2. Literature review

This chapter reviews the literature on hypertension and hyperlipidaemia and their relation to risk factors including age, gender, genetics, diet and weight, alcohol, smoking, lack of activity and co-morbidity. It also examines mediating factors including economic factors, stress/personality, medications, lifestyle modifications and complementary therapies including foot reflexology and foot massage. Finally, it reviews outcomes (quality of life) including physiological, psychological and socioeconomic changes.

2.1 Background to the literature review

The occurrence of hypertension, a chronic condition, is increasing in developing countries such as Thailand due to the sociological, political and economic changes and the associated alterations in people's lifestyles. This follows similar trends in western countries (National Economic and Social Development Board 1997). These lifestyle changes can cause chronic health problems, as a result of poor habits in food and alcohol consumption, lack of physical activity, smoking, and increased stress (National Economic and Social Development Board 1997). Data from an observational health survey in 1995 of Thai people aged 50 years and over demonstrated that the incidence of hypertension in urban females was 1.7 times that of rural females, for two age groups (less than 60 years of age, and 60 years or more). Similarly, for urban males it was 1.7 and 1.5 times that of rural males, for both age groups respectively (Chuprapawan *et al* 1995).

In addition, age, gender, ethnicity, genetic background, family health history and dyslipidaemia are likely to influence hypertension (Kaplan, Lieberman & Neal 2002; Mancia *et al* 2002; Manger & Gifford 2001; National Heart Foundation of Australia 2003).

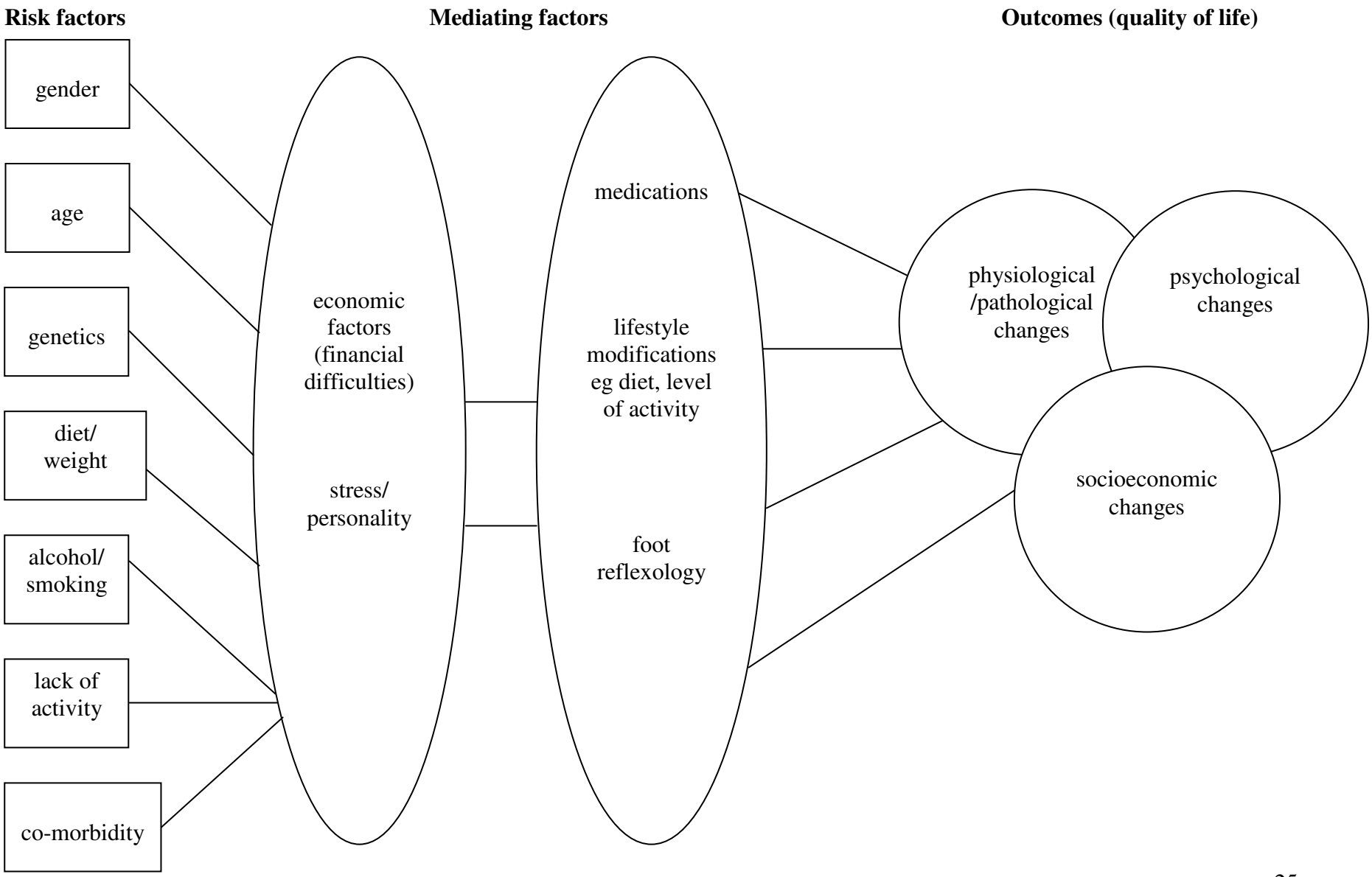
People with a chronic disease may seek ways to reduce their suffering by using both conventional treatment and complementary therapies. Foot reflexology, one of the complementary therapies, is chosen for patients with chronic diseases as a means of improving their quality of life (Hodgson 2000; Milligan *et al* 2002).

This literature review aimed to investigate what is known from previous studies relating to the relationship between hypertension or hyperlipidaemia and:

- risk factors including age, gender, genetics, diet and weight, alcohol, smoking, lack of activity and co-morbidity
- mediating factors including financial difficulties, stress or personality, medications, lifestyle modifications and complementary therapies such as reflexology and massage
- quality of life

The conceptual framework guiding this study is shown in Figure 2.1.

Figure 2.1 Study framework



2.2 Risk factors for hypertension and hyperlipidaemia

Research has demonstrated that many factors including age, gender, genetics, diet, alcohol, smoking, lack of activity, and co-morbidity independently influence risk and also interact to contribute to hypertension or hyperlipidaemia.

2.2.1 Age and gender

Increased age and male gender are important risk factors for cardiovascular disease (National Heart Foundation of Australia 2003). Males have a gene that influences hypertension more than females, when compared at the same age; interestingly, however in postmenopausal women and men of the same age, there is no difference in findings (Williams *et al* 2000).

A study based in a semi-rural Michigan population examined ambulatory blood pressure, related to the effects of age and sex, in 131 patients who had more than two prior office diastolic blood pressure measurements greater than 90 mmHg and less than 115 mmHg. Blood pressure measurements were taken every 10 to 60 minutes over a 24 hour period using the SpaceLabs 90207 computerized ambulatory blood pressure monitor. The results showed that patients aged 65 years or over had a higher mean systolic and lower mean diastolic blood pressure ($p < 0.001$) in the office than those aged less than 65 years. Office mean arterial blood pressures were also higher ($p < 0.001$) in the older patients. For mean ambulatory blood pressure, older patients had higher mean ambulatory systolic blood pressures than the younger age group, but there were no differences in mean ambulatory diastolic blood pressure between the two groups. Men had higher mean ambulatory diastolic and mean arterial blood

pressures than women; however, women had higher systolic ($p < 0.008$) and mean arterial office blood pressures than men (Khoury *et al* 1992).

A similar result was gained in a study of 24 hour ambulatory blood pressure monitoring in 352 healthy Danish subjects aged 20 to 79 years. These participants were divided into groups of 25 to 30 subjects, of each sex, across all age groups. Blood pressure monitoring was measured on the left arm every 15 minutes from 7am to 11pm and every 30 minutes from 11pm to 7am. The study found that systolic blood pressure increased only slightly with age and was significantly higher in men than in women. On the other hand, the diastolic blood pressure increased only slightly with age in both sexes until the 50 to 59 years age group, declined thereafter and was not statistically different between sexes (Wiinberg *et al* 1995).

Research in animals also supports these findings. In one study, blood pressure and heart rates were measured continuously at ten minute intervals for one week in six-month-old spontaneously hypertensive and normotensive rats, using biotelemetry transmitters implanted in the abdominal cavity with the pressure-sensing catheter inserted into the descending aorta below the renal artery. The study showed that male hypertensive rats had significantly higher systolic and diastolic blood pressures compared with hypertensive female rats; normotensive male and female rats had similar diastolic blood pressure, but males had slightly higher systolic blood pressure than females (Maris *et al* 2005).

