

The acute (immediate) specific haemodynamic effects of reflexology

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Declaration

This work has been composed by the candidate. It has not been accepted in any previous application for a degree. This work has been done by the candidate. All quotations have been distinguished by quotation marks and the sources of information specifically acknowledged.

Signed:

Date:

In loving memory of

Joyce Jones

May 28th 1934 – October 15th 2012

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Thesis abstract

Background and purpose: Reflexology is one of the top six complementary therapies used in the UK. Reflexologists claim that massage to specific points of the feet increases blood supply to referred or 'mapped' organs in the body. Empirical evidence to validate this claim is scarce. This three-phase study measured changes in haemodynamic parameters in subjects receiving reflexology treatment applied to specific areas of the foot which are thought to correspond to the heart (intervention) compared with reflexology applied to other areas on the foot which are not (control).

Methods: 16 reflexology-naive healthy volunteers, 12 reflexology-naive patients with chronic artery disease (CAD) and 12 reflexology-naive patients with heart failure (HF) received active and control reflexology treatments in three randomised, placebo-controlled, double-blind repeated measures studies. In each study the subjects were observed over six time periods under the two conditions and randomised to receive either intervention or control treatment. Outcome measures included 'Beat-to-beat' non-invasive continuous measurement of heart rate, diastolic, blood pressure, stroke volume, stroke index, cardiac output, cardiac index, total peripheral resistance, baroreceptor reflex sensitivity, and heart rate variability.

Results: The effects of reflexology treatment were modest. There were no significant differences noted in any of the measured haemodynamic parameters in either the CAD or HF intervention or control groups. Cardiac index decreased significantly in the healthy volunteer

intervention group during left foot treatment (LFT) (baseline mean 2.6; (SD) 0.75; 95% CI +/- 0.38 vs. LFT mean 2.45; SD 0.68; CI 0.35) with an effect size ($p= 0.035$, omega squared effect (w^2) = 0.002; $w = 0.045$).

Conclusion: The findings suggest that reflexology massage applied to the upper part of the left foot in the area thought to relate to the 'heart' may have a modest specific effect on the cardiac index of healthy volunteers, but no specific haemodynamic effect on patients with various gradations of cardiovascular disease.

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List of abbreviations

ACI	Acceleration index
ANOVA	Analysis of variance
ANS	Autonomic nervous system
AoR	Association of Reflexologists
BarDwEv	Baroreceptor Down Events
BarUpEv	Baroreceptor Up Events
BP	Blood pressure
BPM	Beats per minute
BRA	British Reflexology Association
BRS	Baroreceptor reflex sensitivity
BSR	British School of Reflexology
CAD	Coronary artery disease
CHF	Chronic heart failure
CI	Cardiac index
CO	Cardiac output
CVS	Central venous pressure
dBp	Diastolic blood pressure
ECG	Electrocardiogram
GLM	General linear model
HF	High frequency
HF-RRI	High frequency R-R interval
HR	Heart rate
HRV	Heart rate variability
ICG	Impedance cardiography
IIR	International Institute of Reflexology
LVET	left ventricular ejection time
LF	Low frequency

LF-RRI	Low frequency R-R interval
mBP	Mean arterial blood pressure
mmHg	Millimetre of mercury
RCT	Randomised controlled trial
RRI	R-R interval
SAI	State Anxiety Inventory
SI	Stroke index
SV	Stroke volume
sBP	Systolic blood pressure
TF [®] M	Task Force Monitor
TFC	Thoracic fluid content
TPR	Total peripheral resistance
TPRI	Total peripheral resistance index
VAS	Visual analogue scale
VLF	Very low frequency

This thesis has purposefully not referenced any research paper that includes any form of experimentation using animals.

<http://www.buav.org/>

<http://www.peta.org.uk>

<http://www.ciwf.org.uk/>

Chapter 1

Introduction - Reflexology educational literature

Jones J, Leslie, SJ. Reflexology: Science or Belief? (Book chapter), In *Alternative Medicine: Practices, Health Benefits and Controversies*, Nova Publishers, Editors: Kenneth R. Carter and George E. Murphy. Nova Science Publishers Inc; Nov 2012

Thomson P, **Jones J**, Evans J M, Leslie, S J. Factors influencing the use of complementary and alternative medicine and whether patients inform their primary care physician. *Complementary Therapies in Medicine*. 2012;(20): 45-53 [doi:10.1016/j.ctim.2011.10.001]

Chapter 1

1.1. Background to the thesis

This thesis examined the complementary therapy called reflexology. The thesis enquiry was necessary because one of the interventional cardiologists at the Raigmore hospital realised that a number of his cardiology patients were using various forms of complementary and alternative medicine (CAM) alongside their conventional pharmacological, surgical and rehabilitation interventions. When patients asked him about the potential risks and benefits of various CAM, the lack of a robust CAM evidence base meant that he did not have sufficient information to answer their questions from a science and evidenced-based perspective. In response, I was recruited as a PhD student so that a dedicated enquiry could be undertaken into the risks and benefits associated with CAM use in cardiac patients. The PhD brief was simple. I was to use the principles of science and evidence-based medicine in order to establish if any of the popular CAM therapies offered specific risks or benefits for cardiac patients. However I wished to pursue this enquiry was my choice. The investigation began with a brief audit of CAM use amongst cardiology outpatients in the Raigmore hospital. The audit showed that 52% of cardiac outpatients reported using one or more forms of CAM at some point. The top five most popular were reflexology, acupuncture, osteopathy, massage and chiropractic therapies (1). The audit results appeared consistent with published survey evidence which suggests that reflexology, acupuncture and massage are amongst the top six most popular forms of CAM used in the rest of the UK (2). Of these three therapies, reflexology is unique in that it makes very specific (and therefore testable) haemodynamic organ-perfusion claims that are directly relevant to the cardiac patient population. Reflexologists claim that discrete areas of the feet 'map' or correspond to individual organs of

the body. Reflexologists believe that by applying reflexology foot massage techniques to these areas; blood flow is increased to the corresponding organ, via means of a specific reflexology effect. This therapeutic claim is highly relevant to cardiac patients, who often have compromised coronary perfusion rates. Therefore as no data was found to be available to help cardiac patient purchasers and clinicians address the appropriateness, safety and quality concerns of the specific haemodynamic effect claim, this area was identified as a clear research priority and as a consequence, became the focus of this thesis.

1.2. Introduction to the thesis

Reflexology is a complex massage therapy. It is based on the idea that the feet offer a perfect scaled-down representational template of the human body as a fundamental biological design (3). In this model, discreet areas of the feet (called reflex points) are thought to correspond or 'map' to specific internal organs within the body. Each internal organ is thought to be represented by an individual reflex point area (4). Therapists learn the location of these points by studying reflexology foot maps or charts and are trained in distinct massage techniques unique to reflexology (5). The founder of reflexology, Eunice Ingham, claimed that reflexology massage to the associated reflex point on the feet increases blood supply to the organ (6). In her teachings, this specific haemodynamic effect is believed to be quite distinct from non-specific massage components, even though these components can evoke systemic haemodynamic responses in their own right. Non-specific effects include physical touch, therapeutic exchange and placebo effects, (7-10).

