

3. Methods

This chapter covers the study aims, the hypotheses, the research design and methods, data collection and data analysis.

3.1 Introduction

This thesis is based on a randomized controlled trial of foot reflexology in patients with hypertension. The trial was undertaken at the Phramongkutklo Hospital, Bangkok, Thailand, over the period 26 July to 9 December 2004. This research used an experimental design to explore the effects of foot reflexology, in a treatment group compared with light foot massage, in a control group. Subjects were randomly allocated to each group.

3.2 Aim

The aim of this study was to investigate the effect of foot reflexology on reducing blood pressure in patients with hypertension, changes in LDL cholesterol and triglycerides and quality of life. To this end, patients receiving reflexology were compared with patients receiving light foot massage.

3.3 Hypotheses

3.3.1 Primary hypothesis

Null hypothesis: there is no difference in mean blood pressure level between the foot reflexology and light foot massage groups at the end of four weeks of treatment.

Alternative hypothesis: there is a difference in mean blood pressure level between the foot reflexology and light foot massage groups at the end of four weeks of treatment.

3.3.2 Secondary hypothesis one

Null hypothesis: there is no difference in mean LDL cholesterol and triglyceride levels between the foot reflexology and light foot massage groups at the end of four weeks of treatment.

Alternative hypothesis: there is a difference in mean LDL cholesterol and triglyceride levels between the foot reflexology and light foot massage groups at the end of four weeks of treatment.

3.3.3 Secondary hypothesis two

Null hypothesis: there is no difference in mean quality of life between the foot reflexology and light foot massage groups at the end of four weeks of treatment.

Alternative hypothesis: there is a difference in mean quality of life between the foot reflexology and light foot massage groups at the end of four weeks of treatment.

3.4 Research design

One hundred twenty eight patients with hypertension were enrolled in this study. The research project used two protocols: foot reflexology (intervention) and light foot massage (control). Patients were randomly allocated to one of the two groups: intervention or control using a computer program. All patients continued their usual medical treatment for the duration of the study.

3.4.1 Setting

The population of this study consisted of 128 patients with hypertension who attended the hypertensive clinic in the outpatient department of Phramongkutkloa Hospital. This is the third biggest government hospital in Bangkok and, every day, sees approximately 200 patients with hypertension in the hypertensive clinics. Data collection was undertaken between 26 July and 9 December 2004.

3.4.2 Power calculation

A sample size of 128 was required to yield a power of 80%, which is the probability of rejecting the null hypothesis when it is false at 80% (Swinscow 1997) if the difference in mean diastolic blood pressure between the two groups is 5 mmHg. A difference of 5 mmHg was selected as a result of the literature review of hypertension, which revealed that 5 mmHg is a clinically significant difference in diastolic blood pressure.

3.4.3 Inclusion criteria

Subjects were eligible for inclusion in the study if they:

- had hypertension (systolic blood pressure greater than or equal to 140 mmHg, and diastolic blood pressure greater than or equal to 90 mmHg) with or without hyperlipidaemia
- were aged 18 years or over
- had two feet
- gave informed consent to be involved in the study

3.4.4 Exclusion criteria

Subjects were excluded from the study if they:

- had thrombotic disease of the lower extremities
- had foot ulcers, foot infections or had undergone foot surgery
- were pregnant
- had recent major surgery such as open heart surgery
- had broken bones, sprains or bruises of the lower extremities

3.5 Research methods

3.5.1 Recruitment

Before starting this trial, posters were displayed for two weeks on the noticeboard of the outpatient department in Phramongkutklao Hospital. Once the trial commenced, short announcements were made periodically in the outpatient waiting room inviting patients to indicate by show of hand if they would like to participate in the study.

All potential participants were provided with information brochures which identified the study topic, the study objectives, study methodology, potential risks, and treatment benefits (Appendix 6). The investigator clarified this information verbally and provided further details upon request. Patients who wished to participate in the study were asked to read and sign a consent form to confirm their willingness to be involved in the study.

Participants meeting the selection criteria and signing consents were randomly allocated to either control or intervention groups using a computer software program (PEPI version 4.0) (Abramson & Gahlinger 2001).