In summary, males have higher systolic blood pressure than females of the same age and systolic blood pressure in both sexes increases with age while diastolic blood pressure is likely to be similar in both sexes at the same age.

2.2.2 Genetics

Genetics is also claimed to contribute to hypertension. A study of 591 Japanese participants, aged 20 to 59 years, showed that family history was strongly related to the incidence of hypertension especially in older people (Naruse *et al* 1998). It has been shown that in humans, chromosome 17q is associated with the incidence of hypertension (Baima *et al* 1999), and also that the $G_s\alpha$ gene (G_s protein α-subunit) is a factor in blood pressure changes (Jia *et al* 1999).

Another study found that genes were related to a change of blood pressure in between 30% and 50% of individuals (Dominiczak *et al* 2000). A study of the genetic effects on hypertension in 6000 British patients found approximately 3.5 times the risk for hypertension as a sibling of hypertensive person, compared with the risk in the general population (Brown 1996). Data showed that the gene identified as influencing hypertension was found more frequently in hypertensive than normotensive people, and more frequently in normotensive people with hypertensive parents than in those with normotensive parents. In addition, this study also found this gene more often in hypertensive siblings (Williams *et al* 2000).

In animal trials, Devlin *et al* (2000) found that, compared to normotensive rats, hypertensive rats displayed abnormal growth and death of vascular smooth muscle cells resulting from DNA synthesis and apoptosis.

Reseach thus demonstrates that the risk for hypertension can be passed on by hereditary means.

2.2.3 Diet and weight

Consumption of food high in saturated fat, salt or sodium, the level of alcohol intake, and weight gain play an important role in contributing to hypertension. Brien, Beevers & Marshall (1995), the National Heart Foundation of Australia (2003) and the Australian Institute of Health and Welfare (2004) concluded that obesity, saturated fat intake and consumption of food high in salt or sodium related to the incidence of hypertension.

Obesity and body mass index

As the body mass index increases, blood pressure also increases. Kotsis *et al* (2005) found that body mass index was a contributory factor for high blood pressure. A cohort study of 300 Japanese-Americans, using a 10 to 11 year follow-up, found that intra-abdominal fat measured using computed tomography was significantly related to hypertension (Hayashi *et al* 2004).

A similar result was found by Poirier *et al* (2005). This study supported the finding that abdominal obesity as measured by waist circumference related to the increase of systolic blood pressure in both sexes. Another study by Niskanen *et al* (2004) showed that an increase in waist circumference was strongly associated with the development of hypertension. This cohort study investigated the effects of abdominal obesity and smoking on the development of hypertension in 379 middle-aged

normotensive men over an 11 year follow-up period. It found that 124 participants (33%) developed hypertension; factors which substantially related to the incidence of hypertension were cigarette smoking and waist circumference.

Singh *et al* (1997) studied 984 Indian men and 951 Indian women to find the risk factors for hypertension. The study found that being overweight or obese and leading a sedentary lifestyle were significant risk factors for hypertension. Obesity not only significantly increased systolic blood pressure but also decreased insulin sensitivity and vasodilation (de Jongh *et al* 2004). Furthermore, an additional study in the area showed that an increase in body mass index and systolic blood pressure contributed to deaths in both genders, but especially in men (Bender *et al* 2002). There is strong evidence that overweight is a significant risk factor for hypertension.

Consumption of food high in sodium

High sodium intake is found to be a factor influencing hypertension development. In animal trials, it was found that a high sodium intake contributed to an impairment of renal blood flow, a decrease of the glomerular filtration rate and filtration fraction, and also induced albuminuria and hypertension in rats (Sanders *et al* 2005). A similar result was detailed in Yu *et al*'s study (1998) which indicated that a high salt diet caused fibrosis and hypertrophy in the left ventricle and kidney in both hypertensive and normotensive rats.

In a human study, high sodium intake was related to an increase in systolic blood pressure (Hajjar *et al* 2001), and also contributed to hypertensive renal disease,

cerebrovascular disease and impairment in the elasticity of large arteries (Franz, Schmieder & Matthew 1997).

Alcohol consumption

Several studies have demonstrated a non-linear relationship between alcohol and blood pressure. Both blood pressure and the heart rate significantly increased in healthy normotensive men after drinking 40 grams of red wine or beer (Zilkens *et al* 2005). In a study by Nanchadal, Ashton & Wood (2000), the risk of hypertension was also found to increase in people who drank more than 15 alcoholic units a week. Other studies have found that drinking more than 210g alcohol a week induced hypertension (Fuchs *et al* 2001), especially drinking every day or drinking without food (Stranges *et al* 2004; Marques-Vidal *et al* 2001). Consumption of large amounts of alcohol contributes to other health issues. Reynolds *et al* (2003) found that heavy alcohol consumption (more than 60g of alcohol a day) increased the incidence of stroke, however light to moderate consumption of alcohol (less than 15 units a week) decreased the incidence of cerebrovascular accident or cerebrovascular disease (Malinski *et al* 2004; Nanchadal, Ashton & Wood 2000; Sierksma *et al* 2004). Schminke *et al* (2005) found that drinking less than 80g per day of alcohol helped to decrease the thickness of the carotid artery in men, resulting in a decreased incidence of cerebrovascular disease and stroke. Moderate wine consumption (less than 60g of alcohol a day) has been demonstrated to decrease deaths in patients with hypertension (Renaud *et al* 2004).

In conclusion, excess alcohol consumption is related to high blood pressure and its complications, whereas light to moderate alcohol consumption is a factor in

maintaining good health. This may be particularly relevant in individuals where high alcohol intake is linked to poor nutrition, obesity and other risk factors such as smoking.

2.2.4 Smoking

Smoking plays a role as a risk factor for hypertension. A study of the effects of heavy smoking on blood pressure was conducted on 16 normotensive smokers. Ten participants were asked to smoke one cigarette every 15 minutes for one hour, then no cigarettes for one hour. Their blood pressure and heart rates were continuously monitored during the smoking period and during the non-smoking hour. Six other participants were asked to smoke two cigarettes per hour for eight hours. Their blood pressure and heart rates were monitored every ten minutes in ambulatory conditions using the Finapres device. The results showed that blood pressure and heart rates were persistently higher during the smoking times than the non-smoking times in both groups (Groppelli *et al* 1992). Another study of the relationship between smoking and hypertension in 12 417 men from 10 medical centres in Western and Central France found that smokers had significantly greater risk of hypertension compared to non-smokers (Halimi *et al* 2002).

Conversely, two studies showed that smoking had some positive effects on blood pressure. Primatesta *et al* (2001) studied the relationship between smoking and blood pressure and found that smoking caused high systolic blood pressure only in men aged more than 45 years. Women who were light smokers (up to nine cigarettes a day) had lower systolic blood pressure than those who were heavy smokers or who did not smoke. Another study found an inverse association between smoking and

blood pressure in 352 participants, including 161 smokers. Smokers, as compared with non-smokers had statistically significant lower clinical blood pressure, day ambulatory blood pressure, and night ambulatory blood pressure (Mikkelsen *et al* 1997).

Although it can not be assumed from these studies that cigarette smoking contributes to hypertension, smoking in patients with hypertension contributes to complications such as thickness, narrowness and stiffness of the carotid artery (Liang *et al* 2001), subarachnoid haemorrhage (Feigin *et al* 2005), and decreased lifespan (Simons *et al* 2005).

2.2.5 Lack of activity

A decrease in daily activity is related to hypertension. A seven year study of 2548 middle-aged Japanese men who either had no hypertension or took hypertensive drugs assessed the relationship between daily activities and the risk of hypertension. The study found that daily activity was inversely related to the incidence of hypertension (Nakanishi 2005). The same result was found by Singh *et al* (1997). Subjects were 984 men and 951 women in North India. The authors concluded that a sedentary lifestyle was an important risk factor for hypertension.

2.2.6 Co-morbidity

Many clinical conditions such as diabetes, cerebrovascular disease, heart disease and chronic kidney disease are co-morbidities of hypertension. However, the most common causative co-morbidity of hypertension is diabetes mellitus. The combinations of both induce two times the risk of vascular diseases including

coronary artery disease, stroke and peripheral vascular disease (Mancia *et al* 2002). Patients with hypertension and diabetes mellitus are more likely to have chronic kidney disease and end-stage renal disease (Lea & Nicholas 2002), contributing to increasing blood pressure.