The International Institute of Reflexology (IIR) report having at least 25,000 trained member therapists worldwide (11). They deliver training courses through 11 global franchised training

branches (12) and are currently the largest UK reflexology training provider (13). The IIR offers professional reflexology training exclusively and explicitly based on Ingham's theories (14). With this level of international commercial training provision, reflexology clearly has a considerable level of investment. Global spending on complementary and alternative medicine (CAM) is estimated to be \$40 billion per annum (15), with £1.6 billion spent annually in the UK alone (16;17). Reflexology is one of the most popular CAM therapies used in Norway (18), Denmark (19), Northern Ireland (20) and Scotland, England and Wales (16;21). Individual reflexology sessions can cost from £15 (€18) - £70 (€84) per treatment. Typically, 6-8 sessions are recommended by therapists to in order to gain the optimal therapeutic results (22;23). Therefore the cost of an eight-week series could easily be in excess of £400 (€480) if an average of £50 (€60) per session is paid. One review of reflexology even suggests figures of up to £1000 (€1195) per year for repeated blocks of treatment may not be unusual for a patient with chronic health issues (24).

1.2.1. Justification for research

The House of Lords Select Committee report on Complementary and Alternative medicine (17) concluded that any complementary therapy treatment claim should have a body of evidence to substantiate that such a claim can be shown to be a specific effect above and beyond placebo. The Kings Fund Report (2009) also acknowledges the need for complementary therapists to provide robust explanations of how specific key interventions at the heart of their therapies work. This is seen as important in order to justify both clinical worth and cost effectiveness (25). For example, if the claim of a specific haemodynamic effect is proved to be unfounded, it could be argued that reflexology is completely indistinguishable from simple foot massage. Furthermore, 84% of 7032 members of the public who responded to a poll hosted by the Economist website, asking whether research into alternative medicine is a waste

of time, voted in favour of further CAM research (26). And in the local cardiology outpatients audit, 66% of respondents felt that CAM should be available within the NHS and 88% want the NHS to fund more CAM research (1). Therefore reflexology safety and product quality are important healthcare and public interest research priorities (27), particularly in relation to the unique therapeutic claim of a specific haemodynamic effect in reflexology. Any therapy that makes such a definable (and potentially testable) prediction as this should be available to provide evidence to demonstrate that the product quality delivers as claimed. Also, if it does, that the specific haemodynamic effect is safe and effective for all its users.

General adverse treatment effects from reflexology use may include both intrinsic safety issue of contraindication for some patient groups, and extrinsic quality issues such as poor standardisation or quality control of the treatment delivered (27). For the cardiac patient population, the intrinsic safety issue concerns the claim of a specific haemodynamic effect. If the haemodynamic claim is valid, a treatment-induced change in haemodynamic status may be beneficial in some types of cardiac disease. However it may have potential safety issues in others. This effect is important to quantify. A significant proportion of people do not seek advice from their primary healthcare physician before using CAM, or disclose its use afterwards (28). Furthermore, evidence suggests that up to 36% of cardiac patients are using some form of complementary therapy such as homeopathy, herbs and various types of manipulation massage in an attempt to manage aspects of living with cardiac disease that are not met by conventional methods (29;30). The local survey of cardiology outpatients revealed that majority (52%) reported the use of at least one complementary or alternative therapy (1). Cardiologists have voiced concerns that cardiac patients may be particularly vulnerable to the effects of CAM for several reasons. These include adverse drug interaction, reduced adherence to conventional therapies or potential adverse effects amplified by the lack of CAM product standardisation (31).

Reflexology literature appears inconsistent on the appropriateness of reflexology for cardiac patients. 'Heart or circulatory problems' are listed as both an indication for treatment (32;33) and as a contraindication where treatment should be avoided (34-37). Some literature even claims that the treatment-related increase in haemodynamic circulation can adversely stress the cardiovascular system. Also, that it can potentially affect patients with mechanical implants such as pacemakers and artificial heart valves (38). There is also confusion in the educational literature about whether massage applied to the area of the foot thought to be associated with the heart (the heart reflex point) carries with it the risk of a potential adverse effect for cardiac patients. An analysis of teaching books listed in the professional reflexology education recommended reading list (39) reveals that different opinions are clearly evident. Ingham herself claims that cardiac conditions such as angina respond well to reflexology treatment to the heart reflex point area (3). She advises therapists to "*set to and work it (the imbalance) out*", the author stating that "*it is certain no harm can be done by working on a reflex*" (40). In contrast two other authors (41;42) propose a markedly different strategy. The first advises therapists to treat the heart imbalanced reflex area with only a moderate gentle pressure, particularly on older people with chronic heart disease. And to restrict the treatment length to a few minutes only (43). The other (42) advises caution in treating the heart reflex area, stating that it is better to treat the indirect reflex areas rather than the heart point itself, with "*very strong stimuli*" seen as "*harmful*" for patients with heart disease (44).

In addition, foot reflex point variation appears to exist in clinical practice. Rather surprisingly, given the central importance of the therapeutic claim of a specific two-way connection between distinct areas of the feet and increased perfusion of the 'mapped' internal organs, the vast majority of published reflexology maps do not appear to exhibit any consensus about where the various reflex points on the feet are (figure 1.1). Given this degree of variation, it is

not unreasonable to suggest that if the map terrain is inconsistent on the feet, then the therapeutic premise that assumes the existence of two-way haemodynamic connection would appear to be seriously flawed. This indicates a significant product quality issue.

