
Physical limitations	Intervention	30.39	286.500	-1.367	0.17	27.89	354.000	-0.196	0.85
	sham	24.61				27.11			
Social limitations	Intervention	31.54	255.500	-1.923	0.06	25.63	314.000	-1.012	0.31
	sham	23.46				29.37			
Personal relationships	Intervention	32.57	227.500	-2.652	0.01*	28.02	350.500	-0.482	0.63
	sham	22.43				26.98			
Emotional problems	Intervention	32.02	242.500	-2.149	0.03*	25.20	302.500	-1.122	0.26
	sham	22.98				29.80			
Sleep/energy disturbance	Intervention	32.87	219.500	-2.770	0.01*	27.65	360.500	-0.112	0.91
	sham	22.13				27.35			
Severity measures	Intervention	30.52	283.000	-1.425	0.15	25.41	308.000	-0.989	0.32
	sham	24.48				29.59			

*significant at $p \leq 0.05$

6.5.2 Comparison of the intervention group and control group before and after intervention

6.5.2.1 Comparison of physiological outcome measures

The Mann-Whitney U test was used to compare the differences in outcome measures between the intervention group and control group before and after intervention. There were no significant differences in pelvic floor muscle strength, self-reported severity of urine leakage, and number of episodes of urine leakage between the two groups before intervention. After intervention, however, there were significant differences in pelvic floor muscle strength (U = -2.25, p = 0.02) and self-reported severity of urine leakage (U = -2.48, p = 0.01) between the intervention group and

control group, with the intervention group showing a higher overall ranking in these domains than the control group, corresponding to an increase in pelvic floor muscle strength. The intervention group also had a lower overall ranking for severity of urine leakage than the control group after intervention. There was no significant difference in the number of episodes of urine leakage between the intervention group and the control group after intervention (see Table 6.11).

Table 6.11 Comparison of the outcome measures for the intervention and control groups before and after intervention by Mann-Whitney U test

		Before					After			
	group	N	Mean Rank	Mann-Whitney U	Z	*p*	Mean Rank	Mann-Whitney U	Z	*p*
Pelvic floor muscle strength (mmHg)	intervention	27	26.22	330.000	-.618	0.54	32.17	238.500	-2.253	0.02*
	control	27	28.78				22.83			
Self-reported severity of urine leakage	intervention	27	31.17	265.500	-1.936	0.53	22.81	238.000	-2.479	0.01*
	control	27	23.83				32.19			
Number of episodes of urine leakage	intervention	27	28.87	327.500	-.653	0.51	23.81	265.000	-1.759	0.08
	control	27	26.13				31.19			

*significant at $p \leq 0.05$

6.5.2.2 Comparison of one-hour pad test results

A Chi-square test for independence was used to compare the results of the one-hour pad test of the intervention group and control group before and after intervention. The comparison showed that 40.7% (n = 11) of the intervention group and 70% (n = 19) of the control group returned a negative pad test before intervention. The association was not significant. After intervention, 70.4% (n = 19) of the intervention group and 66.7% (n = 18) of the control group returned a negative pad test, and again the association was not significant (see Table 6.12).

Table 6.12 Comparison of the one hour pad test results of the intervention and control groups before and after intervention by Chi-square test for independence

		Before						After					
		Intervention		Control				Intervention		Control			
		n	%	n	%	X^2	*p*	n	%	n	%	X^2	*p*
Pad test	negative	11	40.7	19	70	4.8	0.03*	19	70.4	18	66.7	0.09	0.77
	positive	16	59.3	8	30			8	29.6	9	33.3		

* significant at p≤0.05

6.5.2.3 Comparison of the King's Health Questionnaire (Chinese version) results

The Mann-Whitney U test was used to compare the differences in the CKHQ results of the intervention group and control group before and after intervention. There was no significant difference between the two groups in the domains of impact of incontinence, role limitations, physical limitations, and severity before intervention, but there were significant differences in the domains of social limitations (U = -2.94, p = 0.00), personal relationships (U = -2.73, p = 0.01), emotional problems (U = -3.42, p = 0.00), and sleep/energy disturbance (U = -2.34, p = 0.02). After intervention, there were no significant differences between the two groups in the domains of role limitations, social limitations, emotional problems, and sleep/energy disturbance, but there were significant differences in impact of incontinence (U = -2.01, p = 0.04), physical limitations (U = -2.55, p = 0.01), personal relationships (U = -2.01, p = 0.04), and severity (U = - 2.17, p = 0.03) after intervention, with the intervention group showing the lowest overall ranking across these domains, which corresponded to the least impact of symptoms on quality of life (see Table 6.13).

Table 6.13 Comparison of the King's Health Questionnaire (Chinese version) results of the intervention and control groups before and after intervention by Mann-Whitney U test

		Before					After			
Domain	group	N	Mean Rank	Mann-Whitney U	Z	*p*	Mean Rank	Mann-Whitney U	Z	*p*
Incontinence impact	intervention	27	29.44	312.000	-1.044	0.30	23.65	260.500	-2.011	0.04*
	control	27	25.56				31.35			
Role limitations	intervention	27	31.09	267.500	-1.737	0.08	24.56	285.000	-1.426	0.15
	control	27	23.91				30.44			
Physical limitations	intervention	27	29.69	305.500	-1.043	0.30	22.22	222.000	-2.548	0.01*
	control	27	25.31				32.78			
Social limitations	intervention	27	33.63	199.000	-2.941	0.00*	23.89	267.000	-1.880	0.06
	control	27	21.37				31.11			
Personal relationships	intervention	27	32.76	222.500	-2.731	0.01*	24.37	280.000	-2.013	0.04*
	control	27	22.24				30.63			
Emotional problems	intervention	27	34.69	170.500	-3.417	0.00*	24.44	282.000	-1.488	0.14
	control	27	20.31				30.56			
Sleep/energy disturbance	intervention	27	32.11	240.000	-2.340	0.02*	25.24	303.500	-1.452	0.15
	control	27	22.89				29.76			
Severity measures	intervention	27	29.63	307.000	-1.005	0.32	22.89	240.000	-2.173	0.03*
	control	27	25.37				32.11			

*significant at $p \leq 0.05$

6.5.3 Comparison of the sham and control groups before and after intervention

6.5.3.1 Comparison of physiological outcomes

The Mann-Whitney U test was used to compare the differences in outcome measures of the sham group and control group before and after intervention. There was no statistically significant difference in pelvic floor muscle strength, self-reported severity of urine leakage, or number of episodes of urine leakage between the two groups either before or after intervention (see Table 6.14).

Table 6.14 Comparison of outcome measures for the sham and control groups before and after intervention by Mann-Whitney U test

		Before					After			
	group	N	Mean Rank	Mann-Whitney U	Z	*p*	Mean Rank	Mann-Whitney U	Z	*p*
Pelvic floor muscle strength (mmHg)	Sham	27	27.89	354.000	-.191	0.85	27.39	361.500	-.056	0.96
	control	27	27.11				27.61			
Self-reported severity of urine leakage	Sham	27	29.48	311.000	-1.034	0.30	28.76	330.500	-.645	0.52
	control	27	25.52				26.24			
Number of episodes of urine leakage	Sham	27	28.57	335.500	-.514	0.61	24.78	291.000	-1.312	0.19
	control	27	26.43				30.22			

*significant at $p \leq 0.05$

6.5.3.2 Comparison of the one-hour pad test results

A Chi-square test for independence was used to compare the results of the one-hour pad test of the sham group and control group before and after intervention. Before intervention, 59.3% (n = 16) of the sham group and 70% (n = 19) of the control group returned a negative pad test, and the association was significant. After intervention, 59.3% (n = 16) of the intervention group and 66.7% (n = 18) of the control group returned a negative pad test, but the association was not significant (see Table 6.15).

Table 6.15 Comparison of the one-hour pad test results of the sham and control groups before and after intervention by Chi-square test for independence

		Before						After					
		Sham		Control				Sham		Control			
		n	%	n	%	X^2	*p*	n	%	n	%	X^2	*p*
Pad test	negative	16	59.3	19	70	0.73	0.39	16	59.3	18	66.7	0.32	0.57
	positive	11	40.7	8	30			11	40.7	9	33.3		

6.5.3.3 Comparison of the King's Health Questionnaire (Chinese version) results

The Mann-Whitney U test was used to compare the differences in the CKHQ scores between the sham group and the control group before and after intervention. There were no significant differences in any of the domains of the CKHQ between the two groups before intervention. The sham group had the lowest overall ranking for the CKHQ domains before intervention, corresponding to the least impact of symptoms on quality of life. There were significant differences in the domains of physical limitations (U = - 2.56, p = 0.01) and personal relationships (U = - 2.41, p = 0.02) after intervention, although no significant differences in the domains of impact of incontinence, role limitations, social limitations, emotional problems, sleep/energy disturbance, or severity (see Table 6.16).