2.3 Mediating factors for hypertension and hyperlipidaemia

In addition to the risk factors discussed above, there are mediating factors which affect the lifestyle or quality of life in patients with hypertension or hyperlipidaemia. These elements include economic factors, personality and stress, medications, lifestyle modifications and complementary therapies.

2.3.1 Economic factors

Chronic diseases incur costs for drugs, health insurance, medical consultations, laboratory tests, transportation and food (Dias da Costa *et al* 2002). Low socioeconomic status and financial difficulties were found to be associated with high blood pressure (Kalimo & Vuori 1993; Matthews *et al* 2002; Nilsson *et al* 1994; Steptoe & Marmot 2005). Mendez *et al* (2003) outlined the negative relationship between socioeconomic status and hypertension. This study was undertaken in an urban area of Jamaica, a middle-income developing country. It found that blood pressure was substantially higher in poor men with a low level of education. Conversely, women with a high income experienced higher blood pressure than did those with a low income.

2.3.2 Stress and personality

Stress is claimed to contribute to development of hypertension through its stimulation of the sympathetic nervous system (Kaplan, Lieberman & Neal 2002). A longitudinal observation study of stress on blood pressure in 144 nuns (intervention group) and 138 females from the general population (control group) showed that during the 30 year follow-up period, there was a statistically significant difference in blood pressure between the two groups. Compared to the control group, none of the nuns showed an increase in diastolic blood pressure over 90 mm Hg whereas blood pressure increased in the control group (Timio *et al* 1999).

Chronic stress in caregivers combined with low expression of this stress are also risk factors for hypertension (Shaw *et al* 2003). Particularly in women, suppression of anger increased systolic blood pressure (Helmers *et al* 2000). Stress from work contributed to the risk of hypertension in men (Pickering *et al* 1996; Schnall *et al* 1990; Theorell *et al* 1991). Unemployment and job insecurity were also associated with increased blood pressure in men (Levenstein, Smith & Kaplan 2001).

Some studies did not support the relationship between hypertension, personality and psychological characteristics such as Type A behaviour, anger, anxiety and depression. Friedman *et al* (2001), when studying a group of mild hypertensive men and normotensive men aged 30 to 60 years, found no difference in personality and psychological characteristics. On the other hand, highly defensive people tended to have high blood pressure. A study by Rutledge & Linden (2003) demonstrated that during three years of study, high-defensive participants (a total of 125 American participants) showed higher ambulatory blood pressure than in low-defensive group.

In summary, although the research is mixed, there is evidence that stress is an important risk factor for hypertension.

2.3.3 Hypertension medications

Hypertensive drugs are useful and effective in treating hypertension and preventing its complications, particularly in men (Gueyffier *et al* 1997). It was reported that the rate of using antihypertensive drugs in hypertensive Americans was higher because of their effectiveness (Glynn *et al* 1995). Death rates and complication rates from stroke and coronary heart disease were decreased by using antihypertensive drugs (Brien, Beevers & Marshall 1995; Glynn *et al* 1995). However, although hypertensive drugs do reduce blood pressure, they also have many side effects. Consequently, the aim in using these drugs is to lower blood pressure to below 140/90 mmHg with minimal or no side effects (Kaplan, Lieberman & Neal 2002). For each group of antihypertensive drugs, the benefits and side effects are different and should be their impact on the patient's quality of life should be considered.

Diuretics

Low-dose diuretics are recommended as the drug of choice to treat hypertension (Dickerson & Gibson 2005; Fretheim 2003). Diuretics are more effective in reducing blood pressure than other antihypertensive drugs such as beta blockers (Antonios *et al* 1996; Wright 2000). They also help to reduce health costs since they are less expensive than other antihypertensive drugs (Fretheim, Aaserud & Oxman 2003).

Thiazide diuretics not only effectively decrease blood pressure but also help to decrease the risk of cardiovascular morbidity and mortality by means of a decrease in

left ventricular mass (Gottdiener *et al* 1997; Ibrahim 1999). Low-dose thiazide (25mg/day) combined with potassium sparers help to reduce the incidence of cardiac arrest (Siscovick *et al* 1994).

Diuretics can cause ventricular arrhythmias and sudden death (Hoes *et al* 1995; Kaplan, Lieberman & Neal 2002), glucose intolerance and hyperinsulinemia (Kaplan, Lieberman & Neal 2002) particularly when combined with angiotensin converting enzyme inhibitors (eg captopril) (Hunter *et al* 1999). In contrast, however, Gress *et al*'s study (2000) showed that thiazide diuretics did not induce diabetes in patients with hypertension.

Hypercholesterolemia is another side effect of thiazides and should be avoided in patients with hypertension and hyperlipidaemia (Brien, Beevers & Marshall 1995). Other side effects of diuretics include hypokalemia, hyperuricemia, hypercalcemia, hyponatremia, hypomagnesemia, erectile dysfunction and impotence (Kaplan, Lieberman & Neal 2002). Shahinfar *et al* (1999) found that to reduce side effects (hyperuricemia) on angiotensin II receptor blockers (losartan) is recommended as a combination drug.

Adrenergic inhibitors

Adrenergic inhibitors have been found to reduce blood pressure effectively (Dickerson & Gibson 2005). This group is made up of peripheral inhibitors, central alpha 2 (α_2) agonists, alpha blockers and beta blockers. The side effects of peripheral inhibitors are nasal congestion, depression, an increase in gastric acid, orthostatic hypotension, diarrhoea, fluid retention and failure of ejaculation (Kaplan, Lieberman

& Neal 2002). Central α_2 agonists may cause sedation, a dry mouth and depression. Many patients experience hypotension in addition to sodium and water retention (Dickerson & Gibson 2005). Alpha blockers can cause headache, drowsiness, fatigue and weakness (Kaplan, Lieberman & Neal 2002).

Beta blockers were reported to reduce mortality and morbidity in older patients with hypertension (Dickerson & Gibson 2005), the symptoms of angina pectoris (Wright 2000) and coronary events (Wikstrand, Berglund & Tuomilehto 1991). Therefore, these drugs are suitable for patients with hypertension and myocardial infarction or angina and heart failure (Dickerson & Gibson 2005). However, these drugs can cause bronchospasm, hypoglycemia, depression, poor peripheral circulation, insomnia, bradycardia, fatigue, decreased exercise tolerance, hypertriglyceridemia, and decreased HDL cholesterol (Kaplan, Lieberman & Neal 2002). Shorr *et al* (1997) found no significant increase or decrease in the risk of hypoglycemia when using these drugs in hypertensive diabetic patients. In contrast, another study by Gress *et al* (2000) found that beta blockers contributed to the development of diabetes in patients with hypertension.

Vasodilators

This group consists of direct vasodilators, calcium channel blockers, angiotensin converting enzyme (ACE) inhibitors and angiotensin II receptor blockers. Direct vasodilators cause headaches, tachycardia, flushing, hirsutism and a lupus-like syndrome (Kaplan, Lieberman & Neal 2002). Calcium channel blockers were found to be the first-line drugs for African-Americans as opposed to thiazides (Sareli *et al* 2001). These drugs may induce nausea, headache, hypotension, palpitation,

conduction defects, flush, local ankle oedema and constipation (Kaplan, Lieberman & Neal 2002).

ACE inhibitors and angiotensin II receptor blockers significantly decreased clinical and ambulatory blood pressure and also significantly decreased albuminuria (Lacourciere *et al* 2000). However, the ACE inhibitors significantly increased the incidence of cough (Dickerson & Gibson 2005; Kaplan, Lieberman & Neal 2002; Lacourciere *et al* 2000), hypotension, loss of taste, skin rash, a rare leukopenia, hypoglycemia and impaired renal function (Kaplan, Lieberman & Neal 2002). In addition, angiotensin II receptor blockers contribute to hyperkalemia, hypotension, renal impairment and, rarely, angioedema (Kaplan, Lieberman & Neal 2002).

Using a combination of hypertensive drugs is recommended in patients with hypertension and co-morbidities or risk factors (Dickerson & Gibson 2005). Several studies have shown that using a combination of drugs significantly reduced blood pressure (Ajayi *et al* 1996; Kronig *et al* 1997; Hunter 1999; Ibrahim *et al* 1999). In high risk patients, such as black Africans, combination therapy is significantly more effective than single drug therapy (Ajayi *et al* 1996).