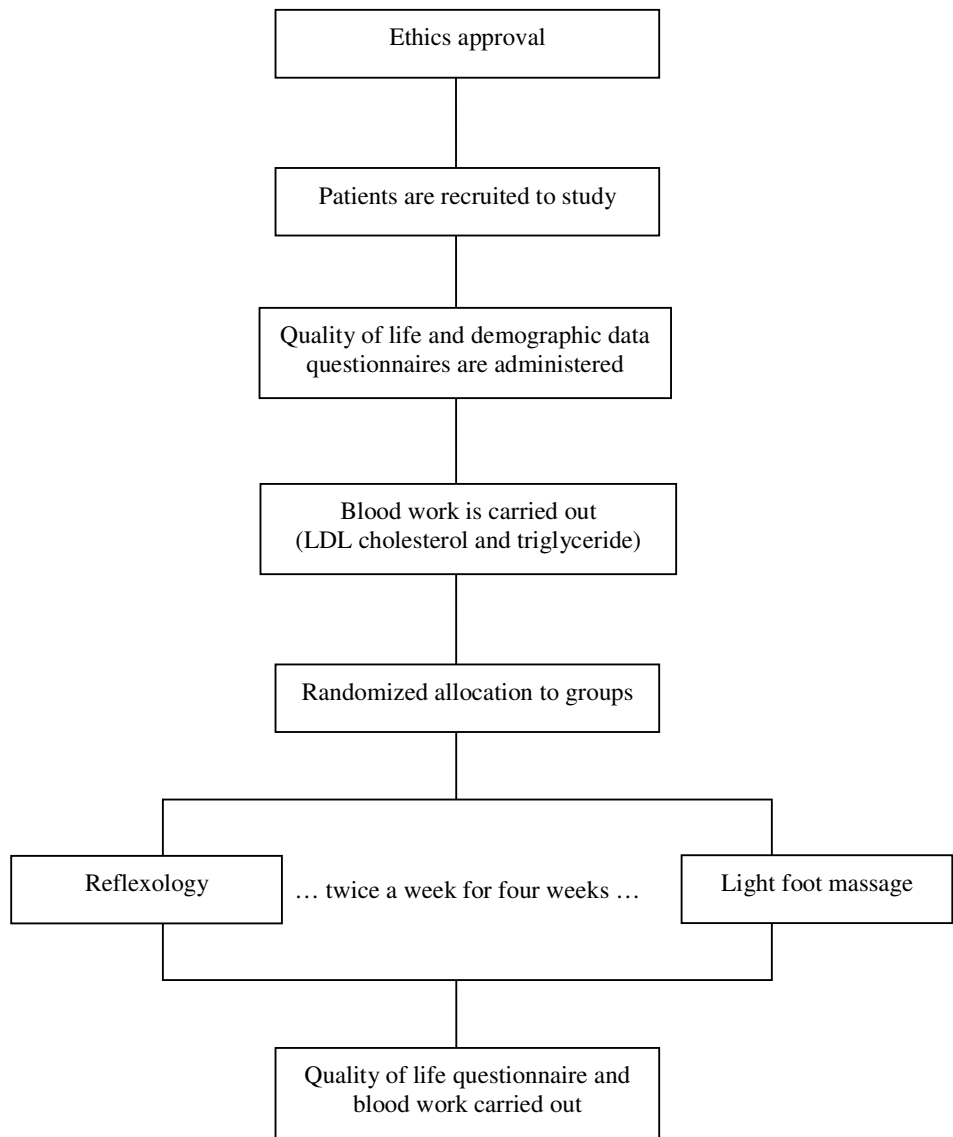
3.5.2 Intervention

Immediately prior to each treatment, patients were provided with ten minutes rest. Following this rest time, their blood pressure level was measured by a nurse's aide in the hypertensive clinic. The light foot massage group (control) received standard medical treatment and, in addition, received a 30 minute light foot massage without pressure on the specific reflex areas. This took place twice a week for four weeks by a trained therapist. The foot reflexology group (intervention) also received standard medical treatment. In addition, this group received a 50 minute period of foot reflexology twice a week for four weeks from one of two therapists trained in reflexology. The foot reflexology procedures are detailed in Appendix 2. The light foot massage procedures are provided in Appendix 3.