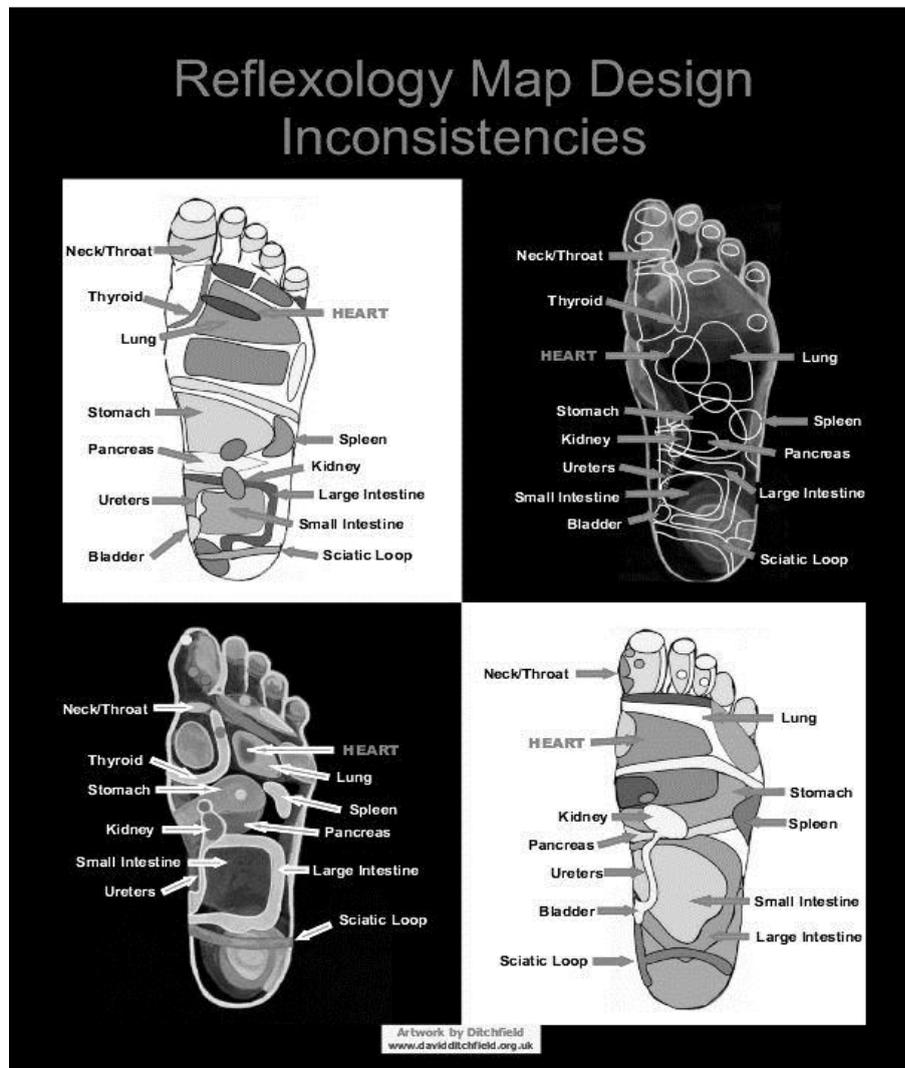


Figure 1.1 **Inconsistent reflexology foot maps**

As no data is available to help cardiac patient purchasers and clinicians address the appropriateness, safety and quality concerns of the reflexology perfusion claim, this area is a clear research priority. Therefore this thesis aimed to examine whether there are any specific haemodynamic benefits, product quality or safety issues associated with reflexology treatment in healthy volunteers and cardiac patients.

1.3. Summary of the remainder of chapter one

Chapter one now examines the educational reflexology literature. This provides a context for chapter two, which examines the reflexology scientific literature. The remainder of chapter one is structured as follows. First, reflexology model validity is defined and its importance to the thesis enquiry explained. For this purpose, the history of reflexology is discussed from the inception to present. This starts with an in-depth analysis of the Ingham text which provides the foundation for commercial reflexology. Next, the contemporary commercial reflexology education and training structure is described. From this, validated sources of reference literature are established and from this list, key modern educational literature is identified. Current reflexology teaching material is then reviewed and contrasted to Ingham's reflexology model. This is done in order to gain a perspective of reflexology that enables sufficient model validity to be established in the thesis.

1.4. Reflexology model validity

In order to accurately represent reflexology in the thesis, it was necessary to establish an understanding of its theory and practice from the perspective of the reflexologist practitioner. Research into CAM therapies need to ensure that the study has accurately reflected the unique theory and practice of the therapeutic intervention. This is defined as establishing model validity for the therapy (45). For example, if a study uses trained therapists to deliver a CAM intervention, were the therapists adequately trained and experienced in delivering the therapy under investigation? And did the treatment procedure adequately represent the therapy under investigation? Also, was the application of the therapy clearly defined, appropriate and accurate for the study population? In other words, the researcher must develop a degree of expertise in the therapy to ensure that the requirements for model

validity has been met (45). To achieve this, only recommended versions of reflexology teaching material endorsed by dominant professional reflexology organisations and the most popular commercial reflexology educators were referenced. This teaching material included the two key historical texts by Ingham that provide the entire conceptual foundation for modern-day reflexology. Ingham's first book was reviewed in depth in order to identify the causal mechanisms thought to be involved in the therapy. And to understand where the inconsistent foot maps, specific haemodynamic effect claim and beliefs regarding cardiac patient indication originated from.

This analysis was possible because despite its international popularity, reflexology is a relatively recent therapeutic invention. This makes it unusual in CAM terms. Most CAM therapies are based on traditional beliefs, theories and cultural meaning of various indigenous populations. These are most typically Asian, African or Eastern, and have been used in these communities often for thousands of years (46). In contrast, the first documented appearance of the theory that provided the foundation for reflexology appeared relatively recently, in early twentieth century America. Therefore reflexology's relatively short history allowed a unique opportunity to examine the haemodynamic claim, proposed treatment effects and hypothesised causal mechanisms from inception to present. Its novel concepts were first described in a book by Dr William H Fitzgerald. Fitzgerald's theories and the subsequent Ingham publications are therefore key reference points for all other reflexology publications to date.

1.5. Early history

1.5.1. Dr William H Fitzgerald

Fitzgerald was the originator of the distinct theory that forms the basis for modern-day reflexology. He was an early twentieth century graduate of the Medical School of University of Vermont (33). In 1912, during his tenure as head and surgeon of the Nose and Throat Department of St Francis Hospital in Hartford, Connecticut, Fitzgerald claimed to have accidentally discovered that pressure on the muco-cutaneous margin (where the skin joins the mucus membrane of the nose) – resulted in an anaesthetic effect as powerful as cocaine. This simple action seemed to him to yield extraordinary results. He spent the next six years experimenting further by applying various forms of pressure to external peripheral areas all over the human body (47;48). His experimentation led him to devise a theory about how two key aspects of the human body worked.

First, Fitzgerald came to believe that the body is divided into ten distinct anatomical zones or regions. He believed this design was biologically fundamental to the design of the human body. He hypothesised that there were five zones on either side of a central median line down the middle of the body, with each zone assumed to be of equal width (49). Each zone was thought to relate to the relevant fingers and toes of the body. The outer-most zone encompassing the thumb and extending up the arm through to the head and down to the greater toe. The next zone relating to the second finger and second toe using the same vertical longitudinal shape and so on (50) (figure 1.2).

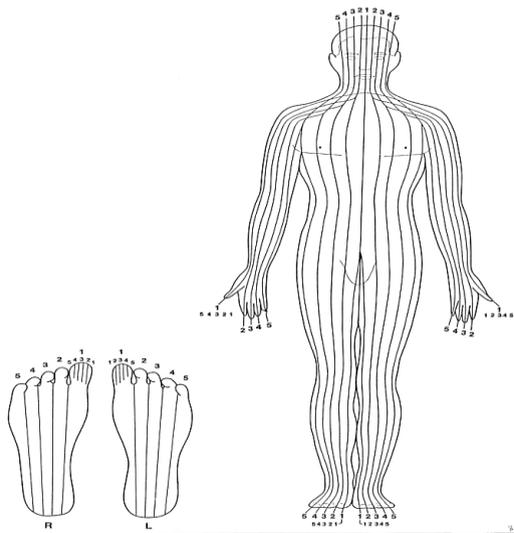


Figure 1.2. **Fitzgerald's conceptual model - the body is divided into ten longitudinal zone areas**

Fitzgerald also believed that the inner and outer aspects of each zone had an active biological correspondence. He thought that all the body parts found in each zone were interlinked, which means that pain or disease in any one part potentially affected the rest of the zone (50). For example, any inflammatory processes or injury in a zone area on the periphery of the body may excite, or be responsible for, disease or inflammation throughout any part of the internal corresponding zone (50). Alternatively, any internal inflammatory disease processes within a given zone may be responsible for peripheral inflammatory imbalances or symptoms manifesting in the external part of the zone (50).

These two ideas were based on his clinical observations of human reflex responses to pain or emotional distress. He interpreted unconscious reflex actions such as the gritting of teeth when in pain, clasp of an injured limb, and the gripping of a chair when in agony, as signs that humans display a native involuntary urge to apply external pressure on the skin in the

relevant zone in times of pain (50). And he believed this automatic response to pain stimulus was specifically designed to stimulate a natural condition of anaesthesia within the zone (49). Based on these assumptions, Fitzgerald hypothesised that it was possible to treat internal pain through sustained, direct (non-accidental) pressure applied to the relevant outer region of the affected zone (51). He then extended the theory and hypothesised that applied external pressure could also 'cure' most types of underlying illness or disease in the internal body region below (52-58). He defined this new theory of the body as "a science" and named the manual pressure technique, zone therapy (50).