2.3.4 Hyperlipidaemia medications

Lipid lowering drugs are used to treat hyperlipidaemia, and many reports have shown them to be effective. Atorvastatin significantly decreased serum cholesterol and LDL cholesterol levels (Harangi *et al* 2004). Statin agents significantly reduced serum cholesterol, LDL cholesterol and triglycerides (Mansur *et al* 1999). The latest statin agent, rosuvastatin, was also proved to lower LDL level, improve triglycerides and

high density lipoprotein (HDL) cholesterol levels (McKenney 2005). Statin agents significantly decreased death, myocardial infarction and stroke (Pan *et al* 2004; Studer *et al* 2005); n-3 fatty acid agents also offered these benefits (Studer *et al* 2005).

Although these drugs provided great benefits to reduce serum lipids, they were reported to cause cancer in rats (Newman & Hulley 1996), but evidence of this in humans is still unclear (Blais, Desgagne & Lelorier 2000; Coogan *et al* 2002; Cyrus-David *et al* 2005).

Overall, hypertensive and hyperlipidaemia medications play significant roles in a patient's quality of life. Some improve their quality of life by lowering blood pressure and serum lipids, decreasing complications and deaths, while some contribute to poor quality of life by virtue of their side effects.

2.3.5 Lifestyle modifications

An unhealthy lifestyle can cause hypertension, so lifestyle modifications are an essential component of hypertensive management (National Heart Foundation of Australia 2003). A United States study of factors associated with hypertension control in the general population examined 3077 non-Hispanic white participants, 1742 non-Hispanic black participants and 1067 Mexican-Americans participants aged 18 years or older with hypertension. It found that the factors influencing hypertension control were lifestyle modifications, including dietary sodium reduction, weight loss and exercise (He *et al* 2002).

Weight loss

Weight gain causes higher blood pressure and conversely, weight loss causes lower blood pressure. There are strong positive correlations between the degree of adiposity and fasting triglycerides. Plasma cholesterol is also positively correlated with body mass index, although less strongly than triglycerides (Thompson 1990).

A study of the long term effects of weight loss and dietary sodium reduction was undertaken on 181 men and women aged 30 to 54 years who participated in hypertension prevention trials in Baltimore in 1987-88. All participants had a diastolic blood pressure of 80 to 89 mmHg and systolic blood pressure less than 160 mmHg. Participants were randomly assigned to one of two 18-month lifestyle modification interventions – including a weight loss group and a dietary sodium reduction group – or to a control group. Over a seven year follow-up, blood pressure was measured by blinded observers using a random-zero sphygmomanometer. The result showed that the weight loss intervention program was associated with a 77% reduction in the incidence of hypertension, whereas the sodium reduction program did not reach statistical significance in reducing the incidence of hypertension (He *et al* 2000).

A meta-analysis of 25 randomised controlled trials to estimate the effects of weight reduction on blood pressure in 4874 participants showed that systolic blood pressure and diastolic blood pressure could be reduced by between -1.05 and -0.92 mmHg respectively for each kilogram of weight loss (Neter *et al* 2003).

Exercise

Aerobic exercise significantly reduced mean systolic and diastolic blood pressure in both hypertensive and normotensive persons (Halbert *et al* 1997; Whelton *et al* 2002). A study of the effects of exercise and weight loss in 99 Americans with stage one to two hypertension (44 in the weight management group combining aerobic exercise with a behavioural weight loss program; 36 in the exercise-only group; 19 in the control group) showed that systolic and diastolic blood pressure were reduced in both active treatment groups after a six month treatment program (Georgiades *et al* 2000).

Exercise significantly decreased intramyocellular lipid in both males and females (White *et al* 2003). Physical activity significantly decreased levels of total serum cholesterol, LDL, triglycerides (Kraus *et al* 2002; Mansur *et al* 1999; Panagiotakos *et al* 2003; Skoumas *et al* 2003), oxidized LDL cholesterol and apolipoprotein B in women, and significantly increased the levels of HDL cholesterol (Kraus *et al* 2002; Panagiotakos *et al* 2003; Skoumas *et al* 2003) and apolipoprotein A1 in women (Panagiotakos *et al* 2003; Skoumas *et al* 2003).

In another study, 155 older men and women (average age 74.2 years ± 0.5) were interviewed regarding their daily physical activity in the previous month; their blood pressures, serum glucose and serum lipids were also tested. The study found that HDL cholesterol was significantly increased and mean blood glucose significantly decreased in physically active older people – defined as those who are physically active for more than five hours a day compared with those who have a sedentary

lifestyle or are physically active for less than five hours a day (Pescatello, Murphy & Costanzo 2000).

Interestingly, a single, short period of exercise could not decrease serum lipids (Imamura *et al* 2000). To achieve benefits from exercise, patients should exercise continually and gradually for 30 minutes or more a day, five times or more a week (Manger & Gifford 2001).

Dietary sodium reduction, low fat diet

The recommended maximum daily sodium intake is 2.4 grams (100 mmol or 6 grams of sodium chloride (NaCl)) (Joint National Committee 2003). High salt intake is strongly associated with high blood pressure and reducing salt intake to 100 mmol a day can lower 3.7 mmHg of systolic blood pressure and 2.0 mmHg of diastolic blood pressure (Elliott 1991). Midgley *et al* (1996) found that a 100 mmol daily salt intake significantly decreased only systolic blood pressure in patients with hypertension.

A meta-analysis study on 734 hypertensive and 2220 normotensive people on the effects of reducing salt intake for four or more weeks showed that salt reduction could significantly lower both systolic and diastolic blood pressures in both groups. A reduction of 50 mmol/d (3g/d), 100 mmol/d (6g/d) and 150 mmol/d (9g/d) in salt intake can decrease systolic and diastolic blood pressure by 3.6/1.9 mmHg, 7.1/3.9 mmHg, and 10.7/5.8 mmHg respectively in people with hypertension, and by 1.8/0.8, 3.6/1.7 and 5.4/2.5 mmHg respectively in normotensive people (He & MacGregor 2003). Reducing salt intake to 5 or 6 grams a day significantly decreased systolic blood pressure in isolated systolic hypertension and significantly decreased systolic

and diastolic blood pressure in combined hypertension patients (He, Markandu & MacGregor 2005). Reducing salt intake to 5 grams a day significantly lowered blood pressure in African patients with hypertension (Swift *et al* 2005).

Diets high in monounsaturated fatty acids such as olive oil, peanut oil, or peanuts and peanut butter helped lower total cholesterol and LDL cholesterol (Kris-Etherton et al 1999). High fibre diets, low fat diets and exercise significantly reduced the serum level of LDL cholesterol for both males and females (Beard *et al* 1996; Stefanick *et al* 1998; Welty *et al* 2002) and also significantly decreased the triglycerides level (Beard *et al* 1996; Welty *et al* 2002), serum glucose (Beard *et al* 1996) and blood pressure (Welty *et al* 2002).

Reduction in alcohol intake and smoking

There is no evidence of a directly positive relationship between smoking cessation and blood pressure, however, quitting smoking provides other benefits. In particular, for patients with hypertension and complications, benefits include a decrease of cardiovascular disease (Chehne *et al* 2002) and improvement of erectile dysfunction (Pourmand *et al* 2004). In addition, smoking cessation decreased deaths in patients with myocardial infarction (Kinjo *et al* 2005), specifically in patients with hypertension and this co-morbidity.

In contrast, two studies showed a negative relationship between smoking cessation and blood pressure. The first study was carried out on 8170 healthy male employees at a steel manufacturing company. After a four year follow-up, the study showed that current non-smokers, quitters for one to three years, and quitters for greater than

three years had significantly higher blood pressure than current smokers respectively. In addition, the incidence of hypertension for current smokers, current non-smokers and quitters was 1.8%, 2.3% and 3.5% respectively (Lee *et al* 2001). The second study was performed on female participants including 2381 non-smokers, 1162 smokers, and 388 ex-smokers. After a mean follow-up of 9.0 ± 5.8 years, the results showed that the ex-smokers had significantly more hypertension than the smokers and non-smokers (Janzon *et al* 2004).