Immediately after treatment, blood pressure level was measured again by the nurse's aide in the hypertensive clinic. LDL cholesterol and triglyceride levels were measured on the first day and the last day of treatment.

A summary of the research design and methods in this study is shown in Figure 3.1 below.

Figure 3.1 Flow chart of study research design and methods



3.6 Data collection

Data was collected by the investigator for 4½ months from 26 July 2004 to 9 December 2004 at the medical outpatient department of Phramongkutkiao Hospital, Bangkok, Thailand. Permission to collect data was given by:

- Flinders Clinical Research Ethics Committee, Flinders Medical Centre/Flinders University, Adelaide, South Australia, and
- Phramongkutkiao Clinical Research Ethics Committee, Phramongkutkiao Hospital, Bangkok, Thailand

3.6.1 Study instruments

Demographic data questionnaire

A demographic data questionnaire was used which included questions on gender, age, marital status, educational background, economic factors (specifically, whether patients had financial problems), duration of hypertension, medical history and treatments, and co-morbidities. It also included questions about lifestyle modification such as fat/salty foods intake, exercise, smoking, alcohol intake, recreation and relaxation (see Appendix 4 for questionnaire). This questionnaire was completed by participants at the first day of the trial.

Quality of life questionnaire

The World Health Organization Quality of Life-BREF (WHOQOL-BREF) questionnaire (World Health Organization 1996) was used. This contains 26 questions including questions about overall quality of life; general health; the individual's satisfaction with physical health, psychological health, social relationships and environment (World Health Organization 1996) (see Appendix 5

for questionnaire). Subjects completed this questionnaire at entry into the study and following four weeks of treatment.

Automatic sphygmomanometer

The OMRON model HEM-705 CP (Tokyo, Japan 1998) was used to measure blood pressure for all participants in the study. It was selected because it is an accurate digital monitor (Brien, Beevers & Marshall 1995; Manger & Gifford 2001). It was calibrated according to the manufacturer's specifications before use.

Blood work

Blood was drawn from each participant according to hospital procedure. It was analysed in the hospital laboratory for cholesterol and triglyceride levels by staff blinded to the participant's treatment group.

3.6.2 Factors affecting blood pressure

Many factors can affect blood pressure eg emotion, exercise, respiration, meals, tobacco, alcohol, temperature, pain, bladder distension (Brien, Beevers & Marshall 1995). The investigator worked to decrease factors affecting blood pressure, as indicated in Table 3.1 below.

Table 3.1 Protocols for taking blood pressure

Action	Rationale
<ul style="list-style-type: none"> - provide a quiet temperature-controlled room - allow the patient to lie down for five to ten minutes before measuring blood pressure - support the patient's arm on the bed and at the level of the heart (the midsternal level) 	<ul style="list-style-type: none"> - to encourage the patient to relax since factors such as emotion, exercise and temperature can induce high blood pressure (Brien, Beevers & Marshall 1995) - if a patient's arm is not supported, it may increase the workload thereby increasing blood pressure and the heart rate. Brien <i>et al</i> found that "Diastolic blood pressure may be raised by as much as 10% by having the arm extended and unsupported during blood pressure measurement." (Brien, Beevers & Marshall 1995, p. 10) - having the arm positioned below heart level causes an overestimation of systolic and diastolic pressures due to blood pooling. In contrast, having the arm positioned above heart level brings about underestimation. An error of 5 mmHg for diastolic pressure can occur even in the supine position if the arm is not supported at heart level (Brien, Beevers & Marshall 1995)

Table 3.1 Protocols for taking blood pressure (continued)

Action	Rationale
- select a cuff or bladder suitable for the individual. Since all participants in the study were adults, the researcher chose two sizes of bladder: one for most adults (size M), another one for obese adults (size L) as provided by the OMRON company, Thailand	- use of an inappropriate bladder can cause overestimation or underestimation of blood pressure. One study showed mismatching of bladder and arm as follows: 'bladder too small (undercuffing) causes overestimation of BP, range of error: 3.2/2.4-12/8 mmHg, as much as 30 mmHg in obesity' 'bladder too large (overcuffing) causes underestimation of BP, range of error: 10-30 mmHg' 'undercuffing is more common than overcuffing' (Brien, Beevers & Marshall 1995, p. 5)