1.5.2. Causal mechanisms

Fitzgerald speculated about several mechanisms of action to explain the analgesic effect of direct (non-accidental) pressure. He considered "nerve block" as one potential component. He hypothesised that applied pressure to the nerves running from an injured zone extremity to the brain potentially "*inhibits or prevents the transmission to the brain, the knowledge of injury*". This was thought to be done by inducing a state of inhibition in the relevant zone nerve impulses (50). The 'curative' mechanism of action was thought to involve lymphatic relaxation and flow stimulation. However apart from the lymphatic system, he offered no other rationale to explain the exact mechanism by which direct (non-accidental) pressure was thought to cure disease (50). Therefore his speculations appeared to be based on nothing more than his personal beliefs about how the body works. Fitzgerald published one book during his lifetime, "Zone Therapy for Relieving Pain at Home" (59) in which he outlined his theories and clinical case studies. There is no mention in this book of a specific haemodynamic effect arising from zone therapy. His only reference to any kind of haemodynamic component is non-specific. He advises against the constriction of blood vessels by "*undue irritation of the nerve zones*" (50) caused by excessive pressure of tight belts, corsets or collars. He offered no specific treatment recommendations for cardiac disease

either. However Fitzgerald's ideas played an important role in the formation of reflexology as his theory of two-way therapeutic correspondences between the internal and external formed the basis of reflexology therapy.

1.5.3. Eunice Ingham

Reflexology as it is practised today was devised by Eunice Ingham. Ingham (1889 – 1974) initially trained and worked as a physiotherapist in the early 1930's (11). Alongside her physiotherapy practice, Ingham learned zone therapy from a student of Fitzgerald's (47). She then made several crucial amendments to its theory and practice and distinguished her version of manual pressure therapy by naming it reflexology. She offered no logical justification for these changes. Therefore the remodelling of Fitzgerald's zone therapy appeared to be based on nothing more than her own personal beliefs about how the body works. Ingham published two books outlining her novel theories, "Stories the Feet can Tell" (1938), and "Stories the Feet Have Told" (1951). These books have a seminal position in contemporary reflexology practice as the theory and practice of reflexology originates from these two publications. They also form the core curriculum of the commercially dominant IIR training method (60).

1.5.4. "Stories the feet can tell" (1938)

In her first book, Ingham acknowledged Fitzgerald's zone model theory (61). But differentiates reflexology from zone therapy by proposing that the feet are the most sensitive external zone area of the body (47). For her, the feet offered a perfect scaled-down representational template of the human body. In this model, the toes represent the head. The ball of the foot represents the upper part of the body. The heel represents the body parts below the waist (62). The left foot represents the left hand side of the body, the right foot the right hand side.

And the midline of the body maps to the medial planter region of both feet. Ingham saw this scaled-down representational template as a fundamental biological design (33).

Within this larger correspondence, she assumed that individual areas on the plantar surface of the feet were linked to distinct bundles of discrete nerve endings. Ingham referred to these areas as reflex points (63). Reflex points on the left foot were thought to correspond to the relevant organ(s) on the left side of the body midline. Reflex points on the right foot were thought to correspond to organs on the right (4). Each individual point corresponded or 'mapped' to a specific internal organ within the body (4) (figure 1.2). The reflex points were assumed to be linked to the referred organ via means of a discrete feedback loop which maintains the two-way correspondence (4;63). The "22 miles of tubing" that make up the blood stream and associated "nerve endings" and capillaries in the feet were believed to form the biological basis for the two-way connection (64).



Figure 1.2. Ingham's reflexology map of the feet

Ingham changed Fitzgerald's sustained manual pressure technique to a form of moving massage techniques unique to reflexology. She developed unique massage techniques, delivered primarily with the thumbs. In her book, the thumb massage technique is described as a "*slow creeping and slight pulling back movement*" (65). And rather than applying static pressure to anywhere in the peripheral zone areas, as Fitzgerald did, she applied moving massage pressure primarily to the reflex points on the feet (62;63). Ingham's rationale for the effectiveness of reflexology massage relied on her theory of the human body as being constantly in motion. She writes that the "*natural muscular activity of each organ*", keeps "*its whole nerve canal free from detrimental obstruction*". She assumed that if a nerve canal or organ becomes 'sluggish', obstruction then impairs the nerve canal flow (63). Obstruction was thought to manifest either as a form of perceived 'grittiness' (a sense of 'crystals' under the planter skin of the sole of the foot), or physical tenderness. For Ingham, the perception of grittiness in a reflex point was a sign of accumulating 'crystals'. And in her model of the human body, crystalline deposits or tenderness either suggested a localised peripheral imbalance. Or they indicated a state of imbalance in the corresponding organ (66). In her writing, Ingham varied in her explanations of the nature of the crystalline substances. She described them at various times as chemical deposits, poisonous acid, crystalline deposits or toxins (61). She offered no explanation as to the origins of these toxins. Nor did she specify the name of a single, identifiable chemical toxin which could be measured or extracted for testing. The only exception to this was the occasional mention of 'calcium' deposits giving rise to 'acid' crystals (63).

Ingham assumed that reflexology massage applied to these gritty or tender foot areas broke down the congestive toxic deposits or 'blockages' in the underlying 'nerves' (66). And as the nerve-reflexes in the feet were mapped to corresponding organs via discreet circulatory feedback loops, the circulation to the corresponding organ would improve as a result (66).

Which for her, meant that “Nature” could then repair whatever may have caused the imbalance in the first place (33). Ingham seemed to distinguish the dissolution of circulatory ‘blockages’ from the potentially hazardous biological interpretation which suggests dislodgement or break-up of a blood clot. The dislodging of a blood clot could turn into a potentially life-threatening circulating embolus. In the case of treating cardiac patients, Ingham’s assertions of dissolving blockages would seem to suggest a product safety concern. Over 2% of post-myocardial infarction (MI) patients present with clinically evident systematic embolisms. Over 60% of patients with a large anterior MI have an increased risk of embolic thrombus (67). However Ingham made no reference to this increased risk amongst the cardiac patient population. This implies that she did not regard the ‘blockages’ between the reflex point and the corresponding organ as being material in nature. This seems somewhat inconsistent with other ideas about reflexology, as she also proposed that blockages (in the form of crystalline deposits) were palpable on the soles of the feet.

Ingham promoted reflexology for the successful treatment of cardiac disease and reported several case studies involving the treatment of cardiac patients in her book. She believed the idea of two-way correspondences to be so fundamental to the biological design of the human body that if she found no tenderness or deposits in the heart reflex of a person medically diagnosed with heart disease, she believed the medical diagnosis to be wrong (68). Ingham regarded the heart reflex point as a potent indicator of the condition of the heart and the coronary arteries (40). Readers are advised that ‘tenderness’ in the heart reflex point area is evidence of congestion in the arteries and veins surrounding the heart. They are then warned that congestion eventually leads to life-threatening clots. Ingham tells her readers that the heart must be “...flushed with the proper blood supply, which you will be able to give it by freeing these nerve endings of all acid or calcium deposits where there is a tender reflex” (40).