Patients with hypertension should limit their alcohol intake to two standard drinks per day or less if male, and one standard drink per day if female. By reducing alcohol consumption, blood pressure can fall substantially in some patients (National Heart Foundation of Australia 2003). However, consuming low to moderate amounts of alcohol (eg two standard beers or two standard glasses of wine) can prevent coronary heart disease (Kaplan, Lieberman & Neal 2002). A meta-analysis of 15 randomized controlled trials to investigate the effects of alcohol reduction on blood pressure in 2234 participants showed that reducing alcohol intake significantly lowered mean systolic and diastolic blood pressure by -3.31 mmHg, and -2.04 mmHg respectively (Xin *et al* 2001).

In summary, lifestyle modifications including weight control, exercise, reducing salt and fat intake and reducing alcohol intake all contribute to lower blood pressure and serum lipids. The relationship between reducing smoking and lowering blood pressure is controversial. Although reduction in smoking does not seem to be related to lower blood pressure, smoking does contribute to narrowing of the blood vessels (Ismail 2005), which relates to increased accumulation of carotid plaque (Ishizaka *et*

al 2005) inducing arteriosclerosis (Jovelic *et al* 2005), and also lowers the high-density lipoprotein synthesis (Ismail 2005). Patients with hypertension are prone to develop cardiovascular disease by smoking.

2.3.6 Complementary therapies

The previous discussion considered a number of general lifestyle mediating factors. The next sections investigate the mediating factors of two complementary therapies – foot reflexology and foot massage – which are claimed to lower blood pressure, serum lipids and improve quality of life.

2.3.7 Foot reflexology

It is claimed that foot reflexology improves blood supply, reduces anxiety, fear and agitation, helps to relieve pain and improves the immune system (Byers 2001; Dougans 2002). As described in Chapter 1, several theories have been advanced to explain these claims. Some scientific studies support these claims although there are minimal studies specifically related to hypertension, serum lipids and quality of life (Frankel 1997; Park & Cho 2004).

Effects on hypertension and baroreceptor reflex

The effects of foot reflexology on blood pressure, serum lipid level and life satisfaction were studied by Park & Cho (2004). Thirty-four patients with essential hypertension participated in the study, including 18 participants in the treatment group and 16 in the control group (who received no treatment). For the treatment group, foot reflexology was provided twice a week for six weeks, as well as self administered foot reflexology twice a week for four weeks. At the end of the study,

systolic blood pressure was significantly decreased in the experimental group compared to the control group. However, there was no significant decrease in diastolic blood pressure between the experimental and control groups. The total cholesterol level, HDL and LDL cholesterol were not significantly decreased for either group, but the triglycerides level was significantly decreased in the treatment group. Life satisfaction was significantly improved in the treatment group.

It is important to note, however, that the small sample size and lack of blinding in Park and Cho's (2004) study may mean that the effects of foot reflexology cannot be accurately represented re reducing blood pressure, serum lipids and quality of life.

Frankel (1997) used a single-blind trial to study the effects of 45 minute reflexology and foot massage sessions on baroreceptor reflex sensitivity, blood pressure and sinus arrhythmia. His aim was to identify whether reflexology and foot massage affect the physiology of the body. Baroreceptor reflex sensitivity was measured using phase IV of the Valsalva manoeuvre, a period in the Valsalva manoeuvre during which blood pressure is substantially raised above the baseline blood pressure and sinus arrhythmia (The American Heritage Stedman's Medical Dictionary 2002). The study included 24 subjects – ten participants in the reflexology group, ten participants in the foot massage group and four participants in the control group who received no intervention. He found that there was no significant difference between the groups in resting blood pressure after intervention. However, there were significantly greater reductions in baroreceptor reflex sensitivity in the intervention groups (foot reflexology and foot massage) than in the control group, but no difference between reflexology and foot massage.

There are similarities between Frankel's study and this researcher's study in that the reflexology procedure for both used the Ingham method for 45 minutes per session all over the feet; and that foot massage was provided as a comparison group. However, there are also many differences. For instance, in Frankel's study the participants did not have hypertension, foot reflexology was performed only twice on each subject in the foot reflexology group, and the sample size was much smaller. For these reasons, the results from his study cannot be fully representative of whether or not foot reflexology can reduce blood pressure in patients with hypertension.

Effects on anxiety and pain

A qualitative study of foot reflexology was performed on 34 cancer patients in a palliative care unit in the north of England to investigate patients' perceptions of treatment. Foot reflexology was provided for four to six sessions. At the end of the study, participants were asked to complete a questionnaire which included both yes/no questions and open-ended questions which explored their perception of received treatment. A thematic analysis was used because of the small sample size and the fact that it was a non-randomized trial. Results showed that the apparent benefits of foot reflexology were to induce relaxation by relieving tension and anxiety. It also promoted comfort and wellbeing in these patients (Gambles, Crooke & Wilkinson 2002).

However, Ross *et al* (2002) found different results in their study of foot reflexology and its effects on anxiety and symptoms in 26 British patients with advanced cancer. They divided the group into two – 14 participants in the foot reflexology group and 12 participants in the foot massage group, using a randomized controlled trial design.

All subjects received either foot reflexology or foot massage without pressing specific areas of the feet, once a week for six weeks by three trained reflexologists. The Hospital Anxiety and Depression Scale (Le Fevre *et al* 1999) was used to measure their anxiety levels, and a 10 point rating score of the severity of ten common symptoms was used to measure symptoms. These scales were administered to participants by blinded interviewers at the start of the study and within 24 hours of each session. At the end of the study, seven participants died, one dropped out, one did not have baseline record, so only 17 participants remained including 7 in the foot reflexology group and 12 in the foot massage group. The results showed that there was no significant difference in the Hospital Anxiety and Depression score between the two groups. However, the symptom score showed a significant improvement in appetite and mobility for the foot massage group. Given that the sample size was small and limited to patients with advanced cancer, findings might not be generalisable to other patient populations.

In another study, a 30 minute foot reflexology session was carried out on 23 inpatients with breast or lung cancer (13 with breast cancer and 10 with lung cancer) to measure levels of anxiety and pain. A visual analogue scale (Cline *et al* 1992; McGuire 1988) was used to measure anxiety level during the selection process; if potential subjects were in an anxious state, they were included in the study. A pre-post crossover trial was used. Participants were randomized into two groups – group A was the treatment group, group B was the control group. Thirty-minute foot reflexology sessions using the Ingham method were carried out. During the session, 15 minutes were spent on specific areas related to pain and cancer sites. The visual analogue scale (Cline *et al* 1992; McGuire 1988) was used to measure anxiety level

and pain intensity. The Short Form McGill Pain Questionnaire (Melzack 1987) was used to measure pain level. In the control group, anxiety and pain were measured before and at the end of the control time (a 30 minute time during a day). In the treatment group, anxiety and pain were measured before and immediately after treatment. The study showed that foot reflexology significantly lowered anxiety levels in patients with breast or lung cancer. Pain was significantly decreased in patients with breast cancer. Since only two patients with lung cancer reported pain, a calculation was unable to be produced for this group (Stephenson, Weinrich & Tavakoli 2000).

A similar study by Stephenson, Dalton & Carlson (2003) explored the effects of foot reflexology on pain in patients with cancer. Thirty-six inpatients with metastasised cancer participated, including 19 in the foot reflexology group and 17 in the control group (who received no intervention). All participants reported a pain score of 2 or higher on the 0 to 10 self-report pain scale of the Joint Commission on the Accreditation of Healthcare Organizations (Joint Commission on the Accreditation of Healthcare Organizations 2001). A 30 minute foot reflexology session was carried out once a day for two days using the Ingham method. Analgesic consumption was recorded for three days using the Opioid Converter (DuPen & DuPen 2000). The pain score was recorded immediately after treatment, three hours after treatment, and 24 hours after treatment. The results showed that foot reflexology significantly decreased the pain score immediately after treatment in the treatment group. There was no significant decrease in pain at three and 24 hours after treatment.

In a randomized controlled trial study of foot reflexology on reducing pain in 29 patients who had knee replacement surgery, reflexology was performed by a trained reflexologist within 24 hours of surgery and three times a week until discharge. Participants included a control group who receive no intervention (nine participants), a foot reflexology group (seven participants) and a placebo group (thirteen participants) who received foot reflexology but without pressing the areas affecting healing of the knee. Pain level, length of hospital stay and time to reach 70º knee flexion were measured. Analgesic consumption and a visual analogue scale (McDowell & Newell 1996) were used to assess pain level. Results showed that there was no significant difference in length of stay or rate of recovery of knee flexion between the three groups. Morphine consumption in the control group was significantly more than in the treatment and placebo groups, but there was no difference between the treatment group and the placebo group (Evans *et al* 1998). Using 'placebo' reflexology may provide potential effects of pressure on surrounding areas that may enhance immune system or improve related organs to pain controlling. Use of light foot massage may have been more appropriate in controlling for potential effects of massage and/or touch as contrasted with reflexology pressure points.