Table 6.16 Comparison of the King's Health Questionnaire (Chinese version) results of the sham and control groups before and after intervention by Mann-Whitney U test

		Before					After			
Domain	group	N	Mean Rank	Mann-Whitney U	Z	*p*	Mean Rank	Mann-Whitney U	Z	*p*
Incontinence impact	Sham	27	27.81	356.000	-0.174	0.86	24.63	287.000	-1.499	0.13
	control	27	27.19				30.37			
Role limitations	Sham	27	24.80	291.500	-1.308	0.19	25.11	300.000	-1.149	0.25
	control	27	30.20				29.89			
Physical limitations	Sham	27	26.46	336.500	-0.494	0.62	22.22	222.000	-2.556	0.01*
	control	27	28.54				32.78			
Social limitations	Sham	27	28.98	324.500	-0.724	0.47	25.59	313.000	-0.958	0.34
	control	27	26.02				29.41			
Personal relationships	Sham	27	27.28	358.500	-0.139	0.89	23.87	266.500	-2.413	0.02*
	control	27	27.72				31.13			
Emotional problems	Sham	27	30.56	282.000	-1.465	0.14	26.83	346.500	-0.321	0.75
	control	27	24.44				28.17			
Sleep/energy disturbance	Sham	27	26.44	336.000	-0.613	0.54	25.06	298.500	-1.571	0.12
	control	27	28.56				29.94			
Severity measures	Sham	27	26.17	328.500	-0.629	0.53	24.57	285.500	-1.381	0.17
	control	27	28.83				30.43			

* significant at $P \leq 0.05$

6.6 Comparison of the mean paired difference in outcome measures among the three groups before and after intervention

6.6.1 Relative changes in outcome measures among the groups

The significant differences in CKHQ scores among the three groups before intervention made it difficult to interpret the after intervention results directly. Although significant differences in the several domains of CKHQ results were found among the three groups after intervention, no conclusive results could be identified.

The after intervention results indicated that the intervention group experienced an improvement in USI symptoms, whereas the control group experienced a minimal improvement or no change. The result of no difference between the two groups might hide true effect of intervention. To illustrate this phenomenon, the relative changes in the outcome measures were calculated (see Table 6.18). As the data obtained from the one-hour pad test and self-reported severity of urine leakage were not continuous, these outcome measures were excluded from the calculations.

Relative change is useful for identifying the clinical significance of outcome measures (Kazis et al, 1989; Wyrwich et al, 2005). As there is no cut-off point in the CKHQ, using the relative change to assess the magnitude of change in the outcome measures allowed any improvement or worsening before and after intervention to be fully assessed.

Analysis of the relative change in outcome measures among the three groups before and after intervention revealed that pelvic floor muscle strength increased in the intervention group from a mean value of 2.74 to 4.89 after intervention, which is a 78.5% relative change. In the sham group, the pelvic floor muscle strength increased from a mean value of 3.19 to 3.48 after intervention, which is only a 9.1% relative change. In the control group, the pelvic floor muscle strength increased from 3.1 to 3.56 after intervention, which is only a 14.5% relative change.

The number of episodes of urine leakage decreased in the intervention group from a mean value of 4.22 to 2.07 after intervention, which is a 50.9% relative change. In the sham group, the number of episodes of urine leakage decreased from a mean value of 4.41 to 3.37 after intervention, which is a 23.6% relative change. In the control group, the mean value decreased from 7.2 to 7.74 after intervention, which is only a 7.2% relative change.

The CKHQ was the instrument used to measure the quality of life of the participants with USI. Lower scores in each domain indicated a better quality of life, and vice versa. The intervention group showed a negative change (improvement) in mean value across all domains. Among the eight domains, impact of incontinence demonstrated the smallest change of -49.4%, whereas personal relationships achieved the largest change of -84.9%. For the sham group, the mean value also showed a negative change across all of the domains. Among the eight domains, role limitations showed the smallest change of -26.7%, whereas personal relationships showed the largest change of -78.6%. For the control group, four out of the eight domains showed a negative change in mean value. Of those, physical limitations showed the smallest change of -10.3% and role limitations the largest change of -27.3%. There were positive changes (worsening) in the mean value of the other four domains, with the largest change of 50% in personal relationships and the smallest change of 5.1% in emotional problems (see Table 6.17).

Table 6.17 Relative changes in outcome measures among three groups

	Intervention (n=27)					Sham (n=27)					Control (n=27)				
	Before		After			Before		After			Before		After		
	Mean	SD	Mean	SD	Change (%)	Mean	SD	Mean	SD	Change (%)	Mean	SD	Mean	SD	Change (%)
Pelvic floor nuscle strength (mmHg)	2.74	2.67	4.89	2.50	78.5	3.19	2.5	3.48	2.33	9.1	3.1	2.68	3.56	2.31	14.5
Number of episode of urine Leakage	4.22	4.54	2.07	2.91	-50.9	4.41	5.27	3.37	5.22	-23.6	7.2	14.5	7.74	15.8	7.2
CKHQ															
Incontinence impact	68.00	23.64	34.4	23.6	-49.4	63.1	21.5	36.93	21.51	-41.4	62	18	45.67	21.2	-26.2
Role limitations	48.1	24.58	20.3	23.20	-57.7	29.6	26.2	21.67	22.09	-26.7	38	18.40	27.78	21.2	-27.3
Physical limitations	49.9	31.01	17.9	23.95	-64.1	38.4	29.5	17.30	23.76	-54.9	41	22.3	37.07	29.4	-10.3
Social limitations	28.70	24.41	8.19	17.3	-71.5	18.4	23.1	10.63	16.13	-42.4	12	14.9	14.74	17.4	20.2
Personal relationships	20.3	19.19	3.07	9.22	-84.9	8.63	18.1	1.85	7.03	-78.6	7.4	13.2	11.07	17.2	50.2
Emotional problems	39.9	26.01	12.7	19.1	-68.3	24.96	19.4	15.89	15.36	-36.3	17	12.7	17.56	16.6	5.1
Sleep/energy disturbance	22.3	22.20	3.70	9.58	-83.4	8.07	17	2.52	6.15	-68.8	9.2	14	10.48	18	13.7
Severity measures	41.07	19.92	18	18.2	-56.1	33.6	16.3	20.48	13.8	-39	35	16.8	26.96	16.5	-22.7

change(%)=mean(post)-mean(pre)/mean(pre)

6.6.2 Comparison of the mean paired differences in the outcome measures among the three groups before and after intervention

The relative change data for the three groups in Table 6.17 show that the magnitude of change was largest in the intervention group, second largest in the sham group, and third largest in the control group. A Kruskal-Wallis test was thus performed to compare the paired mean differences among the three groups and determine whether these changes were significant. A significant difference was found in the change in the outcome measures of pelvic floor muscle strength, self-reported severity of urine

leakage, episodes of urine leakage, and all of the CKHQ domains. The results indicate that there was a significant change after intervention in both the objective physiological outcomes and subjective outcomes (see Table 6.18), with a definite improvement after intervention being observed in the intervention group.