Ingham's treatment strategy recommended that practitioners work the heart reflex area gently at first (if tender). However she advised that they return to work on it two or three times during the treatment session. In cases of acute Angina Pectoris, she claimed to have treated a number of cases very successfully and advises the following treatment approach -
“..if the pain extends up toward the shoulder and neck, work up towards the root of the fourth and fifth toes. Keep trying until you find the tenderness, then set to and work it out...you must work on the foot according to the location the pain around the heart. If the pain extends down toward the arm, work around the base of the little toe, as pointed out and directed for trouble in the shoulder. Since it is certain no harm can be done by working on a reflex, there is no need to hesitate, but set out and do all the good that can be accomplished” (40)

1.5.5. “Stories the feet have told” (1951)

In her second book, Ingham seemed to have re-interpreted her original notions of “Nature” as being the healing agency invoked by reflexology massage. She now described the internal healing energy as ‘electro-magnetic’. Furthermore, the reflex points in the feet were no longer described as nerve bundles, but as ‘terminals’ involved in the flow of electro-magnetic force throughout the body (69). In a chapter entitled “Terminals”, she made an analogy between her hypothesised reflexes and the ‘terminal’ ends of the arteries, where they transform into veins. She now speculated that ‘blockages’ impede the beneficial conduction of the electro-magnetic forces of the earth into the feet terminals (70). Ingham also introduces calcification of the arterial vessels as the key cause of high blood pressure. She cites the primary cause of this condition as faulty ‘elimination’ or tension often found following a ‘distorted mental attitude’ (71). However it is not clear whether she related the calcium involved in hypertension to be the same calcium involved in her crystalline toxic deposit theory. In this second book, she offered no direct treatment strategy for either calcification reduction or faulty elimination, save for adopting a more cheerful countenance (71).

1.5.6. Inconsistencies in Ingham's reflexology theories relevant to the thesis aim

As the commercially dominant IIR offers professional training exclusively and explicitly based on Ingham's theories (14), her treatment strategies for both cardiac patients and the heart reflex point were highly relevant to this thesis enquiry. Ingham repeatedly asserts in her work that there is a direct feedback system between peripheral reflex areas of the feet and the corresponding internal organs of the body. And that by virtue of this distinct connection, reflexology massage is able to improve or restore blood circulation to the corresponding organ (66). However the analysis of Ingham's reflexology revealed that the inconsistent foot maps and haemodynamic effect claim have their roots in her work. As the thesis aim was to provide the first quality and safety data for reflexology in cardiac patients - based on Ingham's assumption of a two-way, haemodynamically active connection - these inconsistencies highlighted the product quality issues inherent in the commercially dominant version of reflexology.

First, with regards to the inconsistent foot maps, Ingham changed the location of many of the reflex points throughout her 30 year reflexology teaching career. The point locations were changed at various times in order to make their organ correspondences more anatomically accurate in the representational template model. This was reportedly done in response to increased scepticism from the medical profession (47). Ingham offered no explanation in her two books as to how the existence of a two-way haemodynamically active connection could be maintained if the 'mapped' reflex points changed location. Nor is this theoretical inconsistency discussed on the IIR website. Furthermore, if Ingham's idea of scaled-down representation of the body on the feet is taken literally, the heart reflex point should be located on the medial aspect of the left foot for accurate anatomical representation. Yet

Ingham continued to believe that the heart reflex point was located in the mid region of the ball of the left foot, in the area beneath the fourth and fifth toes. Of all the reflex points, this was the one point location that remained consistent throughout her teaching career (47). As the location appeared to be determined by little more than intuitive opinion, it seemed incongruent with her theory that the feet offer an anatomically accurate scaled-down representational model template of the human body. Again, there is no discussion of this incongruent reflex point placement in her books or on the IIR website.

The analysis of Ingham's reflexology also revealed that the beliefs regarding cardiac patient indication emerged from her work. Ingham's recommendations for treating cardiac patients and the heart reflex point itself clearly implied that she saw no harm in working the heart reflex area. Furthermore, she advised repeated work to the area during a treatment session. Therefore, for the purpose of the thesis enquiry, Ingham's law for treating patients with any gradation of heart disease was categorised as a '*therapy specific benefit*' belief. In other words, she saw no risk in working the heart reflex point, or in returning to work the point, regardless of any underlying cardiac disease. Furthermore, she believed that treatment would provide a specific benefit to the cardiac patient receiver, regardless of cardiac disease origin.

As there are evident conflicts in reflexology literature regarding the indication of reflexology for cardiac patients and treatment strategies for the heart reflex point, it was necessary to compare modern reflexology therapeutic beliefs with Ingham's therapeutic beliefs. The aim of this was to understand why some practitioners regard reflexology as contra-indicated for cardiac patients, despite Ingham's assurances to the contrary. And to understand how modern practitioners resolve the reflex point location inconsistencies in clinical practice. For this purpose, the contemporary reflexology education and training structure was identified so that only validated and approved sources of reference literature were referenced.

1.6. Contemporary reflexology in the UK

As CAM therapies including reflexology became more popular in the UK, The House of Lords Select Committee report on CAM (2000), the Kings Fund Report (2008), Professor Stone's voluntary regulation proposals and the Federal Working Group recommendations (21;25;72;73) reported on the need for improving professional CAM research and educational training standards. The Complementary and Natural Healthcare Council (CNHC) was set up to regulate professional standards for a UK-wide voluntary register of CAM practitioners. This register includes reflexologists (74). The CNHC aims to protect the public by ensuring that CAM registrants meet minimum practitioner quality and product safety standards in their practice. Based on this assurance of quality, the Department of Health recommend potential purchasers of CAM to consult a CNHC registered practitioner wherever possible (75). Suitably qualified reflexologists are currently eligible for entry to the CNHC Register if they have undertaken a validated programme of education. And have gained professional registration status which meets the CNHC requirements (76). If the practitioner applies for CNHC registration, they are obliged to continue a set amount of professional development training every year. Membership of the CNHC means that the reflexology profession is more open to public scrutiny. But at the same time, it is a form of guarantee to the public that the reflexologist has achieved an approved level of training. And that the training has been recognised as being of professional standard. Registration of the CNHC is voluntary at this time, but it is generally assumed that membership will become mandatory in due course.

The CNHC currently recognises three professional reflexology associations in the UK which exist to represent the interests of professional reflexologists. These are the British Reflexology Association (BRA), the International Federation of Reflexologists (IFR) and the Association of Reflexologists (AoR). These member associations sit within the larger UK Reflexology Forum council, a top-level organisation which operates as a voluntary overall regulator of the

profession. In 2004, in line with the CNHC requirements for standardisation of training, the Reflexology Forum developed a set of common standards for the practice and training of reflexology. These standards now form the “core curriculum” of reflexology training. They are based on the National Occupational Standards set down by the Skills for Health Council. The curriculum, called the *‘Level 3, 7 Unit Reflexology Practitioners Diploma’* consists of 7 pre-defined modules (77). This modular core curriculum was adopted by all the major accredited reflexology training providers. It was also recognised by CAM/health and beauty vocational awarding bodies, such as City & Guilds, VCTC, ITEC and ABC Awards (77-79). Reflexology students must meet all seven module requirements, gain a current first aid certificate and have professional indemnity insurance to be eligible to join the AoR or IFR. However there is no professional obligation to maintain the first aid certification after graduation. BRA membership criteria differs in that they only offer membership to those practitioners who have successfully completed the bespoke Eunice Ingham modular training at one of the IIR training centres. However completion of the core curriculum is not a mandatory pre-requisite for professional practice; any person can set up business as a reflexologist and operate without professional member or accredited status, regardless of the standard, length or quality of their training.