Tovey (2002), using a single-blind trial design, studied the effects of foot reflexology on reducing symptoms in 34 patients with irritable bowl syndrome. Nineteen participants received a 30-minute foot reflexology session and 15 participants received foot massage without pressing specific areas on the feet. Both groups received either foot reflexology or foot massage once a week for four weeks and then once a fortnight for two sessions. Three symptoms – abdominal pain, constipation or

diarrhoea, and abdominal distention – were measured using a Health Assessment Sheet (Whorwell 1984) before the first intervention, during the intervention, after the intervention, and at the three month follow-up. Results showed no significant differences between the two groups in improvement of abdominal pain, constipation/diarrhoea and abdominal distention.

In a Danish study, foot reflexology was used for six months on 220 patients with migraine and/or tension headache. A headache diary was recorded by patients for one month before treatment and during treatment. Qualitative interviews were performed at the end of the study. The results showed that foot reflexology helped decrease headache in 81% of patients – 19% of these no longer took medication. However, the study did not show how long each treatment session took (Launso, Brendstrup & Arnberg 1999).

In summary, the effects of foot reflexology on reducing anxiety and pain are not strongly supported by all previous studies.

Effects on symptom management for patients with cancer

A study of the effects of 40 minutes of foot reflexology on nausea, vomiting and fatigue was performed in 34 Korean patients with breast cancer who were undergoing chemotherapy. There were 18 participants in the foot reflexology group and 16 in the control group (who received no intervention). A non-equivalent pre-post design was used to measure nausea, vomiting and fatigue. After four sessions of treatment, there was a statistically significant decrease in nausea, vomiting and fatigue in the treatment group compared to the control group (Yang 2005).

Fatigue was measured in 20 patients with terminal cancer in the Palliative Care Unit, National Sanyo Hospital, Japan. A combination of complementary therapies was used including aromatherapy, foot baths and foot reflexology. Participants first had three minutes of aromatherapy and foot baths in warm water with lavender oil, and then received foot reflexology with jojoba oil and lavender oil for ten minutes. The Cancer Fatigue Scale (Okuyama *et al* 2000) was used to measure fatigue before treatment, and one and four hours after treatment. Results showed that there was a significant decrease in fatigue by using this combination of complementary therapies (Kohara *et al* 2004).

Effects on premenstrual syndrome and menopausal syndrome

Reflexology is claimed to balance the function of glands and organs of the body (Byers 2001; Dougans 2002). A randomized control study was carried out on 35 American women who suffered premenstrual syndrome. They received a 30 minute session of ear, hand and foot reflexology once a week for eight weeks. The study was divided into 18 participants in the foot reflexology group and 17 participants in the placebo reflexology group. The placebo group received foot reflexology procedures without pressing the specific areas related to organs contributing to premenstrual syndrome. A daily diary including a seven day symptom score was provided to all participants to complete every day for seven days before menstruation. This score comprised a four point rating scale (0-3) to measure 38 premenstrual symptoms. It was completed by participants before treatment for two months, during treatment for two months, and after treatment for two months. The study concluded that there was significantly greater decrease in premenstrual syndrome in the foot reflexology group

than in the placebo group; this decrease included both somatic and psychological symptoms such as breast tenderness, abdominal bloating, menstrual cramps, anxiety, depression and irritation (Oleson & Flocco 1993).

In contrast, Williamson *et al* found no significant difference in the improvement of psychological symptoms including anxiety and depression and physiological symptoms such as flushes, night sweats and sleep problems in 76 British menopausal women. Thirty-nine participants received a 45 minute foot reflexology session, and 37 participants received non-specific foot massage. Both groups received nine sessions of either foot reflexology or non-specific foot massage (once a week for six weeks followed by once a month for three months). The Women's Health Questionnaire (Hunter 1992) was used to measure anxiety and depression. A visual analogue scale (McDowell & Newell 1996) was used to measure the severity and frequency of flushes and night sweats (Williamson *et al* 2002).

Effects on encopresis and constipation

Bishop (2003) studied 48 children with encopresis (faecal incontinence) or chronic constipation who received 30 minutes of foot reflexology once a week for six weeks. The children were aged three to fourteen years. A questionnaire to monitor bowel movements and soiling patterns was completed for a seven day period before, during and after the intervention. A questionnaire for parents on their attitudes towards foot reflexology was completed before and after the intervention. The results found that the number of bowel movements significantly increased and the incidence of soiling significantly decreased. In addition, 72% of parents felt satisfied with the treatment their children had received.

Effects on multiple sclerosis

Foot reflexology may contribute to the balance of the central nervous system in patients with multiple sclerosis. One study looked at 53 patients with multiple sclerosis. They were split into two groups – 27 in the foot reflexology group and 26 in the foot massage group who received either 45 minutes of foot reflexology or foot massage without pressing the specific areas on the feet. This took place once a week for 11 weeks at the multiple sclerosis centre, Israel. The intensity of paresthesias (numbness and the tingling feeling like pins and needles), urinary symptoms, muscle strength and spasticity were measured at the start of the study, after six weeks of treatment, at the end of the study, and at a three month follow-up. The visual analogue scale (McDowell & Newell 1996) was used to measure the intensity of paresthesias. The American Urological Association Symptom Score (Bdesha *et al* 1994) was used to measure urinary symptoms. Spasticity was assessed using the Ashworth Score and muscle strength was measured using the British Medical Research Council Scale (Smith *et al* 1994). The results showed a significant improvement in paresthesias, urinary symptoms and spasticity in the foot reflexology group. In particular, the intensity of paresthesias was significantly improved even at the three month follow-up stage. However, there was no significant difference in muscle strength between the groups (Siev-Ner *et al* 2003).

Effects on asthma

The idea that reflexology can improve asthma symptoms was not supported by a randomized, double-blind, control study at an allergy unit in Copenhagen. Forty outpatients with bronchial asthma participated in the study – sessions took place once a week for ten weeks. Twenty participants received 45 minutes of reflexology, and

20 participants received placebo reflexology where the specific reflexology areas were not pressed. Peak flows were monitored by patients themselves immediately after getting up in the morning and in the evening during the two weeks before treatment, ten weeks of treatment, and the two weeks after treatment. No changes in peak flows were shown between the two groups. Lung function was measured as forced expiratory volume in one second and forced vital capacity at the first, fifth and tenth visit. There was no significant difference in improvement of lung function between the groups. Bronchial sensitivity to histamine was measured before the start of treatment and at the end of the study for one week. An improvement in bronchial sensitivity was detected in both groups but it did not reach significance. The quality of life was measured before and after treatment using SF-36 (a multi-purpose, short-form health survey with only 36 questions) (Ware & Sherbourne 1992). There was no significant difference in quality of life between the two groups (Brygge *et al* 2001).

In summary, the effects of foot reflexology on reducing symptoms are not strongly supported by previous studies. Study limitations included small sample sizes, very specific patient group (no blinding), limited justification for duration or type of intervention, limited controlling for touch or massage compared to reflexology, and/or untested outcome measures.

2.3.8 Foot massage

Massage is a well known and accepted therapy (Domenico & Wood 1997; Hayes & Cox 1999; Hulme, Waterman & Hillier 1999; Walker & Walker 2003). Massage can be applied on the entire body, or on particular areas such as the face and foot.

Different types of massage are used in different cultures eg Swedish remedial massage, traditional Chinese massage and traditional Thai massage. Some massage procedures are similar to each other, and some are different (Domenico & Wood 1997). However, all kinds of massage are claimed to bring many benefits for the physical, mental and emotional states of clients. Massage is claimed to increase blood and lymph circulation, relieve pain and tension, induce relaxation, relieve anxiety, improve sleep, relieve constipation, improve mental and emotional states, increase the feeling of safety and openness, increase awareness of feelings and needs, and induce emotional release, self-acceptance and a state of wellbeing (Domenico & Wood 1997; Walker & Walker 2003). These claims are scientifically explored in many studies as detailed below.