Table 6.18 Comparison of the mean paired differences in outcome measures for the three groups by Kruskal-Wallis test

	Group	Mean Rank	*H*	*p*
Pelvic floor muscle strength	Intervention	29.94	9.92	0.01*
	Sham	46.94		
	Control	46.11		
Number of episodes of urine leakage	Intervention	48.59	6.03	0.05*
	Sham	41.13		
	Control	33.28		
CKHQ				
Incontinence impact	Intervention	48.00	6.47	0.04*
	Sham	42.33		
	Control	32.67		
Role limitations	Intervention	52.91	10.89	0.00*
	Sham	35.02		
	Control	35.07		
Phyiscal limitations	Intervention	51.65	14.74	0.00*
	Sham	43.52		
	Control	27.83		
Social limitations	Intervention	54.74	18.58	0.00*
	Sham	40.06		
	Control	28.20		
Personal relationships	Intervention	53.33	18.65	0.00*
	Sham	39.93		
	Control	29.74		
Emotional problems	Intervention	56.94	23.08	0.00*
	Sham	39.17		
	Control	26.89		
Sleep/energy disturbance	Intervention	52.00	11.80	0.00*
	Sham	37.98		
	Control	33.02		
Severity measures	Intervention	53.8	14.12	0.00*
	Sham	38.87		
	Control	30.33		

Paired difference= value before intervention- value after intervention

*significant at $p \leq 0.05$

6.7 Summary of the results

Tables 6.19a to 6.19b summarize the hypotheses set in Chapter 3. Table 6.19a illustrates the results of the three-group comparisons before and after intervention. The findings show that there was a significant difference in pelvic floor muscle strength. As five domains of the CKHQ were significantly different across the groups before intervention, it was impossible to compare the CKHQ scores across the three groups after intervention. Physical limitations was the only domain to show no significant difference before intervention, but was significantly different among the three groups after intervention.

Table 6.19b illustrates the results obtained from the two-group comparison before and after intervention. There were no significant differences between the sham group and control group in the majority of the outcome measures after intervention, and significant differences in only two domains of the CKHQ after intervention. This reflects the similarity of the two groups after intervention.

The two-group comparison further showed a significant change after intervention in both pelvic floor muscle strength and self-reported severity of urine leakage in the intervention group compared with the other two groups. As some improvement was observed in all three groups after intervention, a Kruskal-Wallis test was used to compare the changes in the three groups before and after intervention. A significant improvement in pelvic floor muscle strength, number of episodes of urine leakage,

and all of the CKHQ domains was observed in the intervention group after intervention.

In conclusion, the intervention group demonstrated promising outcome effects, especially in terms of pelvic floor muscle strength and self-reported severity of urine leakage compared with the sham and control groups.

Table 6.19a Summary of the hypothesis testing: three-group comparison

Hypothesis 1

a. The hypothesis of no significant difference among the intervention group, sham group, and control group in terms of pelvic floor muscle strength is rejected after intervention.

b. The hypothesis of no significant association among the intervention group, sham group, and control group in terms of the one-hour pad test is accepted after intervention.

c. The hypothesis of no significant difference among the intervention group, sham group, and control group in terms of number of episodes of urine leakage is accepted after intervention.

d. The hypothesis of no significant difference among the intervention group, sham group, and control group in terms of self-reported severity of urine leakage is accepted after intervention.

e. The hypothesis of no significant difference among the intervention group, sham group, and control group in terms of the CKHQ domains of i) impact of incontinence, ii) role limitations, iii) social limitations, iv) emotional problems, v) sleep/energy disturbance, and vi) severity measures is accepted but the domains of i) physical limitations and ii) personal relationships is rejected after intervention.

Table 6.19b Summary of the hypothesis testing: two-group comparison

Hypothesis 2

a. The hypothesis of no significant difference between the intervention group and sham group in terms of pelvic floor muscle strength is rejected after intervention.

b. The hypothesis of no significant association between the intervention group and sham group in terms of the one-hour pad test is accepted after intervention.

c. The hypothesis of no significant difference between the intervention group and sham group in terms of number of episodes of urine leakage is accepted after intervention.

d. The hypothesis of no significant difference between the intervention group and sham group in terms of self-reported severity of urine leakage is rejected after intervention.

e. The hypothesis of no significant difference between the intervention group and sham group in terms of all domains of the CKHQ is accepted after intervention.

Table 6.19b Cont'd

Hypothesis 3

a. The hypothesis of no significant difference between the intervention group and control group in terms of pelvic floor muscle strength is rejected after intervention.

b. The hypothesis of no significant association between the intervention group and control group in terms of the one-hour pad test is accepted after intervention.

c. The hypothesis of no significant difference between the intervention group and control group in terms of number of episodes of urine leakage is accepted after intervention.

d. The hypothesis of no significant difference between the intervention group and control group in terms of self-reported severity of urine leakage is rejected after intervention.

e. The hypothesis of no significant difference between the intervention group and control group is accepted in the CKHQ domains of i) role limitations, ii) social limitations, iii) personal relationships, and iv) sleep /energy disturbance, but rejected in the domains of i) impact of incontinence, ii) physical limitations, iii) emotional disturbance, and iv) severity measures after intervention.

Table 6.19b Cont'd

Hypothesis 4

a. The hypothesis of no significant difference between the sham group and control group in terms of pelvic floor muscle strength is rejected after intervention.

b. The hypothesis of no significant association between the sham group and control group in terms of the one-hour pad test is accepted after intervention.

c. The hypothesis of no significant difference between the sham group and control group in terms of number of episodes of urine leakage is accepted after intervention.

d. The hypothesis of no significant difference between the sham group and control group in terms of self-reported severity of urine leakage is rejected after intervention.

e. The hypothesis of no significant difference between the sham group and control group is accepted in the CKHQ domains of i) impact of incontinence, ii) role limitations, iii) social limitations, iv) emotional problems, v) sleep/energy disturbance, and vi) severity measures, but rejected in the domains of i) physical limitations and ii) personal relationships after intervention.

CHAPTER 7

DISCUSSION

7.1 Introduction

The results reported in Chapter 6 indicate that the use of acupressure can have a positive effect in managing women with urodynamic stress incontinence (USI). This chapter further examines the findings. It starts with a summary of the key findings, then goes on to discuss the quality of the study design and methods, the theoretical support for the results, and the implications of the findings.

7.2 Summary of the key findings

At baseline, there were no significant differences among the three groups of participants, that is, the intervention group, the sham group, and the control group. The baseline data included demographic characteristics, urine leak profiles, and baseline measurements of pelvic floor muscle strength, a one-hour pad test, number of episodes of urine leakage, and self-reported severity of urine leakage. After a course of acupressure intervention, a significant difference in pelvic floor muscle strength was observed. In particular, significant differences were found between the intervention and sham groups and the intervention and control groups in pelvic floor muscle strength and self-reported severity of urine leakage. There was also a

significant difference in the mean paired differences among the three groups in pelvic floor muscle strength and episodes of urine leakage before and after intervention. In terms of quality of life as measured by the CKHQ, there was a significant mean paired difference among the three groups in all of the domains before and after intervention, with positive improvements being found in the intervention group in which acupressure was used as the standard treatment protocol.

The intervention group was found to have experienced a significant improvement in pelvic floor muscle strength and episodes of urine leakage in all measures except for the one-hour pad test. A significant improvement in all of the domains of the CKHQ was also observed.

7.3 Efficacy of acupressure in treating USI

There is no previous well-controlled study on the effect of acupressure in managing women with USI as measured by pelvic floor muscle strength. Various other modalities of acupoint interventions have been reported in studies of the management of USI, such as acupuncture alone (Zheng et al., 1990) or in combination with pelvic floor training (Mi & Chen, 2003) or moxibustion and TCM (Qin et al., 2004; Yang, 2004). Other interventions reported include acupoint injections (Zhang & Gao, 1999) and acupoint thread-embedding in combination with pelvic floor training (Zhang & Lu, 2004). However, most of these studies have evaluated the effect of acupoint interventions based on subjective outcomes alone. A few studies mention the use of urodynamic investigation (Zheng et al., 1990; Zhang

& Lu, 2004) or pad tests (Mi & Chen, 2003) as objective measures, but no detailed description is given of how these objective measurements were taken. Due to these limitations, the findings of previous studies cannot be compared with the findings of this study.

7.3.1 Evidence of the efficacy of acupressure in terms of objective and subjective outcomes

In this study, the effects of acupressure were measured using both objective and subjective outcome measures. Pelvic floor muscle strength was the primary objective outcome measure, and was assessed using a perinometer. The participants undergoing acupressure had a relatively greater improvement in pelvic floor muscle strength compared with the sham and control groups, in which no significant improvement in pelvic floor muscle strength was observed. The results thus demonstrate that acupressure can have a significant effect in improving the pelvic floor muscle strength of women with USI in physiological terms.

The secondary outcome measures also reflected an overall improvement in USI among the participants undergoing the intervention. The outcome measures consisted of a one-hour pad test, number of episodes of urine leakage, self-reported severity of urine leakage, and the CKHQ. The statistical tests showed an improvement in the number of episodes of urine leakage and the overall CKHQ. However, the intervention had no significant effect on other general outcomes, the one-hour pad test, or the self-reported severity of urine leakage. The results of the

mean paired difference test also showed an improvement in episodes of urine leak after the intervention. Unfortunately, the difference in improvement among the groups could not be further verified by the severity of urine leakage data because these data were categorical, whereas the one-hour pad test data were nominal data.