3.7 Data analysis

1. Demographic data was analysed in terms of frequency and percentage.
2. Differences in baseline results between the two groups were analysed in terms of mean and standard error of mean.
3. Difference in outcome measures between the two groups post-treatment were explored using independent samples t-tests.
4. Analysis of Co-variance (ANCOVA) was used to assess differences post-treatment adjusting for baseline levels.
5. All tests were analyzed using SPSS 12.0 for Windows (SPSS Inc. 2003)

3.8 Ethical considerations

The research proposal was approved by Flinders Clinical Research Ethics Committee, Flinders Medical Centre/Flinders University, Adelaide and the Research and Ethics Committee, Phramongkutklao Hospital, Bangkok. The study was conducted in accordance with the National Health and Medical Research Council National Statement on Ethical Conduct in Research Involving Humans (NHMRC) 1999 guidelines (Commonwealth of Australia 1999).

Before taking part in the study, participants were asked to sign a consent form confirming their willingness to participate. They were also informed that they could withdraw from the study at any time without any impact on their treatment.

4. Results

This chapter reports the study results and data analyses including the demographic characteristics, medical history, medical treatment, and pre and post intervention outcomes of systolic blood pressure, diastolic blood pressure, LDL cholesterol, triglycerides and quality of life.

4.1 Demographic characteristics of participants

For this study, the 128 participants were divided into two groups (64 in the foot reflexology group (intervention), and 64 in the light foot massage group (control). The participants had hypertension, with or without hyperlipidaemia, and attended the hypertensive clinic in the outpatients department of Phramongkutklo Hospital, Bangkok, Thailand between 26 July and 9 December 2004.

Demographic data for the participants was collected and then analysed against gender, age, marital status, educational background, economic factors (specifically, financial difficulties), duration of hypertension, medical history and period of treatment for hypertension, and co-morbidities. Lifestyle data such as fat/salty foods intake, smoking, alcohol intake, exercise and recreation/relaxation was also determined. The data is presented and discussed in Tables 4.1 - 4.8 and Figures 4.1 – 4.3 below.

4.1.1 Demographic characteristics of age and gender

Most of the participants in each group were female – 79.7% in the foot reflexology group, 71.9% in the light foot massage group. The majority of participants in each group were aged between 51 and 70 years – 73.4% for both groups (see Table 4.1 below).

Table 4.1 Demographic characteristics of age and gender

Characteristic	Foot Reflexology Group	Light Foot Massage Group
	(n = 64) %	(n = 64) %
Gender		
Male	20.3	28.1
Female	79.7	71.9
Age		
40-50 years	9.4	9.4
51-60 years	35.9	35.9
61-70 years	37.5	37.5
71-80 years	14.1	17.2
81-90 years	3.1	-

4.1.2 Demographic characteristics of marital status, education and economic factors

More light foot massage participants (70.3%) reported being married than foot reflexology participants (57.8%). In line with this, the number of participants who reported being in the 'divorced/separated/widowed' category was less in the light foot massage group (20.3%) than in the foot reflexology group (32.8%).

Both groups reported achieving similar levels of education eg 35.9% of participants in the foot reflexology group had received secondary school education, against 37.5% of participants in the light foot massage group.

The majority of participants in both groups did not have financial problems – 73.4% in the foot reflexology group, 68.8% in the light foot massage group.

Table 4.2 below illustrates these results.

Table 4.2 Demographic characteristics of marital status, education and economic factors

Characteristic	Foot Reflexology Group (n = 64) %	Light Foot Massage Group (n = 64) %
Marital status		
Single	9.4	9.4
Married	57.8	70.3
Divorced/separated/widowed	32.8	20.3
 Level of education		
No education	1.6	3.1
Primary school	26.6	29.7
Secondary school	35.9	37.5
College/university	35.9	29.7
 Economic factors - financial difficulties		
Yes	26.6	31.3
No	73.4	68.8

4.1.3 Duration experiencing hypertension

There was substantial difference between the groups in the length of time that participants had been diagnosed with hypertension. In the category 'more than 15 years', participants in the light foot massage group had almost nine times (14.1%) the number of participants who had had hypertension for more than 15 years, compared with participants in the foot reflexology group (1.6%) (Figure 4.1).