A randomized control study was carried out on 87 Australian inpatients with cancer to investigate the effects of a ten minute foot massage on pain, nausea and relaxation. All participants were randomly allocated into a control group or an intervention group. Of the three sessions, one was a control intervention where participants were asked to take a rest, watch television or read in bed. Two sessions were the intervention condition where participants were given a foot massage for ten minutes. Each of the three sessions took place at night for three nights sequentially. Pain, nausea and anxiety were assessed before and after each session using a visual analogue scale (McDowell & Newell 1996). Heart rates were monitored (as a relaxation indicator) before intervention and after intervention for 10 to 20 minutes. The results indicated that foot massage significantly decreased pain and nausea and significantly improved relaxation in patients with cancer (Grealish, Lomasney & Whiteman 2000).

A non-blinded randomized controlled trial study of a session of 20 minutes of foot massage or 20 minutes of guided relaxation was carried out on 25 British patients who had undergone coronary artery bypass graft surgery. It included seven participants in a control group who received no treatment, nine participants in a guided relaxation group who listened to a relaxation tape and used a muscle relaxation technique, and nine participants in a foot massage group. Wellbeing was assessed immediately before and after the intervention including psychological aspects such as level of pain, anxiety, tension, calmness, rest and relaxation, and physical aspects such as systolic blood pressure, diastolic blood pressure, pulse and respiration. The visual analogue scale (McDowell & Newell 1996) was used to measure psychological aspects. The results showed no significant difference in physical aspects between groups after the intervention. With regard to the psychological aspects, only the level of calmness significantly reduced in both intervention groups. For the foot massage group, an improvement was found in level of relaxation and reduction of tension and pain (Hattan, King & Griffiths 2002).

A five minute foot massage was performed on 59 British women who underwent laparoscopic sterilization. Thirty participants (intervention group) received foot massage and standard analgesia and 29 participants (control group) received only standard analgesia. Satisfaction, memory and analgesia consumption were assessed. An open-ended questionnaire comprised of six questions was given to participants to complete at the end of the study to measure satisfaction and memory. The 0 to10 Numerical Rating Scale (McCaffery & Pasero 1999) was used to measure pain intensity for five phases including arrival at the ward, ten minutes before the foot massage, five minutes after the foot massage, when ready for discharge, and when

leaving the ward. The study found that there was no significant difference in satisfaction, memory, post-operative pain experience or consumption of analgesia between the intervention and control groups. However, there was a significant difference in the mean pain scores that were analyzed over time. These scores were lower in the foot massage group than in the control group (Hulme, Waterman & Hillier 1999).

A thirty minute foot, back, neck and shoulder massage was performed on nine American hospitalized males with cancer to measure pain perception, anxiety and relaxation. The massage was provided once a day for two evenings. Pain and relaxation were assessed using the visual analogue scale (McDowell & Newell 1996) before and immediately after the intervention. Anxiety was measured using the Spielberger State Anxiety Inventory (Spielberger *et al* 1983) before and immediately after the intervention. Physical aspects were monitored as a relaxation indicator including heart rate, respiratory rate and blood pressure before, immediately after, and ten minutes after the intervention. The study found that massage significantly reduced the level of pain and anxiety, and also improved relaxation. However, the relaxation indicators as measured by heart rate, respiratory rate and blood pressure were not conclusive. The study found no significant changes in the heart rate and diastolic blood pressure; only the respiratory rate and systolic blood pressure significantly decreased (Ferrell-Torry & Glick 1993).

In a critical care unit, a five minute foot massage was carried out on 25 British patients to measure physiological and psychological stress. Heart rate, arterial blood pressure, respiration rate and peripheral oxygen saturation were measured as

indicators of physiological and psychological stress or a state of relaxation. These measures were monitored five minutes before, during treatment (between feet), and five minutes after the intervention. An average of 2.7 sessions was performed on each patient with some patients receiving more sessions than others. The study showed a significant decrease in heart rate, mean arterial blood pressure and respiration rate during the foot massage intervention. However, there was no significant effect on peripheral oxygen saturation from the intervention (Hayes & Cox 1999).

Similar results were found for a Thai foot massage study which measured vital signs as an indicator of relaxation and comfort. Twenty older people aged 61 to 69 years (four men and sixteen women) were given Thai foot massage and their vital signs measured, using a pre-test/post-test quasi-experimental design. The results showed that Thai foot massage significantly decreased pulse rate, respiratory rate and blood pressure level after treatment, whereas temperature significantly increased (Jirayingmongkol *et al* 2002). Although details of Thai massage procedures were not given, it appears that some procedures are similar to western foot massage but most are different. Some procedures of Thai foot massage use a small stick to rub some parts of the feet (Subjaruean, Deeviset & Toieum 2002).

In summary, studies have indicated that foot massage seems to be an effective treatment for inducing relaxation. However, study limitations included small sample sizes, very specific patient group (no blinding), limited justification for duration or type of intervention, and/or untested outcome measures.

2.3.9 Comparison of complementary therapies as mediating factors

As outlined in the studies discussed above, one of the benefits of both foot reflexology and foot massage is to assist in achieving a state of relaxation. However, to reach this same result, both complementary therapies have different principles. Foot reflexology uses the principle that pressing the specific points on the feet related to specific glands and organs can reorganize underactive or overactive glands or organs to achieve balance. Foot massage emphasizes muscle relaxation using massage techniques, without pressing on specific areas. The current study used a light foot massage control group in order to control for the demonstrated relaxation effects of light foot massage alone thus highlighting any effects of reflexology pressure points.

Overall, previous studies did not clearly indicate whether foot reflexology can help lower blood pressure, LDL cholesterol and triglyceride levels. This study aims to explore these gaps as well as building on previous studies dealing with the effects of foot reflexology on quality of life.

2.4 Outcomes

The sections below discuss the quality of life outcome factors including physical health changes, psychological changes and socioeconomic changes related to risk factors and mediating factors. Some factors contribute to positive changes while others bring negative changes.

2.4.1 Negative changes in quality of life

Antihypertensive agents

Hypertension contributes to a significant decrease in patients' quality of life especially changes in physical health (Erickson, Williams & Gruppen 2001). The study by Erickson, Williams & Gruppen (2001) examined the relationship between symptoms related to hypertensive drugs and physiological and psychological quality of life in Americans. The control group had 100 healthy participants. The intervention group had 125 patients with hypertension who were taking hypertensive drugs. The Symptom Distress Checklist (Anderson & Testa 1994; Anderson, Nackley & Testa 1995; Testa *et al* 1991) was used to measure symptoms – it includes 51 symptoms related to hypertensive drugs, frequency and level of distress caused by symptoms. The SF-36 Health Survey, version 1.0 (Ware & Sherbourne 1992) was used to assess quality of life. The study found that symptoms and distress were significantly higher in the intervention group, and quality of life scores were significantly lower in the intervention group particularly in physiological areas including pain, general health, physical functioning, social functioning and vitality; sexual problems were a major cause for distress. There were no significant differences in psychological areas between the groups.

Another study by the same researchers was conducted over a six month period on 125 American outpatients with hypertension who were taking hypertensive drugs. The number of symptoms and symptom distress were assessed using a modified Symptom Distress Checklist (Anderson & Testa 1994; Anderson, Nackley & Testa 1995; Testa *et al* 1991) and medical records. The Symptom Distress Checklist used yes/no questions to assess 51 symptoms, their frequency and the extent that the

symptoms caused distress. The SF-36 Health Survey (Ware & Sherbourne 1992) was used to measure quality of life including physical and psychological variables. The relationship between number of symptoms, symptom distress and quality of life was explored. The results showed a strong inverse relationship between age, length of treatment, number of symptoms and quality of life particularly in physiological areas. Symptom distress showed an inverse relationship with quality of life in psychological areas (Erickson, Williams & Gruppen 2004).

A decrease in sexual desire, erectile dysfunction and difficult ejaculation in men with hypertension are proven side effects of some hypertensive drugs such as diuretics, β-blockers, and centrally acting antiadrenergic drugs (Fogari & Zoppi 2002). Erectile dysfunction significantly reduced the quality of life in men with hypertension (Kushiro *et al* 2005). This study was conducted on 347 Japanese men aged 40 to 59 years, including 102 men with hypertension in the hypertension group and 245 healthy men in the control group. Calcium channel blockers, β-blockers, angiotensin-converting enzyme inhibitors, α_1- blockers, diuretics and other hypertensive drugs were given to the hypertension group. Quality of life and erectile dysfunction were assessed. The Medical Outcome Study SF-36 Health Survey (Ware & Kosinski 2001) was used to measure quality of life. The five item version of the International Index of Erectile Function (Rosen, Cappelleri & Gendrano 2002) was used to assess erectile dysfunction. The results showed erectile dysfunction was significantly higher in the hypertension group compared to the control group. Hypertension with erectile dysfunction was the significant variable in lowering the quality of life in men with hypertension. Particularly, erectile dysfunction contributed to a decrease in physical, mental and emotional vitality, and general health.