The statistical tests revealed diverse findings for the CKHQ results before and after intervention. Further tests of the mean paired difference among the three groups showed a significant overall improvement in the CKHQ after intervention. This result further supports the primary and objective findings. Logically, an improvement in physiological condition should have a positive effect on various aspects of quality of life. The aspects of quality of life measured included impact of incontinence; physical, social, and role limitations; personal relationships; emotional problems; sleep/energy disturbance; and severity measures.

Caution is warranted in interpreting the findings, as other physiological effects on USI cannot be overlooked. The positive physiological outcome of improved pelvic floor muscle strength appears to be one of the effects of the acupressure intervention. However, the study did not investigate other anatomical changes or physiological outcomes, such as changes in bladder capacity, muscle wall pressure in the bladder, and urethral impact, and possible improvements in these areas cannot be ruled out. Nevertheless, the general effect of acupressure cannot be neglected, although not conclusively proven. The reported reduction in urine leakage, along with the improved pelvic muscle strength, resulted in a significant improvement in the

symptoms of USI among the participants, thus establishing that acupressure can have a curative effect on urine incontinence.

7.3.2 Theoretical basis for the results

The acupoints treated in this study were based on those identified in the previous studies discussed in Chapter 3 on managing women with USI. According to the theory proposed by DeLancey in 1994, to maintain urine continence, the pelvic organs should not compress against the urethra. The pelvic floor muscles act as a hammock to maintain the pelvic organs in position. Hence, the urethra is kept in place by the contraction of the surrounding muscles. The levator ani muscles, which are located in the vagina and rectum, cause the anterior and upward movement of the pelvic organs (Messelink et al., 2005). In this study, acupressure exerted on specific acupoints promoted the circulation of qi in an upward direction. Through this uplifting action, the pelvic organs were prevented from compressing on the urethra, and continence was restored.

In TCM, the kidneys govern the lower part of the body. The conception vessel through which qi passes arises in the pelvic cavity and connects with the genito-urinary organs (Ellis et al, 2004). Kidney deficiencies lead to the sinking of qi and the interruption of qi circulation. The acupoints such as Zhongji (CV3), Guanyuan (CV4) and Qihai (CV6) along the conception vessel serve to harmonize the flow of qi. In the course of the intervention, some participants reported feeling the distension of the abdomen or a sensation of bearing down, which may be

symptomatic of sinking qi (Liu, 1988). By promoting the circulation of qi along the conception vessel, health problems related to the genito-urinary organs can be alleviated and the functions of the related organs strengthened (Li, 2007). When the circulation of qi is regulated, yin and yang are harmonized and deficiencies of the kidneys are corrected. The flow of qi in the vessel should move in an upward direction from the perineum to the lower lip. The principle of the intervention in this study was thus to strengthen qi to restore its ability to rise (Liu, 1988). In theory, the effect of acupressure on USI occurs through this mechanism.

7.3.3 Impact of concomitant medical problems

The prevalence of low back pain among the participants of this study was 54.3%. According to Kegel (1956) and Hodges (2007), building up the pelvic floor muscles can improve pelvic fatigue and low backache. As the application of acupressure improves pelvic floor muscle strength, it may also have a positive effect on low back pain.

From the TCM perspective, deficiencies in kidney qi and the functioning of the bladder can lead to genito-urinary problems. These may also contribute to low back pain and gynecological or sexual problems (Young, 2001). Low back pain may occur because the flow of qi is impeded (Wu, 1999). In this study, the majority of the participants with USI also had back pain. However, this medical problem has seldom been reported as a predisposing factor for USI. A study by Finkelstein (2002) explored the medical problems associated with urinary incontinence in Canada, and

found a strong association between musculoskeletal problems and urinary incontinence. Another study explored the relationship between respiratory problems, back pain, and urinary incontinence (Smith, Russell & Hodges, 2006). The results indicated those both respiratory and urinary dysfunctions were significantly related to back pain in women. However, neither of these studies identified which types of urinary incontinence were associated with back pain. The physiological factors behind such associations thus merit further study.

7.4 Stringent methods to enhance the quality of the study

7.4.1 Application of the Consolidation Standard of Reporting Trial (CONSORT)

Valid and reliable of results are obtained through a high-quality study design, implementation, and analysis. In this study, randomization was adopted to ensure that selection bias was controlled. The validity and reliability of the instruments used were checked to confirm their appropriateness and consistency. The inter-rater reliability of the location of the acupoints was examined to ensure the accuracy of the intervention. The blinding of the participants in the intervention and sham groups avoided information bias that may have affected the objectivity of the outcome measures. Both objective and subjective outcome measures were included to better understand the outcome effects.

The CONSORT checklist (Moher, Schulz & Altman, 2001) was used as the fundamental guide for the study from recruitment to data analysis. This standard

emphasizes transparency in the study process to generate an accurate outcome. By using this standard, major errors such as missing information were avoided.

7.4.2 Use of a sham group and a control group

A sham group was included in the study to rule out the possibility that the effects were due to therapeutic ritual or other placebo interventions. The actual contribution of the intervention was delineated by comparison with the sham group and control group. The results proved that the sham group did not experience any improvement in objective outcomes, that is, pelvic floor muscle strength and episodes of urine leakage. The findings on the subjective measures of quality of life also demonstrated that the "dummy" intervention had no effect, as illustrated by the similar relative change in CKHQ scores between the sham and control groups. This finding indicates that the sham intervention worked no better than the control intervention.

It has been stated elsewhere (Paterson & Dieppe, 2005) that sham groups should not be used in acupoint intervention studies, as sham interventions can influence the effect of interest. This study did not show support for this idea, as the objective physiological findings for the sham group did not interfere significantly with the casual relationship of interest. The problems with using sham groups identified in previous studies were probably due to measurement issues.

7.4.3 Strategies to minimize the attrition rate

A high attrition rate can be a threat to the internal validity of an experiment (Given et al., 1999). In this study, the dropout rate was low at only 4.9%, and thus the sample met the necessary number of participants to achieve a power of 94% at an alpha level of 0.05. Such a low attrition rate did not occur by coincidence. Strategies were followed to minimize the attrition rate and to ensure that it was representative.

First, the frequency of contact and the duration of each contact session were fully explained to the participants in the intervention and sham groups. The investigator encouraged the participants to suggest an appropriate time of day to come for the intervention sessions. It was important to allow the participants to choose their own time to minimize the interference with their daily schedule. A flexible time span was offered that extended from early in the morning to late at night. One of the participants came for her intervention session early in the morning before work, and a number of participants came after working hours, some quite late in the evening. Other participants brought their children with them to the intervention sessions.

It was important that the participants arrived punctually for each session to avoid delaying the start of the next session. If there was any unforeseeable delay, then the investigator encouraged the participant to inform the investigator so that an alternative time could be arranged. Common unforeseeable delays included traffic jams, a prolonged office meeting, or urgent meetings. Sometimes, participants called in sick on the day of the intervention session. The investigator provided a contact

telephone number to each participant to allow them to rearrange intervention appointments at short notice. Occasionally, one or two of the participants forgot an appointment. The investigator then called them straight away on the day of the missed appointment to reschedule.

As the participants in the control group performed pelvic floor training on their own, their motivation to continue participating in the study and its effect on the attrition rate were a potential problem. To avoid a high dropout rate due to reduced commitment in the control group, the participants in this group were offered the option of receiving acupressure after the study had finished as an incentive.

7.5 Quality of life of women with USI

7.5.1 Implications of the findings for the quality of life of women with USI

In addition to improving the quality of life of the participants through the intervention, this study also demonstrated that quality of life is a useful outcome indicator for USI. Previous studies have compared the negative impact on quality of life of various types of urinary incontinence. In one study, women with overactive bladders and mixed urinary incontinence had significantly higher scores in the "sleep and energy" domain than those with stress incontinence (Borges et al., 2009). Another study reported that urge incontinence has a greater impact on social isolation and emotional disturbances than stress incontinence (Grimby et al., 1993).