The Reflexology Forum’s core curriculum has a recommended reading list of original teaching texts published on the forum website (appendix 1). When the list was searched for available publications for the thesis analysis, many of the books appeared to be out of print or no longer available, except as second-hand versions. However seven of the key available teaching texts were still available, including the two key foundational books written by Eunice Ingham. Based on this available sample, the views of the other five authors provided a ‘snapshot’ of what more contemporary reflexology educational theorists believe about the appropriateness of

reflexology for cardiac patients and their recommendations for treatment of the heart reflex point itself. And enable a comparison to be made with Ingham's original beliefs.

1.7. Contemporary reflexology literature

Using Ingham's haemodynamic theories and confident approach to treating cardiac patients as a reference point, the remaining five educational texts will now be discussed. This is done in order to understand why some practitioners regard reflexology as contra-indicated for cardiac patients, despite Ingham's assurances to the contrary. And to determine the degree of inconsistent treatment advice given in contemporary reflexology teaching literature. The texts are "Reflexology Today", "The Complete Guide to Foot Reflexology", "Reflexology: A Better Way to Health", "Reflex Zone Therapy of the Feet: A Textbook for Therapists" and "Complete reflexology: Therapeutic Foot Massage for Health and Wellbeing". The responses of each author were categorised according to whether their advice constituted a '*therapy specific benefit*' or '*therapy specific risk*' belief. A '*therapy specific benefit*' belief implies that the author sees reflexology treatment as indicated for cardiac patients. And treatment to the heart reflex point as appropriate in this patient group. This view indicates that the author's beliefs reflect Ingham's original therapeutic beliefs. A '*therapy specific risk*' belief category suggests that the author considers reflexology or treatment directly to the heart reflex point contra-indicated for cardiac patients. This view would put them at odds with Ingham's therapeutic beliefs. The five key teaching texts were examined using this criterion.

"Reflexology Today", was written by Doreen Bayley. The author was a nurse who studied with Ingham. Bayley is generally accredited with bringing Ingham's reflexology to the UK. She states that reflexology can be of great use in helping various heart conditions; however this recommendation comes with caveats. She advises that the method of treatment should be

varied according to the nature of heart trouble. She appears to believe that treatment to the heart reflex point has particularly 'potent' effects on the heart itself and describes a case where overstimulation of the heart reflex point led to the person having to spend a week in bed recovering. In the event of a subject (client) experiencing a 'heart attack', she states that the therapist should set to work on the heart reflex area found in the left foot as quickly as possible. She states that the impulse effect of this single action has been known to successfully resuscitate heart attack victims (43). In cases where the receiver has tachycardia, Bayley also gives a cautionary warning that the therapist should give a general relaxation treatment before approaching the heart reflex point. Her rationale being that if treatment is given to the heart reflex point first, it may adversely increase the elevated pulse rate further. In the case of older subjects with any form of chronic heart disease, Bayley recommends proceeding with caution, advising that the therapist only works for a few minutes on the heart reflex point at first, and only increases the intensity of treatment once the patient has relaxed (43). Given the caution she advises with regards to treatment of both cardiac patients and the potency she ascribes to the heart reflex point use, it seemed appropriate to categorise Bayley's approach as a '*therapy specific risk*' belief in relation to treating cardiac patients and/or the heart reflex point.

In "Reflexology: A Better Way to Health", author Nicola Hall states that the heart reflex point is an important area to work in all cases of heart or circulatory disease (80) and that when any reflex area is worked, there is an increase in the blood circulation to the corresponding organ (81). More specifically, she claims that reflexology can successfully treat "*angina, heart attack, hypertension hypotension...and thrombosis*" and for all these conditions, lists the heart reflex point as the key point to work (82). However she strongly recommends care to be taken when treating the heart reflex area in clients with chronic heart disease due to the risk of "*over-stimulating*" the heart itself (82). No clear explanation is given of the over-stimulation

process. Based on her cautionary approach to treatment of the heart reflex point in cardiac patients and the potency she ascribes to the heart reflex point use, it seemed appropriate to categorise Hall's approach as a '*therapy specific risk*' belief in relation to treating cardiac patients and/or the heart reflex point.

In contrast to this approach, Kevin and Barbara Kunz, the authors of "The Complete Guide to Foot Reflexology" appear to have no concerns about treatment to the heart reflex point. Nor do they see reflexology as contra-indicated for any gradation of cardiac disease. They specifically disregard what they describe as the 'myth' that reflexology can cause a "*heart attack*", stating that reflexology is "*totally safe*" (83). They recommend treating both the heart reflex point and lung area in the event of "*heart attacks*", along with the sigmoid colon reflex point (in case pocketing of gas has caused the increased pressure on the chest cavity). In cases of angina, they advise treating the heart reflex point "*thoroughly*". This same confident technique is advised for treating hypertension, except that the solar plexus, kidney and adrenal points are indicated rather than the heart reflex point. Again, the authors stress that reflexologists should work the relevant areas repeatedly and thoroughly to reduce blood pressure. Given that the authors advise no caution when treating cardiac patients and regard reflexology treatment as totally safe for cardiac disease conditions, their approach was categorised as a '*therapy specific benefit*' belief in relation to treating cardiac patients and/or the heart reflex point.

A more cautionary form of practice is recommended in "Reflex Zone Therapy of the Feet: A Textbook for Therapists". Here, author Hanne Marquardt advises caution in treating the heart reflex area and states that it is better to treat the indirect reflex areas rather than the heart point itself. She cites deep vein thrombosis and an aneurysm (if known) as absolute contraindications. For treatment of the heart, the guiding treatment principle is stated as

“depress hyper-excitability and stimulate flaccidity”, with *“weak stimuli”* being seen as beneficial and *“strong stimuli”* as *“detrimental”*, and *“very strong stimuli”* as *“harmful”*. The author stresses that this principle of caution, particularly in relation to overstimulation, applies particularly to patients with heart disease (44). Based on her cautionary approach to treatment of the heart reflex point general and the potency she ascribes to the heart reflex point use, Marquardt’s approach was categorised as a *‘therapy specific risk’* belief in relation to treating cardiac patients and/or the heart reflex point.

In the *“Complete reflexology: Therapeutic Foot Massage for Health and Wellbeing”*, author Inge Dougans states that reflexology can do no harm, however she advises caution when clients present with thrombosis as she believes treatment could cause the blood clot to move (80). However she does not offer any cautionary advice regarding treatment techniques to the heart reflex point. Also, there is no indication or contra-indications given in regard to clients with cardiac disease. Dougans does not offer any objection to treating cardiac patients and regards reflexology treatment as totally safe for all disease conditions apart from diagnosed thrombosis. Therefore her approach was categorised as a *‘therapy specific benefit’* belief in relation to treating cardiac patients and/or the heart reflex point.

1.8. Conclusion

The analysis of reflexology from inception to present in this chapter aimed to establish an understanding of the therapy from the perspective of the reflexologist practitioner. This was necessary in order to establish an accurate representation of reflexology in the thesis. The analysis confirmed a lack of consensus amongst contemporary reflexology theorists regarding reflexology indication for cardiac patients. It also confirmed that there was no consistent, standardised reflexology treatment strategy for the heart reflex point evident in modern

teaching literature. This lack of consensus presented a challenge in how to devise a valid and safe reflexology treatment for use in the thesis experiment. The intervention had to be able to compromise between the '*therapy specific risk*' and '*therapy specific benefit*' approach of the varying authors. In addition to the treatment type, the problem of the inconsistency of the heart reflex point location in reflexology foot maps had to be addressed as well.