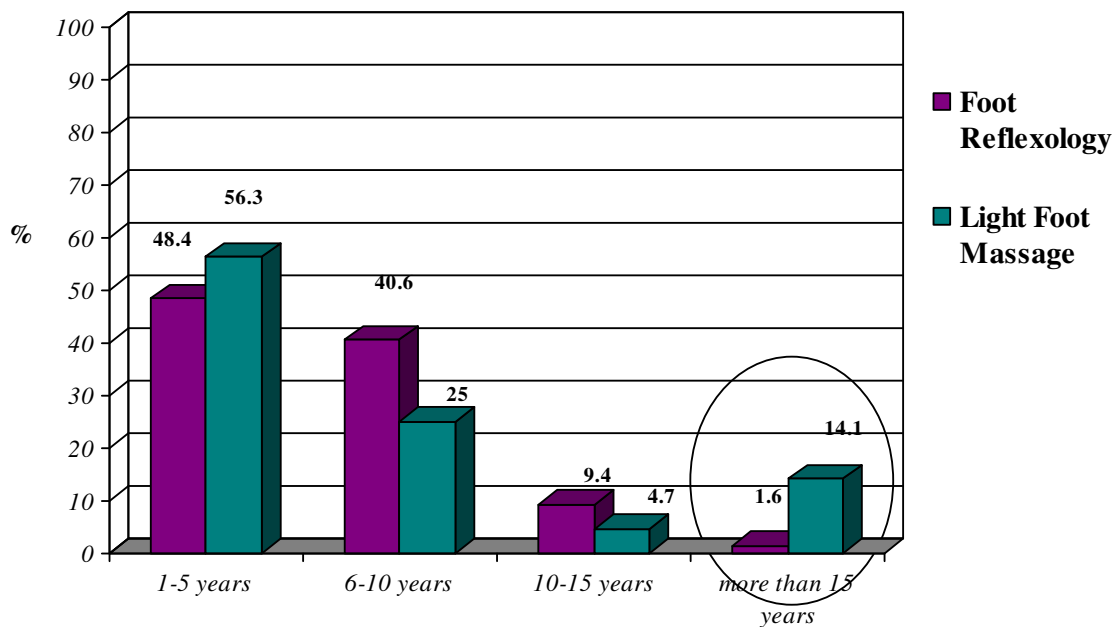


Figure 4.1 Duration experiencing hypertension

4.1.4 Duration having treatment for hypertension

Results for the length of time having treatment for hypertension (Figure 4.2 below) reflected the results for the length of time experiencing hypertension (Figure 4.1 previously). The groups demonstrated substantial differences.

The most substantial difference was for the period 'more than 15 years' where participants in the light foot massage group had almost eight times (12.5%) the number of participants who had been treated for hypertension for more than 15 years, compared with participants in the foot reflexology group (1.6%) (Figure 4.2).