Most previous studies agree that USI has a less negative impact on various domains of quality of life than other types of urinary incontinence (Simenova, Milsom, Kullendorff, Molander & Bengtsson, 1999). This is mainly because women with USI can predict and control urine leakage by limiting their physical activity. A study conducted by Kelleher and colleagues (1997) compared the quality of life of women with USI and women with other symptoms of urinary incontinence, and found that women with USI were less likely to report that their symptoms had a large impact on their quality of life, and were more likely to develop coping strategies to avoid the problem. However, as there is no acceptable or minimal reference for quality of life measures in USI studies, this study highlighted the change in quality of life as an outcome, as this may also reflect the progress of a health problem (Robinson et al., 2003).

7.5.2 Relationship between coping strategies and quality of life

As illustrated by the results for the various domains of the CKHQ, the quality of life of the participants showed different degrees of change. As time went on, the participants had developed different coping strategies to avoid the symptoms of urine leakage, which is commonly observed in people with USI. Most of the participants reported avoiding physical activity because of urine leakage. Although coughing and sneezing also cause urine leakage, this may actually have a positive impact on health. As these conditions are unpredictable, some of the participants tried to avoid them by being more aware of their general health. Some used different methods to

avoid catching a cold or a cough, such as always bringing extra clothing or a scarf to protect their body from the cold.

Urine leakage also occurs due to physical exertion. Many of the women reported preventing urine leakage by avoiding physical exercise. Some used to take part in physical exercise, but after having bad experiences of urine leakage during these activities felt that they had no choice but to avoid participation. The most commonly mentioned physical exercises were those related to jumping and running.

The avoidance of physical exercises was reflected in the domain of physical limitations in the CKHQ. Two items measured physical limitations: one concerned bladder problems affecting physical activities and the other bladder problems affecting the ability to travel.

Compared with the participants in the sham and control groups, the women in the intervention group experienced a significant improvement in the physical limitations domain of the CKHQ. It may be that their symptoms caused fewer physical limitations due to an improvement in pelvic floor muscle strength after receiving acupressure.

Physical limitations and the frequency and severity of urine leakage are the main concerns of women with USI (Abrams, 2003). Women experiencing small or occasional urine leaks tend to minimize episodes of urine leakage by avoiding

physical activity and visiting the toilet frequently to avoid the impact of urine leakage (Robinson et al., 2003). Such avoidance of physical activity due to fear of urine leakage may result in social isolation (Radley, 2004). If this issue of physical limitation is left unattended, then a vicious cycle of isolation may ensue. Before the intervention, some of the participants mentioned that they visited the toilet more frequently to minimize the number of episodes of urine leakage. However, increasing the frequency of urination may distort normal voiding habits, which can affect the normal functioning of the bladder. This could have an even greater negative impact on quality of life. A common improvement reported by the participants receiving acupressure was a decreased frequency of urination. This was observed as early as halfway through the course of intervention. Some of the participants were unaware that they were visiting the toilet less until their friends or spouse observed the change. One of the participants used to visit the toilet more frequently than her husband before the intervention, but afterwards visited the toilet much less than her husband.

7.6 Age, BMI and USI

A study by Brown and Miller (2001) explored the age ranges of women reporting urine leakage during physical exercise. Among the different age ranges reporting urine leakage during physical activity, more than 33.3% of women between 48 to 53 years of age avoided physical exercise because of urine leaks, whereas those in younger age and older age groups seldom reported the avoidance of physical exercise. A high BMI is associated with USI (Brown et al., 1999; Person, Wolner-

hanssen & Rydhstroem, 2000), and has been found to be significantly more likely in women in middle to older age (Smith et al., 2006).

Similar findings were observed in this study. The majority of the participants were aged between 41 to 60 years old, most had a high BMI of more than 23 kg/m^2, and most mentioned that they avoided physical exercise to minimize urine leakage. The limited participation in physical activities may be one of the reasons for the high BMI.

Many studies have reported that a high BMI increases the risk of urine leakage (Huang et al., 2006; Minassian, Stewart & Wood, 2008). However, women with a normal BMI can still experience urine leakage. Further, there is no evidence on whether the condition of urine leakage developed before or after women with a high BMI gained weight. It is thus possible that their weight gain may have been accelerated by severe urine leakage.

7.7. Implications of the study

7.7.1 Clinical implications

7.7.1.1 Patient education

It is necessary for healthcare professionals to be more aware of the needs of women with urine incontinence. The reluctance of many women to seek help may be related to a lack of knowledge and lack of understanding on the part of healthcare professionals (Davis & Kumar, 2003). Most of the participants in this study had

attained at least a secondary school education, and may have had a greater expectation that healthcare professionals would provide useful information on managing USI. They may also have been more open to different interventions, especially non-invasive interventions. Healthcare providers need to be well equipped with knowledge of the possible interventions available for incontinent women.

7.7.1.2 Advice on weight reduction

Another factor that may prevent women from seeking treatment is a lack of understanding between healthcare professionals and women with USI. Often, healthcare providers advise women to reduce their body weight to reduce the episodes of urine leakage. However, this advice presents women with a dilemma. If they have chosen to cope with the problem by avoiding physical exercise, then they may not want to put themselves at risk of urine leakage by performing physical exercises to reduce their weight. A recent study reported that the condition of urine leakage can be improved by a weight loss of just 5% (Auward et al, 2008) to 10% (Wing et al, 2010).

It is certain that maintaining an optimum body weight benefits health as a whole. As the women who had chosen to avoid physical exercises in this study were those who had experienced the embarrassing situation of urine leakage during exercise, it would be a big hurdle for them to overcome the associated psychological distress and become sufficiently confident to take part in physical exercises again. However, this

hurdle was overcome by some of the women in the intervention group who experienced an improvement in urine leakage. One woman used to run in the park every morning before her urine leakage problem worsened. Before the last two sessions of acupressure, she mentioned that she had tried running again and had experienced no urine leakage, and that she would consider resuming running regularly if the improvement was sustained. This indicates that condition of urine leakage can be managed by acupressure as an adjunct intervention, thus giving sufferers greater confidence to participate in weight reduction training.

7.7.1.3 Hiding behind coping strategies

Women with USI try to avoid the symptoms by developing coping strategies to ease the problem. Studies on the prevalence rate of USI among women in younger age have indicated that most develop coping strategies to avoid embarrassing situations and to be able to continue with their lives (Davis & Kumar, 2003). Avoidance behavior arises from feelings of shame, stereotyping by society, cultural beliefs (Norton et al., 1998; Shaw, 2001), and myths. Common myths about USI include the notion that wearing a pad is the only way to manage the problem, that incontinence is part of the normal aging process, and that there is no intervention available to manage the problem. There is also reluctance to face the problem because of perceptions of the nature of the interventions available (Newman, 1999). As surgical interventions are invasive in nature, women experiencing urine leakage are likely to carefully weigh up the pros and cons of such interventions. Many

women with incontinence have indicated that surgical interventions are not their preferred option for managing the problem (O'Donnell et al., 2005).

Limited information and resources may be factors affecting the treatment-seeking behavior of women with USI (Davis & Kumar, 2003). Awareness of the importance of seeking early intervention is of paramount important. A local study reported on the inadequacy of knowledge related to urinary incontinence, finding that more than 90% of respondents thought that better education about the problem was needed (Wong et al, 2006). Similar observations were made in this study. Most of the women had attained a high level of education, and had found that information related to the management of urine leakage in the community was inadequate. They had tried to cope with the problem on their own, and had not sought medical advice due to other more pressing health problems, especially gynecological problems. This delayed the management of their urine leakage problem. Healthcare providers should be sensitive to the concerns of patients. The nature of their job brings nurses into frequent contact with patients in a clinical setting, and they are thus in the best position to assess the condition of urine leakage comprehensively and to provide advice on management options (Davis & Kumar, 2003).

7.7.1.4 Preventive measures for high - risk groups

Several risk factors for the development of USI in women have been identified. A study conducted by Wilson et al. (1996) studied the relationship between the incidence of urine leakage and mode of delivery among postpartum women, and

found that the symptom of USI appeared before pregnancy. Early preventive intervention should thus be promoted among this at-risk group to decrease the prevalence of urine leakage. As there are generally no adverse reactions to acupressure, it could be used as a prophylactic intervention for women at high risk of developing USI, including primiparous and menopausal women and those with a high BMI. The self-administration of acupressure could also be promoted whenever appropriate.