The next stage in the thesis enquiry was a systematic literature search. The aim of the search was to identify whether there was any existing evidence to support the specific haemodynamic effect claims in any population group. And to establish whether there was any existing safety or quality evidence regarding reflexology use in the cardiac patient population. The review also aimed to identify whether any study had developed a suitable protocol which could be adapted to support the thesis aim in the healthy volunteer and cardiac patient group. The findings of the systematic literary review are described in the next chapter.

Chapter 2

Literature review –

Reflexology scientific literature

Jones J, Thomson P, Irvine K, Leslie SJ. Is there a Specific Haemodynamic Effect in Reflexology: A Systematic Review of Randomised Controlled Trials? *Journal of Alternative and Complementary Therapies*. 2012; doi:10.1089/acm.2011.0854

Chapter two

2.1. Literature review

2.1.1. Review aim

The aim of the review was to systematically evaluate RCT's involving reflexology as the primary intervention. This was done to identify whether there was any existing evidence to suggest a reflexology treatment-related, specific haemodynamic effect on individual organ perfusion levels. This effect, regardless of the organ involved, should be differentiated from a generalised systemic haemodynamic response to non-specific effects. Without this hypothesised active two-way connection, it could be argued that reflexology is completely indistinguishable from simple foot massage. The review also aimed to identify whether any existing study had already developed a design which could systematically control for non-specific effects in order to isolate a specific active component. And if not, what challenges had prevented the researchers from achieving this aim? The purpose of this was to identify whether any study had developed a suitable protocol which could be adapted to support the thesis aim in the cardiac patient group. The review also sought to identify whether any reflexology study had recruited from the highly relevant cardiac patient population. Also, whether the reflexology interventions and map inconsistencies been addressed in any way so that they take into account the existing educational literature treatment strategy and foot map inconsistencies?

2.1.2. Search strategy

A full literature search was conducted in order to identify any studies involving reflexology and using the RCT or controlled trial design that met the criteria of the review questions. The following literature sources were used.

Electronic literature sources (Abstract and citation databases)

MEDLINE – (Biomedical literature)

EMBASE – (Biomedical literature)

CINAHL – (Nursing & Allied Health Professional literature)

BRITISH NURSING INDEX – (Nursing literature)

CENTRAL – (Cochrane Central Register of Controlled Trials)

COCHRANE – Database of Systematic Reviews (Biomedical & Healthcare literature)

Grey literature

Association of Reflexologists database of reflexology literature

Google Scholar – www.google.com (Advanced search portal)

Other sources

The bibliographic references from all retrieved articles were also manually searched in order to find studies not identified by electronic searches.

2.1.3. Search terms

The following search terms were used and adapted as required for the various databases.

1. ((reflex adj therapy) or ((foot and massag*) or (feet and massag*) or zone therapy)).mp.
2. reflexology.mp.
3. 1 or 2
4. (hand* and massag*).mp.
5. 3 or 4
6. (pp or ph).fs.
7. 5 and 6
8. randomized controlled trial.pt.
9. controlled clinical trial.pt.
10. randomized controlled trials/
11. random allocation/
12. double-blind method/
13. single-blind method/
14. 8 or 9 or 10 or 11 or 12 or 13
15. animal/
16. human/
17. 15 and 16
18. 15 not 17
19. 14 not 18
20. 7 and 19

2.1.4. Eligibility criteria

Due to the heterogeneity of published reflexology studies, titles and abstracts of randomised controlled trials (RCT's) of reflexology using adult subjects (including healthy volunteers) without age limitation, and physiological outcomes for any type of human condition, published up to September 2011, were initially retrieved. The RCT methodology inclusion criterion was applied and there were no language limits.

2.1.5. Types of interventions and controls

Reflexology foot massage techniques as the intervention versus sham reflexology treatment, simple foot massage, conventional treatment or no treatment as the control. There was no restriction on the duration or style of reflexology treatment, or when or where it was applied.

2.1.6. Study selection

The titles and abstracts of all identified RCT's involving any type of reflexology and using adult subjects were read to determine eligibility. Relevant national and international full text articles were retrieved (figure 2.1). After applying the inclusion and exclusion criteria, papers that included primary or secondary haemodynamic outcomes were identified. Studies using simple foot massage rather than reflexology therapy as the intervention were excluded even if they included haemodynamic outcomes (10;84). In one foot massage study, patients in critical care had a drop in heart rate (baseline 97.3 beats per minute (bpm) vs. intra-treatment 94.7 bpm vs. post-treatment 96.3, $p < 0.003$) and mean arterial blood pressure (baseline 85.5 vs. intra-treatment 83.6 vs. post-treatment 85.1, $p < 0.05$) following a five-minute foot massage. However as the foot massage had no reflexology component or context, the results were

thought to be associated with the relaxation aspect of simple foot massage. Therefore the study was not included in the review.

2.1.7. Objective outcome measures and data items

Outcomes identified from the papers were examined in order to determine whether, and to what extent, was there any scientific evidence to suggest that reflexology treatment to distinct areas of the feet (reflex points), using touch techniques unique to reflexology, produces a specific and therapeutically beneficial haemodynamic effect. An effect from which it can be inferred that an increase in blood supply to the corresponding organ(s) occurred as claimed. Outcomes included any haemodynamic parameter potentially involved in the regulation of circulating blood volume and flow. These included heart rate, systolic and diastolic arterial blood pressure. These were selected as they have a common mean metric across all the studies and could be used to infer a change in organ perfusion rates. Other less common parameters were included if directly relevant to the enquiry.

2.1.8. Risk of bias in individual studies

The methodological quality of identified papers was assessed using The Cochrane Library recommended Quality Assessment Tool for Quantitative Studies checklist (EPHPP) (85). Each paper was scored based on the tool criteria. Selection bias, study design, confounders, blinding, data collection methods, withdrawals and drop-outs, intervention integrity and analysis components of each study were rated. Scores in the checklist categories summary range from 1 – 3, with 1 indicating the highest strength. Each paper was then scored overall as either 1 = strong, 2 = moderate, or 3 = weak using the EPHPP global criteria. The studies were assessed as being double-blinded if the participants, data collector and/or data analyst

were blinded to intervention allocation, as therapist blinding is not possible in the special case of reflexology. Otherwise, the trial was defined as a controlled clinical trial. Systematic differences in the care delivered to study participants which can introduce performance bias were accounted for by the explicit inclusion and exclusion criteria being applied to the studies under consideration (86).

2.2. Results

Out of the 48 RCT full-text reflexology research papers retrieved, 12 papers that included primary or secondary haemodynamic outcomes were identified (87-98) (figure 2.1). Five RCT studies using foot massage rather than reflexology therapy (7-10;99) were excluded even though they included haemodynamic outcomes. The 12 RCTs involving a reflexology intervention met with the inclusion criteria and contained sufficient and appropriate haemodynamic data. A summary of their eligibility criteria, design characteristics and results is summarised in table 2.1. The experimental design quality of the studies was assessed using the CASP critical analysis tool (100). Although the majority of studies used common haemodynamic outcomes, the lack of understanding of how reflexology works made classification of the interventions difficult (101). The analysis showed that there was significant heterogeneity; therefore systematic meta-analysis of the data was not possible. So for the thesis review, the studies were differentiated first by EPHPP score. Differentiating the studies by EPHPP quality score, six of these 12 had a global rating of 'weak' (87;94-98), 4 were rated as 'moderate' (88;89;92;93) and 2 scored as 'strong' (90;91) (see table 2.2). The papers were then classified by type and duration of reflexology intervention and finally by common and less common interpretable haemodynamic parameters.