Women with hypertension also showed a decrease in sexual function (Duncan *et al* 2001). This study, which aimed to measure sexual function, was carried out on 112 women patients with hypertension and 112 healthy women. A mailed self-administered questionnaire was used to assess sexual function. The results showed that the women with hypertension experienced more difficulty in achieving lubrication and orgasm than the healthy women.

Economic factors (financial difficulties)

Patients with hypertension who have a low income are likely to also have a low quality of life. Cote *et al* (2005) studied health-related quality of life in 91 Canadian patients with hypertension over a nine month period (35 in the intervention group, 56 in the control group). The French-Canadian version of the SF-36 Health Survey (Dauphinee *et al* 1997) was used to assess quality of life. On the first visit, the intervention group was provided with a computer-assisted educational program related to antihypertensive medication. All participants had their blood pressure measured three times each visit for three pharmacy visits and three home visits. The results showed that the intervention group with a high income had a significantly higher quality of life according to a 'higher in vitality' score between baseline and post-intervention. The intervention group with a low income had a significantly lower quality of life according to a 'lower in mental health' score between baseline and post-intervention.

Stress

Stress is a major factor influencing the quality of life of patients with hypertension and a low income. A study of 183 American patients with hypertension and a low

income investigated their quality of life related to stress events in a two year period. The Life Experiences Survey (Sarason, Johnson & Siegel 1978) was used to assess major stress events in the past six months, and the Weekly Stress Inventory (Brantley *et al* 1997) was used to assess minor stress events in the past week. The SF-36 Health Survey (Hays, Sherbourne & Mazel 1993) was used to measure quality of life. Over a two year period, each participant completed a total of seven, Weekly Stress Inventory two Life Experiences Survey and four SF-36 surveys. The results found that both major and minor stresses significantly impacted on the quality of life of patients with hypertension and a low income (Ames, Jones & Brantley 2001).

Co-morbidity

Patients with hypertension and co-morbid conditions tend to have a lower quality of life. Quality of life as measured using the SF-36 Health Survey (Ware, Kosinski & Keller 1994; Ware & Gandek 1998) was explored in 92 Canadian patients with hypertension and angina and/or myocardial infarction (Lalonde *et al* 2004). The authors concluded that patients with hypertension and cardiac conditions had a significant decrease in quality of life especially in the area of physical health (Lalonde *et al* 2004).

2.4.2 Positive changes in quality of life

Antihypertensive agents

Some antihypertensive drugs such as the calcium channel blocker manidipine may improve patients' quality of life. In one study over 48 weeks, 10-20mg of manidipine or 5-10mg of amlodipine was provided once daily after breakfast to 361 Italian participants – 183 in the manidipine group and 178 in the amlodipine group. After 12

weeks of treatment, their quality of life was assessed using the Subjective Symptoms Assessment Profile (Dimenas *et al* 1990) and General Wellbeing Schedule (McDowell & Newell 1996). The Subjective Symptoms Assessment Profile assessed symptoms in six areas including emotional distress, gastrointestinal symptoms, peripheral circulatory symptoms, cardiac symptoms, sexual life and dizziness. General Wellbeing Schedule evaluated anxiety, depressed mood, positive wellbeing, self control, vitality and general health. The results showed that both drugs were efficient in lowering blood pressure, however manidipine improved quality of life more as it contributed significantly less to ankle oedema (Zanchetti *et al* 2001).

The same group of hypertensive agents (lacidipine) also improved quality of life in patients with hypertension. In a 2001 study, 248 patients with hypertension from five countries including Argentina, Brazil, Columbia, Mexico and Venezuela were divided into two groups: 120 patients received 4mg lacidipine once daily for 16 weeks while 128 patients took 30mg nifedipine Gastro-Intestinal Therapeutic System over the same period. The Psychological Semipersonalized Score (Ferreira *et al* 1992; Mosler *et al* 1993) was used to assess quality of life and physical activity at the end of the first week before treatment (placebo week), end of the first week, the tenth week and the sixteenth week of treatment. The results indicated that lacidipine significantly increased quality of life in patients with hypertension, with a reduction of both side effects and blood pressure as compare to the other groups (Velasco *et al* 2001).

A study by Benetos *et al* (2000) demonstrated that the effective reduction of blood pressure combined with minimal side effects from antihypertensive drugs are

important factors in improving quality of life for patients with hypertension. In a French study, the combination of low-dose diuretic and β-blocking agent (2.5mg bisoprolol, 6.25mg hydrochlorothiazide) or use of 5mg amlodipine also improved quality of life in older people with hypertension. The bisoprolol-hydrochlorothiazide combination was given to 84 older patients with isolated systolic blood pressure, while another 80 older patients with isolated systolic blood pressure took amlodipine. This took place once daily in the morning for 12 weeks. Their quality of life was assessed using a self-administered assessment tool designed to evaluate anxiety, depression, general health, positive wellbeing and vitality. This tool was administered at the end of two to four weeks before treatment (placebo week), and at the end of 12 weeks. The results concluded that quality of life was significantly increased by both groups of drugs, with a decrease in systolic blood pressure. The study also found that reducing stress was an important factor in improving quality of life (Benetos *et al* 2000).

Some antihypertensive agents such as losartan (an angiotensin II receptor antagonist) not only reduced blood pressure but also improved cognitive function in patients with hypertension, resulting in a reduction in annual health care costs and an increase in quality of life (Tedesco *et al* 2002). In same drug group, candesartan, has also demonstrated improved quality of life in older patients with hypertension. In this study, 4937 elderly patients with mild to moderate hypertension from six countries including France, Germany, Netherlands, Sweden, UK, and USA took either 8 to 16mg candesartan daily (1428 participants) or a placebo with other antihypertensive drugs (1422 participants). Quality of life was assessed using three measures: the Psychological General Wellbeing (Dupuy 1984) Index, the Subjective Symptoms

Assessment Profile (Dimenas *et al* 1990) and the EuroQoL Health Utility Index (Feeny *et al* 1995; Torrance *et al* 1995). The Psychological General Wellbeing measured wellbeing by assessing anxiety, depressed mood, positive wellbeing, self control, general health and vitality. The Subjective Symptoms Assessment Profile measured symptoms related to hypertension and treatment including cardiac symptoms, dizziness and peripheral/circulatory symptoms. EuroQoL Health Utility measured current health including physical, mental and social functioning. After an average 3.7 years of follow-up, results showed that the treatment group displayed a significant improvement in quality of life, with a decrease in anxiety and cardiac symptoms, and an increase in general health and wellbeing (Degl'Innocenti *et al* 2004).

Foot reflexology

Foot reflexology may contribute to an improvement in quality of life for patients with cancer. Twelve British patients receiving palliative care for cancer were given either a 40 minute foot reflexology session or placebo reflexology (without pressing reflexology points) for three sessions every other day. The visual analogue scale (Holmes & Dickerson 1987) was used to assess quality of life against 18 components including appearance, appetite, breathing, communication with doctors, nurses and family, concentration, constipation, diarrhoea, fears for the future, isolation, micturition (urination), mobility, mood, nausea, pain, sleep and tiredness. The results indicated that 100% of the reflexology group had an improvement in quality of life, against only 33% of the placebo group. Appetite, breathing, constipation, diarrhoea, fears for the future, pain, nausea, sleep, communication and tiredness were the areas most reported as having improved (Hodgson 2000).

Another study of foot reflexology in patients with cancer supported these results. Twenty patients in Scottish hospice care received foot reflexology for six weeks (three sessions or more for each participant). Their quality of life and satisfaction with treatment were measured using a self-report questionnaire with open-ended questions. Results showed that foot reflexology improved quality of life in these patients, with a reduction in physical and emotional symptoms – 95% of participants felt more comfortable, relaxed and calm following the reflexology treatments (Milligan *et al* 2002).

2.5 Conclusion

The literature review shows that people with hypertension suffer or have a decrease in quality of life as a result of many factors such as co-morbidity, financial difficulties, stress events and treatment. However, there is the potential for an improvement in symptoms or quality of life by modifying some aspects of their lifestyles or by using complementary therapies.