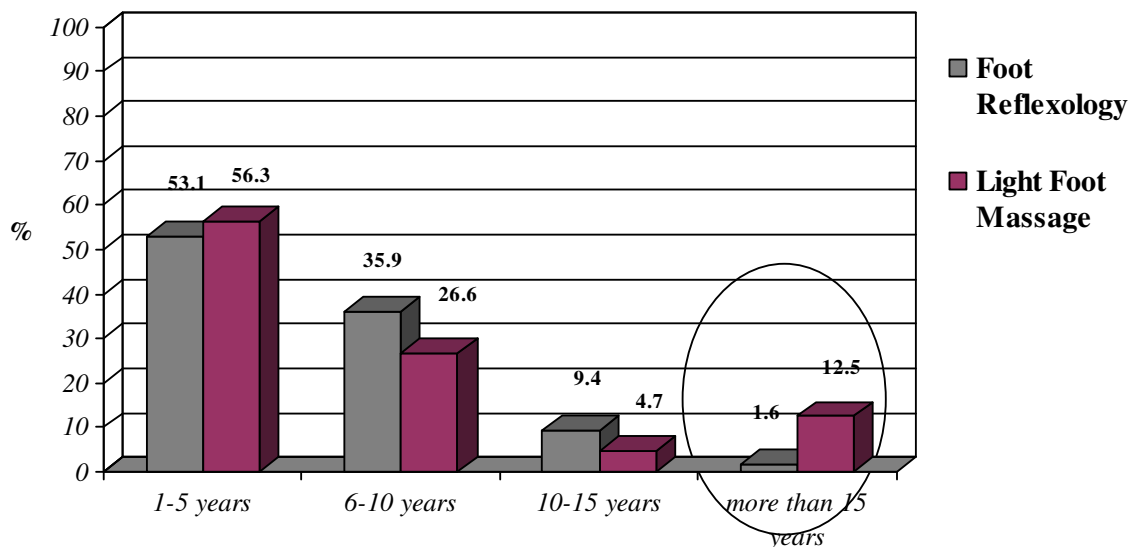


Figure 4.2 Duration having treatment for hypertension

4.1.5 Lifestyle characteristics of fat/salty foods intake, smoking and alcohol intake

Almost 70% of participants in the two groups ate fat/salty foods more than once a week – 67.2% in the foot reflexology group, 68.7% in the light foot massage group.

Most participants did not smoke – 96.9% and 98.4% in the foot reflexology and light foot massage groups respectively. The majority of participants did not drink alcohol at all – 89.1% in the foot reflexology group and 95.3% in the light foot massage group. These results may be related to gender, which was mainly female (79.7% in the foot reflexology group, 71.9% in the light foot massage group). In Thai culture and religion, most women do not smoke and drink.

Table 4.3 Lifestyle characteristics of fat/salty foods intake, smoking and alcohol intake

Characteristic	Foot Reflexology Group (n = 64) %	Light Foot Massage Group (n = 64) %
Fat/salty foods intake		
Never	1.6	3.1
<1/wk	31.3	28.1
1-6/wk	59.4	57.8
Daily	7.8	10.9
Smoking		
Yes	3.1	1.6
No	96.9	98.4
Alcohol intake		
Never	89.1	95.3
<1/wk	9.4	1.6
1-6/wk	1.6	3.1
Daily	-	-

4.1.6 Lifestyle characteristics of exercise and recreation/relaxation

Almost 40% of participants (39.1%) in the foot reflexology group and 45.4% of participants in the light foot massage group had a sedentary lifestyle, exercising less than once a week. Against that, just over 60% of the foot reflexology participants (60.9%) and 54.7% of the light foot massage participants exercised more than once a week.

More than 90% of participants in each group had recreation or relaxation time more than once a week – 90.7% in the foot reflexology group, 95.4% in the light foot massage group. Table 4.4 displays these results.

Table 4.4 Lifestyle characteristics of exercise and recreation/relaxation

Characteristic	Foot Reflexology Group	Light Foot Massage Group
	(n = 64) %	(n = 64) %
Exercise		
Never	26.6	43.8
<1/wk	12.5	1.6
1-6/wk	40.6	42.2
Daily	20.3	12.5
Recreation/relaxation		
Never	3.1	1.6
<1/wk	6.3	3.1
1-6/wk	31.3	31.3
Daily	59.4	64.1

4.1.7 Top six co-morbidities of the two study groups

There was little difference in both groups related to the top six co-morbidities and also other co-morbidities as shown in Appendix 7, Table 1. Some participants had more than one co-morbidity, thus the total does not equal 100%.