7.7.2 Fostering the integration of Eastern and Western medicine

The provision of a range of intervention options for women with USI should not focus only on the number of interventions offered, but also the variety. This study has demonstrated the beneficial effect of acupressure as an alternative intervention for USI. As it is non-invasive in nature, acupressure may be an ideal choice of intervention to promote both physical and psychosocial well-being.

There is currently a global trend of people adopting alternative interventions. From the patients' point of view, Western and Eastern medicine serve different purposes. Many patients use alternative interventions as remedies, especially for chronic health problems (Harmsworth & Lewith, 2001; Lam, 2001; WHO, 2002b), and Western medicine to relieve acute health problems (Lam, 2001). Healthcare providers should respond proactively to the increasing trend of seeking alternative healthcare services.

Previous studies exploring the attitude, knowledge, and belief of alternative interventions among nursing students (Uzun & Tan, 2004; Yeh & Chung, 2007) and medical students (Yildirim et al., 2010). Nursing students were found to have a more positive attitude toward alternative interventions than medical students (Yildirim et al., 2010). Most students have used or are willing to use alternative interventions (Chua & Furnham, 2008). Nurse Practitioners (Sohn & Cook, 2002) and nursing students (Uzun & Tan, 2004) indicated that they will offer alternative interventions if they are equipped with the appropriate knowledge Acupoint intervention, as a non-invasive alternative intervention, should thus be promoted among nurses as a potential intervention for their patients.

7.7.3 Evolving role of nurses in complementary alternative medicine

The Nursing Board of Hong Kong has recognized the importance of meeting the needs of society in terms of adopting alternative interventions, and accordingly updated the syllabus guideline for subjects for registered nurses in Hong Kong in 2009 to include Chinese medicine nursing and complementary alternative medicine. In addition to knowledge of Western medicine, nurses in Hong Kong should be equipped with basic knowledge of TCM and TCM interventions. Preparing healthcare providers with such knowledge will lay the foundations for the integration of alternative interventions into the existing healthcare system.

Nurses are in a good position to extend their role to include the provision of alternative interventions. The nature of their job also puts nurses in an ideal position

to empower patients with knowledge of alternative intervention options. Most often, women with USI hide their symptoms by developing coping strategies. Given their continued interaction with women, often due to other health problems, nurses are in a good position to assess and identify incontinent women in need. Most of the participants in this study were reluctant to undergo surgical interventions due to their invasive nature, and sought non-invasive alternatives. This may be one of the reasons for the high response rate. Acupressure could thus be offered as a non-invasive intervention for women with USI, along with pelvic floor training. As acupressure is non-invasive, nurses should consider the therapeutic use of acupressure as one of the healthcare services that they provide.

7.8 Limitations

This study has several limitations. First, a single-blinded research approach had to be adopted because the researcher was also the intervention provider. Hence, the researcher was fully aware of the groups to which the participants belonged. However, the occurrence of bias in interpreting the effects of the intervention was minimized by the inclusion of objective outcome measures such as pelvic floor muscle strengths and one-hour pad test.

Second, the study cannot be easily compared with other similar trials due to methodological heterogeneity. Different acupoint interventions have different modalities. Further, as the size and shape of the vaginal probes of perinometers from different manufacturers may not be the same, it is difficult to compare the present

findings on pelvic floor muscle strength with those from other studies due to differences in measurement (Bø, Raastad & Finckenhagen, 2005).

Third, the therapeutic relationship between participant and practitioner may affect the outcomes of the study. Samstag et al. (1998) found that participants in the dropout group rated this relationship poorly compared with those participants with good and poor outcomes. In this study, the dropout rate was low. Although there was no formal measure of the psychotherapeutic change of alliance in this study, the outcomes of the study might have been affected by the therapeutic relationship between participant and practitioner. Positive alliances should be built up during the early stage of intervention to ensure the outcomes of the study (Martin, Garske & Davis, 2000). The therapeutic alliance could be measured along with the outcomes in future studies.

Fourth, the immediate effects of the study outcomes have been evaluated. However, the study design did not adopt a three-time-point model due to time constraints. The long-term effects of acupressure intervention for women with USI should be considered for further study.

Fifth, the results obtained from the study were based on the effects of acupressure on women with USI. Other modalities such as Chinese herbal medicine and moxibustion could be used independently or together with acupressure to boost the effects of the intervention. However, these were outside the scope of this study.

Further study could be considered to explore the effectiveness of other modalities of TCM for managing USI.

7.9 Recommendations for further study

7.9.1 Course of intervention

The complete course of intervention in this study was thirty sessions at three times per week. This course of intervention was based on previous studies on the management of similar conditions but using different acupoint interventions. Hence, the course of intervention was based on expert opinion, but was not fully researched. Future research could explore different frequencies and intervention durations to determine the optimum regime of intervention.

7.9.2 Methods and measures for understanding the mechanism of effects

There is increasing study of the mechanisms acupoint stimulation in benefiting the human body, including the bladder. For example, it has been found that the stimulation of acupoints can induce the production of β-endorphins (Bergstrom, Carlsson, Lindholm & Widengren, 2000) to increase or decrease the storage of urine in the bladder. Zheng et al. (1990) studied the effect of acupuncture in managing women with general lower urinary tract symptoms, including frequency and urgency of urination, incomplete urination, and sense of fullness over the abdomen. They measured the effect of acupuncture by analyzing the cortisol level in urine before and after intervention. The results showed a decrease in the cortisol level in urine in the treatment group compared with the control group. A recent research study suggested

that the stimulation of acupoints may reduce the number of c-Fos-positive cells in the pontine micturition center, thereby improving the symptoms of USI (Chung et al., 2008).

This study has demonstrated that acupressure can enhance pelvic floor muscle strength. However, other effects of acupressure, such as neuroanatomical changes or biological changes, are unclear (Benedetti et al., 2005; Pacheco-Lopez, Engler, Niemi & Schedlos, 2006). Future research could investigate other changes induced by the stimulation of the acupoints used in this study. The use of imaging techniques and electromyography could also help to better determine the anatomical and electro-physiological changes induced by acupressure intervention for USI.

The participants in this study were diagnosed as USI using western methods. TCM diagnosis was not undertaken as part of the inclusion criteria in this study. Further studies could examine participants' individual responses to acupressure intervention for managing USI diagnosed with TCM.

CHAPTER 8

CONCLUSION

Urodynamic stress incontinence is a common health problem in women. The management of USI usually involves either surgery or pelvic floor muscle training. Women are often hesitant to choose surgical interventions due to their invasive nature and potential complications. Pelvic floor training requires formal training and persistent practice, and lack of compliance often limits its success. There is thus increasing demand for alternative interventions for USI.

The use of complementary and alternative medicine has drawn the attention of healthcare providers and consumers. Complementary and alternative medicine is often viewed as a powerful means of relieving symptoms. Traditional Chinese Medicine rests on the philosophy of restoring health as a whole by correcting imbalances of yang and yin and qi vacuity or stagnation in the meridian system. TCM is playing an increasingly prominent role healthcare provision. Acupressure, which is one of the acupoint interventions used in TCM, is a popular alternative intervention for regulating the flow of qi in the meridian system that is safe and non-invasive.

In this study, a search of the literature and consultation with current TCM experts led

to the development of an acupressure protocol for managing USI. A randomized control trial using a sham and a control group was then conducted following a stringent research process.

The results produced evidence of a positive effect of acupressure in terms of both physiological and general outcomes. Compared with the sham and control groups, participants receiving genuine acupressure experienced a significant improvement in pelvic floor muscle strength. An improvement in self-reported severity of urine leakage and episodes of urine leakage was also shown by various tests. The intervention group showed obvious improvements over the other two groups in terms of relative change in magnitude in the various domains of quality of life. Although a subjective effect on quality of life was also demonstrated in the sham group, it can be accounted for by the placebo effect. These results confirm the efficacy of acupressure in treating USI.

This study contributes to the application of TCM modality in dealing with Western diagnosed health problems. Health care is a fundamental need of mankind. Knowledge and technology that contribute to better health care should not be restricted to one perspective, especially when there are gaps in the management of a health problem. Open-minded clinicians and healthcare researchers are becoming increasingly interested in TCM. However, quality research on TCM is lacking. This study employed a stringent research framework to achieve positive results that strengthen the body of knowledge on managing USI with acupressure.