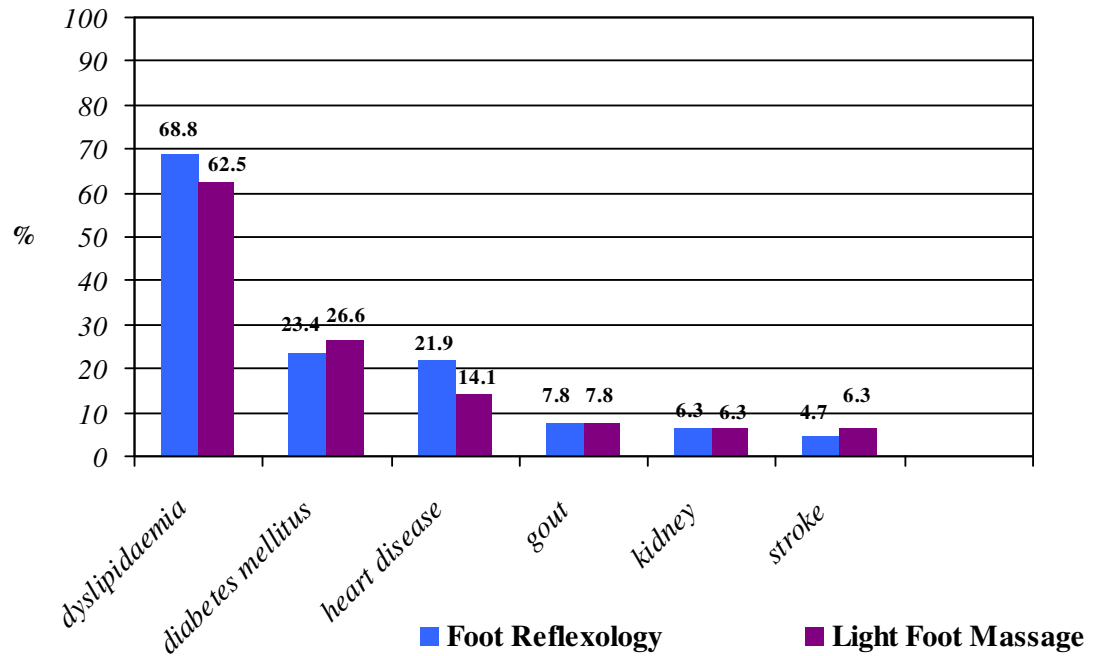


Figure 4.3 Top six co-morbidities of the two study groups

4.1.8 Top ten medical treatments of the two study groups

There was little difference in both groups related to the top ten medical treatments and also other treatments as shown in Appendix 7, Tables 2-4. Some participants had more than one medical treatment, thus the total does not equal 100%.

Table 4.5 Top ten medical treatments of the two study groups

Medical treatments	Foot Reflexology Group	Light Foot Massage Group
	(n = 64) %	(n = 64) %
Antihyperlipidaemic agents	51.6	51.6
Beta-blockers	39.1	43.8
ACE inhibitors	37.5	31.3
Diuretics	34.4	42.2
Anticoagulants, antithrombolytics & fibrinolytics	32.8	28.1
Anti-anginal drugs	25.0	26.6
Antidiabetic drugs	23.4	25.0
Angiotensin II antagonists	21.9	23.4
Calcium antagonists	18.8	23.4
Other antihypertensives	9.4	12.5

4.2 Outcomes and results

Blood pressure, LDL cholesterol, triglycerides and quality of life before receiving the interventions as baseline results were analysed using mean and standard error of mean in both groups. Post-intervention outcomes were measured after four weeks of the intervention by using the independent samples t-test and Analysis of Co-variance (ANCOVA) (Vanitbancha 2003; Wongrattana 2001).

4.2.1 Baseline results of blood pressure, LDL cholesterol, triglycerides and the quality of life

There was little difference in means of systolic blood pressure, diastolic blood pressure, LDL cholesterol, triglyceride levels and quality of life scores between groups before treatment. Participants in the foot reflexology group had slightly higher systolic blood pressure than those in the light foot massage group, while diastolic blood pressure, LDL cholesterol and triglycerides were slightly higher for participants in the light foot massage group.

Mean of quality of life and health satisfaction scores were slightly higher for participants in the foot reflexology group than for participants in the light foot massage group. Mean of physical health, psychological health, social relationships and environment scores for participants in the light foot massage group were slightly higher than for participants in the foot reflexology group (see Table 4.6 below).

Table 4.6 Baseline results of blood pressure, LDL cholesterol, triglycerides and the quality of life

Outcomes	Foot Reflexology Group (n = 64)		Light Foot Massage Group (n = 64)	
	Mean	SEM ¹	Mean	SEM
Pre systolic blood pressure	126.7	1.9	125.7	2.5
Pre diastolic blood pressure	72.7	1.0	73.6	1.1
Pre LDL cholesterol	126.8	4.3	128.6	4.2
Pre triglyceride	130	9.2	136.7	7.6
Pre quality of life				
Quality of life score	3.6	0.1	3.4	0.1
Health satisfaction	3.1	0.1	3.0	0.1
Physical health	62.3	1.7	65.0	1.6
Psychological health	64.9	1.7	67.0	1.9
Social relationships	69.9	1.7	74.0	2.1
Environment	63.4	1.3	66.1	1.9

¹ SEM = Standard Error of Mean

4.2.2 Post intervention results

Compared to pre intervention, the difference in adjusted mean of diastolic blood pressure level in participants in the light foot massage group indicated it reached significance. However, this was due to an increase in diastolic blood pressure of 0.9 mmHg in the reflexology group compared with a decrease of 0.2 mmHg in the control group. Moreover, an increase of 0.9 mmHg is not considered to be clinically significant. Differences for both groups in mean of systolic blood pressure, LDL cholesterol, triglycerides levels, and quality of life scores were neither statistically nor clinically significant (see Table 4.7 below).

Table 4.7 Post intervention results

Outcomes	Foot Reflexology Group (n = 64)		Light Foot Massage Group (n = 64)		Unadjusted Significance	Adjusted Significance
	Mean	SEM ¹	Mean	SEM		
Systolic blood pressure	126.5	2.0	125.1	2.5	0.657	0.703
Diastolic blood pressure	73.6	1.1	73.4	1.1	0.869	0.049
LDL cholesterol	123.1	4.6	132.2	4.8	0.177	0.286
Triglycerides	132.4	10.8	134.8	8.3	0.860	0.690
Quality of life						
Quality of life score	3.7	0.1	3.5	0.1	0.189	0.234
Health satisfaction	3.3	0.1	3.3	0.1	0.885	0.338
Physical health	65.3	1.4	66.9	1.8	0.498	0.804
Psychological health	66.4	1.7	70.4	1.9	0.108	0.171
Social relationships	68.3	2.0	71.9	2.2	0.226	0.510
Environment	64.7	1.4	66.5	1.7	0.404	0.959

¹ SEM = Standard Error of Mean

The findings showed that foot reflexology did not lower blood pressure in patients with hypertension, and also did not decrease LDL cholesterol and triglyceride. In addition, it had little impact on the quality of life in these patients.

4.3 Participants' comments

Although not part of the null hypotheses, participants were asked to respond to two questions related to their satisfaction with the treatments they received, either foot reflexology or foot massage. The first question explored how satisfied participants were with their treatment, with a response scale of very much, average, or not satisfied. The second open ended question asked how participants felt after treatment.

Fifty-four participants (84.4%) in the foot reflexology group and 48 participants (75%) in the light foot massage group responded to these questions. Responses to the open ended question indicated that many participants felt comfortable, relaxed, and believed that treatment could relieve fatigue, numbness and cramps in their feet. Responses to the satisfaction scale are shown in Table 4.8 below, the remainder of the responses are shown in Appendix 8.

Table 4.8 Participants' comments about treatments they received

Comments	Foot reflexology	Light foot massage
	n = 54 n (%)	n = 48 n (%)
Satisfaction		
Very much	43 (67.2%)	42 (65.6%)
Average	11 (17.2%)	6 (9.4%)
Feel comfortable	22 (34.4%)	17 (26.6%)
Feel relaxed	15 (23.4%)	12 (18.75%)
Relieves fatigue, numbness, cramps	15 (23.4%)	9 (14.1%)

The results showed no differences in blood pressure, LDL, triglycerides and quality of life between groups. However, foot reflexology and foot massage provided benefits to these patients. Discussion of all outcomes was detailed in Chapter 5.