In terms of advanced nursing practice, increased knowledge of the application of complementary and alternative therapies, including TCM, will broaden the scope of nursing. The efforts of nursing academics and researchers in the area of TCM and alternative therapies have meant that the application of alternative interventions is gradually being accepted by nurses. The trend of integrating alternative medicine into clinical use is likely to continue. This study shows that acupressure is a safe intervention that can be assisted in the management of USI as adjunct to standard therapy. The use of imaging techniques and other physiological parameters in future studies would better reveal the mechanism and TCM theory underlying the identified effects of acupressure on women with USI.

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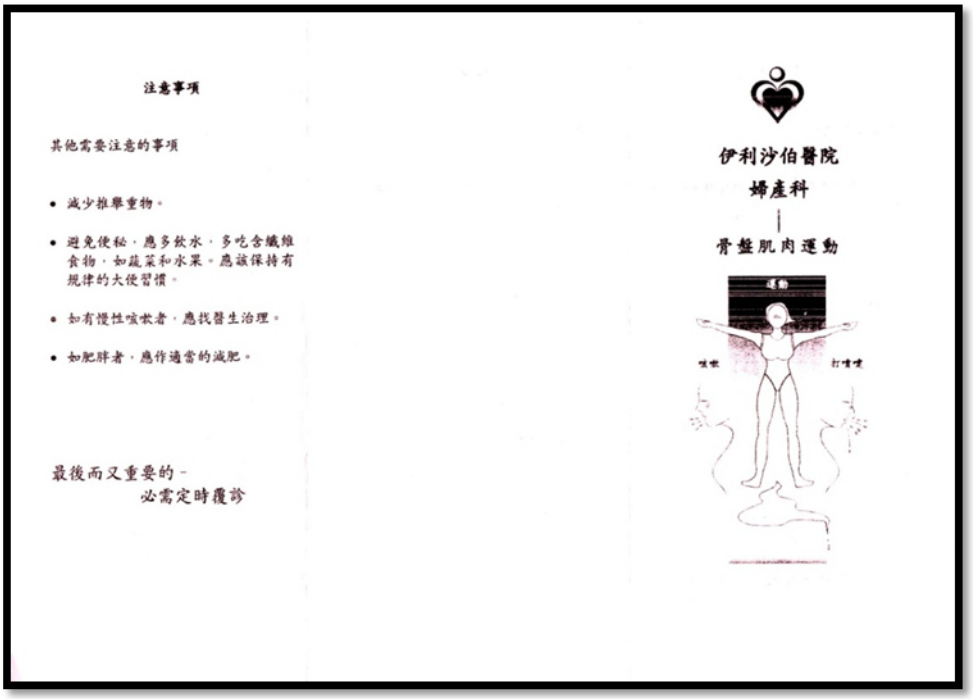
APPENDIX 1 Pamphlet on pelvic floor training (Queen Elizabeth Hospital)



注意事項

其他需要注意的事項

- 減少推舉重物。
- 避免便秘，應多飲水，多吃含纖維食物，如蔬菜和水果。應該保持有規律的大便習慣。
- 如有慢性咳嗽者，應找醫生治理。
- 如肥胖者，應作適當的減肥。

最後而又重要的 -
必需定時覆診

伊利沙伯醫院
婦產科

骨盤肌肉運動

骨盤肌肉

什麼是骨盤肌肉？

骨盤肌肉是由多層的肌肉組成，形成筲箕狀，由尾骨伸展到前面的恥骨。用處是用以承托膀胱、子宮和直腸。但部份婦女因生產或年紀漸長，使骨盤肌肉鬆弛，便會有大、小便失禁和子宮下垂的現象。

黑色部份指示骨盤肌肉

骨盤肌肉運動

骨盤肌肉運動的好處

- 保持骨盤肌肉的韌度
- 有助改善應力性失禁，減少在咳嗽、打噴嚏和運動時漏尿。
- 有助減少因更年期缺乏女性荷爾蒙而引致的骨盤肌肉鬆弛。
- 有助產後婦人之骨盤肌肉收緊。

骨盤肌肉運動

1. 放鬆自己，幻想自己想放屁，但因環境影響，需要忍著。然後把肛門向上收縮，數五下，放鬆十下，保持正常呼吸（注意不要收緊腹部肌肉）。
2. 重複"收縮和放鬆"運動，每天共六十次。
   若能力許可，收縮時間可逐漸延長至十秒。
3. 另外，每天進行快促一收一放的運動共三十次。
4. 當你把握以上運動的做法，你便可以隨意在任何時間和地方做骨盤肌肉運動；如
   - 刷牙時
   - 洗澡時
   - 上廁所後
   - 看電視時
   - 坐車時
   - 接電話時等
5. 同時，你更可以在快將遇到以下情形時做骨盤肌肉運動，以阻止小便遺漏；如
   - 咳嗽
   - 打噴嚏
   - 提舉東西
   - 推重物
   - 做運動等

請堅持做以上這個練習，
不要放棄!

APPENDIX2 Demographic data and urine leakage profile

THE HONG KONG POLYTECHNIC UNIVERSITY
SCHOOL OF NURSING

Date: _____ **Code: _____**

Part I: Demographic data

Age
- ❑ < = 20
- ❑ 21 - 30
- ❑ 31 - 40
- ❑ 41 - 50
- ❑ 51 - 60

Education
- ❑ no education
- ❑ no formal education
- ❑ primary level
- ❑ secondary level
- ❑ tertiary level or above

Marital status
- ❑ single
- ❑ in a relationship
- ❑ married
- ❑ divorced
- ❑ widowed

Occupation _____

Parity _____

Height _____ cm

Weight _____kg

BMI _____ (kg /m^2)

Part II: Health history

General health	❍ good ❍ fair ❍ poor
Menopause	❍ yes ❍ no
Smoking	❍ yes ❍ no
Alcohol consumption	❍ yes ❍ no
Chronic cough	❍ yes ❍ no
Chronic back pain	❍ yes ❍ no
Other coughing/sneezing related health problem	_____
Bowels	❍ normal ❍ constipation ❍ diarrhea ❍ faecal incontinence
History of urine leakage	How long have you had a problem with urinary leakage? _____ Do you lose urine during: ❍ sneezing ❍ coughing ❍ laughing ❍ lifting heavy objects ❍ nervousness ❍ rushing

❍ walking
❍ stooping
❍ squatting
❍ getting up from a chair
❍ jumping
❍ running
❍ other
_____

Management of urine leakage

Any pad used?

❍ yes, number of pad per day: _____
❍ no

Are you avoiding certain activities because of a urine loss problem?

❍ yes, please specify: _____
❍ no

Part III: Investigations

How do you rate your severity of urine leakage at this moment?

❍ total continent
❍ mild/occasional
❍ moderate
❍ severe incontinence

Pelvic floor muscle strength _____

Pad-weighing test

Pre: _____ gram (s)

Post: _____ grams (s)

_____ gram (s) ❍ positive ❍ negative

Episode of urine leakage _____

APPENDIX 3 King's Health Questionnaire (Chinese and English versions)

Part IV: King's Health Questionnaire developed by Kelleher et al (1997)

請在適用的答案上加上✓號
Please put a tick in the appropriate answer

			①	②	③	④
1	你的膀胱問題對你有幾大影響？ How much do you think your bladder problem affects your life?		完全沒有 not at all	很少 a little	中度 moderately	很多 a lot
2a	你的膀胱問題對你處理家務有幾大影響？ 例如：清潔、買餸、等等… To what extent does your bladder problem affect your household tasks (e.g. cleaning, shopping, etc.)?		完全沒有 not at all	很少 a little	中度 moderately	很多 a lot
2b	你的膀胱問題對你返工或進行日常户外活動有幾大影響？ Does your bladder problem affect your job, or your normal daily activities outside the home?		完全沒有 not at all	很少 a little	中度 moderately	很多 a lot
3a	你的膀胱問題對你的體力活動有幾大影響？ 例如：散步、跑步、運動、健身、等等… Does your bladder problem affect your physical activities (e.g. going for a walk, run, sport, gym, etc.)?		完全沒有 not at all	很少 a little	中度 moderately	很多 a lot
3b	你的膀胱問題有否影響你去旅行的能力？ Does your bladder problem affect your ability to travel?		完全沒有 not at all	很少 a little	中度 moderately	很多 a lot
3c	你的膀胱問題對你的社交生活有否受到限制？ Does your bladder problem limit your social life?		完全沒有 not at all	很少 a little	中度 moderately	很多 a lot
3d	你的膀胱問題有否影響你去見或探訪朋友？ Does your bladder problem limit your ability to see/visit friends?		完全沒有 not at all	很少 a little	中度 moderately	很多 a lot
4a	你的膀胱問題有否影響你和你伴侶的關係？ Does your bladder problem affect your relationship with your partner?	不適用 not applicable	完全沒有 not at all	很少 slightly	中度 moderately	很多 a lot
4b	你的膀胱問題有否影響你的性生活？ Does your bladder problem affect your sex life?	不適用 not applicable	完全沒有 not at all	很少 slightly	中度 moderately	很多 a lot
4c	你的膀胱問題有否影響你的家庭生活？ Does your bladder problem affect your family life?	不適用 not applicable	完全沒有 not at all	很少 slightly	中度 moderately	很多 a lot

5a	你的膀胱問題有否令你覺得抑鬱？ Does your bladder problem make you feel depressed?	完全沒有 not at all	很少 slightly	中度 moderately	很多 a lot
5b	你的膀胱問題有否令你覺得焦慮或神經緊張？ Does your bladder problem make you feel anxious or nervous?	完全沒有 not at all	很少 slightly	中度 moderately	很多 a lot
5c	你的膀胱問題有否令你覺得不安？ Does your bladder problem make you feel bad about yourself?	完全沒有 not at all	很少 slightly	中度 moderately	很多 a lot
6a	你的膀胱問題有否影響你的睡眠？ Does your bladder problem affect your sleep?	從來沒有 never	有時 sometimes	時常 often	一向 all the time
6b	你有否覺得筋疲力盡或疲倦？ Do you feel worn out/tired?	從來沒有 never	有時 sometimes	時常 often	一向 all the time
7	你有否因為膀胱問題而令你需要？ Do you do any of the following?				
a	用護墊保持乾爽 Wear pads to keep dry?	從來沒有 never	有時 sometimes	時常 often	一向 all the time
b	注意飲水份量 Be careful how much fluid you drink?	從來沒有 never	有時 sometimes	時常 often	一向 all the time
c	更換剛弄濕了的內衣褲 Change your underclothes when they get wet?	從來沒有 never	有時 sometimes	時常 often	一向 all the time
d	擔心你有氣味 Worry in case you smell?	從來沒有 never	有時 sometimes	時常 often	一向 all the time
e	覺得尷尬 Get embarrassed because of your bladder problem?	從來沒有 never	有時 sometimes	時常 often	一向 all the time

APPENDIX 4 Information sheet (Chinese and English versions)

THE HONG KONG
POLYTECHNIC UNIVERSITY
香港理工大學
護理學院
School of Nursing

香港 九龍 紅磡
Hung Hom Kowloon Hong Kong

有關資料

(穴位療法 - 女性應力失禁)

香港理工大學護理學系研究生現正進行一項有關<女性應力失禁穴位治療研究>，誠邀女性經診斷患有應力失禁參與此項研究計劃。這項研究的目的是研究穴位療法對應力失禁病人的成效。

參加者在整個療程前後會安排接受免費棉巾測試、量度盆底肌肉的舒張力，以瞭解參加者之漏尿程度。所有自願參加者均以電腦隨機抽樣方法分為三組：穴位按壓組、穴位安慰按壓組、慣常治療組。三組參加者均學習盆底肌肉運動，其中穴位按壓組及穴位安慰按壓組均接受為期大約兩個半月、平均每個禮拜需接受三次之穴位按壓療程。

此項研究計劃之療程均不會對閣下引起任何危險或不必要的痛楚。預期此研究所得的資料和數據可更了解參加者在治療前後因應力失禁對生活質素的影響，及穴位按壓對應力失禁的效用有其大的貢獻。

為確保本研究之療程對參加者的真正成效，所有自願參加者均要求在治療期間，不會接受本研究以外有關治療應力失禁的療程。

閣下享有充分的權利在研究開始之前或之後決定退出這項研究，而不會受到任何對閣下不正常的代過或責任追究。凡有關閣下的資料均會保密，一切資料的編碼只有研究人員知道。

如果閣下有任何對這項研究的不滿，請隨時與香港理工大學人事倫理委員會秘書親自或寫信聯絡(地址：香港理工大學人力資源辦公室 M1303室轉交)。

如果閣下想獲得更多有關這項研究的資料，請與張嘉碧女士聯絡，電話 2766 6324 或接觸她的導師汪國成教授，電話 2766 6398。

謝謝閣下有興趣參與這項研究。

THE HONG KONG
POLYTECHNIC UNIVERSITY
香港理工大學
護理學院
School of Nursing

香港 九龍 紅磡
Hung Hom Kowloon Hong Kong

INFORMATION SHEET

Effect of acupressure on women with urodynamic stress incontinence

You are invited to participate in a study conducted by PhD candidate of School of Nursing, the Hong Kong Polytechnic University. The aim of the study is to evaluate the effectiveness of acupressure on women with urodynamic stress incontinence

To understand the condition of urine leak of the participants, each participant will be arranged to participate in pad testing and pelvic floor muscle strength measurement before and after intervention. The voluntary participants will be randomly assigned to three groups with the use of a computer generator the intervention group, sham group, or control (usual care) group. All the participants will be required to practice pelvic floor muscle exercise. For those who are randomized into intervention group and sham group, they should receive intervention three times a week for a total of thirty sessions. Each session lasted for about thirty minutes. The course of intervention was completed in around two and a half months.

The modality of intervention in this study will not cause any injury or induce unnecessary pain. It is expected that this study will provide information and data for better understanding of the participants on the impact to quality of life, and effectiveness of acupressure on urodynamic stress incontinence.

The participants should not undergo any other intervention to manage urodynamic stress incontinence during the study period to avoid obscuring the real effects of the intervention.

You have entirely right to refuse to participate or withdraw from the study at anytime throughout the study. Your decision will not cause any detrimental effect to your normal intervention or assume any accountability to this research. All data collected from you will be kept confidential and for this study purpose. Information is coded and coding is restricted to be accessed by the investigator only.

If you have any complaints about the conduct of this research study, please do not hesitate to contact Secretary of the Human Subjects Ethics Sub-Committee of The Hong Kong Polytechnic University in person or in writing (c/o Human Resources Office in Room M1303 of the University).

If you would like more information about this study, please contact Ms Chang Ka Pik at telephone number 2766 6324 or the supervisor Professor Thomas Wong at telephone number 2766 6398.

Thank you for your interest in participating in this study.

APPENDIX 5 Consent form (Chinese and English Versions)

THE HONG KONG
POLYTECHNIC UNIVERSITY
香港理工大學
護理學院
School of Nursing

香港 九龍 紅磡
Hung Hom Kowloon Hong Kong

參與研究同意書

(穴位療法 - 女性應力失禁)

本人		同意參加由	張嘉碧女士
負責執行，	汪國成教授、鍾慧儀 教授、黃漢光醫生、梁榮能教授		監督的研究項目，

我理解此研究所獲得的資料可用於未來的研究和學術交流，然而我有權保護自己的隱私，我的個人資料將不能洩漏。

我對所附資料的有關步驟已經得到充分的解釋，我理解可能會出現的風險，我是自願參與這項研究。

我理解我有權在研究過程中提出問題，并在任何時候決定退出研究而不會受到任何不正常的待遇或責任追究。

參加者姓名: _____

參加者簽名: _____

見證人姓名: _____

見證人簽名: _____

研究人員姓名: _____

研究人員簽名: _____

日期: _____

THE HONG KONG
POLYTECHNIC UNIVERSITY
香港理工大學
護理學院
School of Nursing

香港 九龍 紅磡
Hung Hom Kowloon Hong Kong

CONSENT TO PARTICIPATE IN RESEARCH

Effect of acupressure on women with urodynamic stress incontinence

I _____ hereby consent to participate in the captioned research conducted by Ms Chang Ka Pik and is supervised by Prof Thomas KS Wong, Prof Joanne WY Chung, Dr Thomas HK Wong, Prof Albert WN Leung.

I understand that information obtained from this research may be used in future research and published. However, my right to privacy will be retained, i.e. my personal details will not be revealed.

The procedure as set out in the attached information sheet has been fully explained. I understand the benefit and risks involved. My participation in the project is voluntary.

I acknowledge that I have the right to question any part of the procedure and can withdraw at any time without penalty of any kind.

Name of participant _____

Signature of participant _____

Name of researcher _____

Signature of researcher _____

Date _____