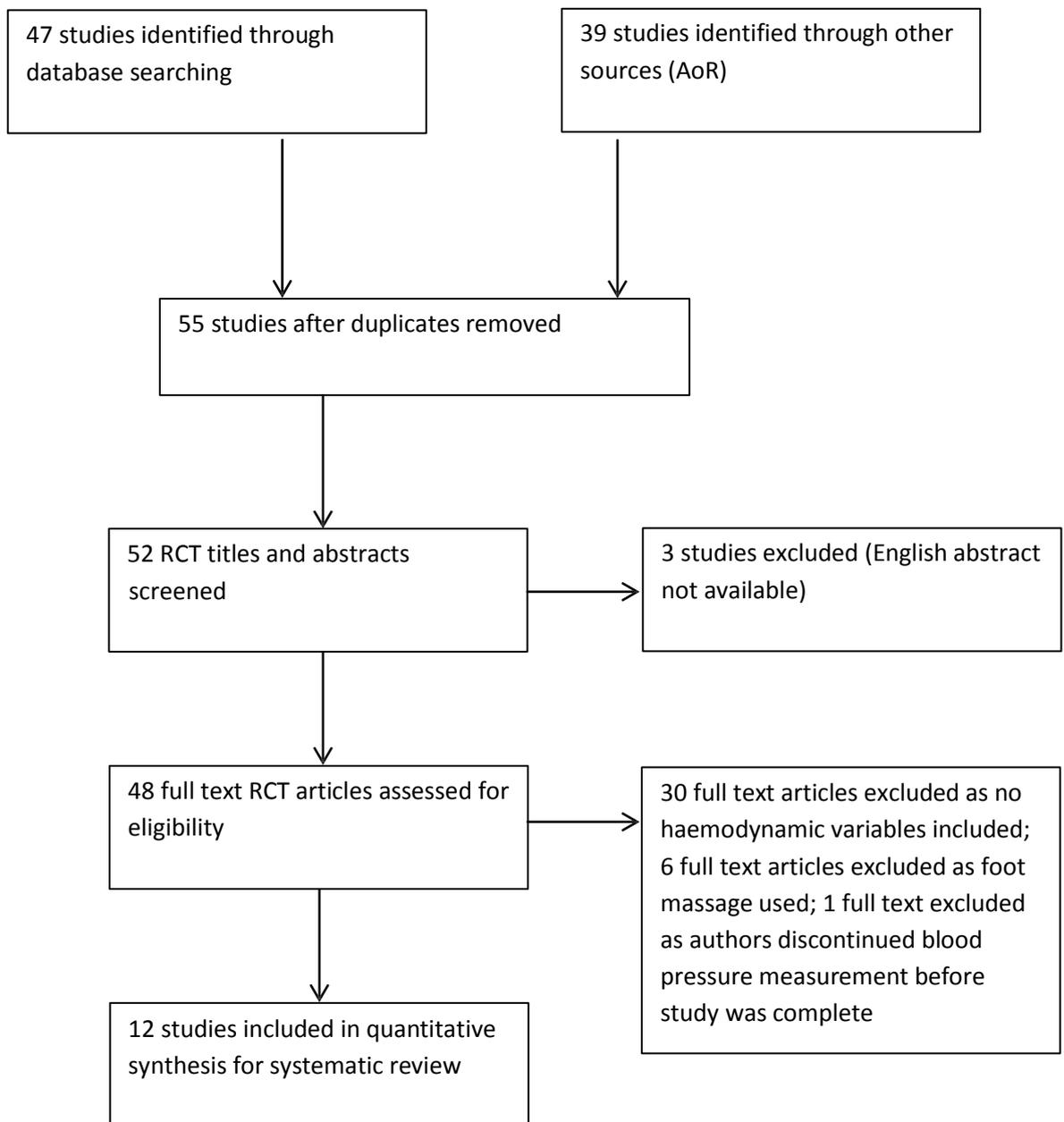


Figure 2.1. **Flow diagram showing study selection and recruitment process**

Table 2.1. Study characteristics

Authors, Year (Ref number)	Design	EPHPP Score	Participant Characteristics	Intervention	Reflexology style/duration	Control	Haemodynamic outcome measure	Main result
Hodgson & Andersen, 2008 (21)	Repeated measures, crossover	Strong	Nursing Home residents with mild-moderate dementia	4 sessions of reflexology over 4 weeks	Style and foot map not identified; detailed treatment protocol described	4 weeks of friendly chat sessions	Post-test sBP & dBP and HR collected on the treatment day	No inter-group significant difference
Mackereth et al, 2009 (25)	Repeated measures, crossover	Strong	Patients diagnosed with MS; Reflexology naïve	6 weekly sessions of reflexology, then 4 week washout period;	Ingham reflexology style, no detail of treatment length or focus	6 weekly sessions Progressive Muscle Relaxation training then 4 week washout period	Pre & post-test Blood Pressure and (HR)	Systolic BP favoured PMR (p = 0.002); Significant pre to post-session changes in sBP (P = 0.0016) & HR (p = 0.001) irrespective of treatment type
Sudemeier et al, 1999 (27)	Placebo controlled, double-blinded RCT	Moderate	Healthy, slender volunteers between 18-38 years old	Single reflexology treatment to zones corresponding to right kidney	Reflexology style and foot map not identified; Anatomical location of target zone given	Placebo group treated on 'non-kidney' areas;	Pre, intra & post-test resistive index changes in the right kidney renal arcuate artery	Intervention group resistive index significantly lower intra-treatment (p = 0.001); significant post-test drop in sBP for intervention group (=p = 0.014) & control (p = 0.048) & HR intervention (p 0.008) & control (p = 0.018)
Mur et al, 2001 (28)	Placebo controlled, double-blinded RCT	Moderate	Healthy volunteers	Single treatment to zones corresponding to the doudenum, ileum, ileocecal valve, colo ascendus and transversum	Style and foot map not identified; no anatomical descriptions of zone locations given	Reflexology applied to areas related to the eyes, ears and lungs	Pre, intra & post resistive index changes in resistive index for the superior mesenteric artery	Intervention group resistive index significantly lower intra-treatment (p = 0.021) significant post-test drop in BP for intervention group (=p = 0.05)
Gunnarsdottir & Jonsdottir, 2007 (19)	RCT	Moderate	18+ years, on a waiting list for Coronary Artery Bypass surgery	5 sessions of Reflexology over 5 days pre & post surgery	Ingham reflexology style & foot map used; special attention on all glands and the solar plexus areas	Lying in bed, neutral lubricant cream applied to feet then rest for 30 minutes	Pre & post sBP & dBP, HR, respiration rate	Systolic blood pressure lowered significantly in the control group (P < 0.05)

Frankel B, 1997 (20)	RCT; non-random allocation if reflexology familiar	Moderate	≥ 19 years to ≤ 25, reflexology naïve	Single treatment	Ingham reflexology style & foot map; treatment to all parts of the foot carried out twice	Foot massage	Pre & post-test Baroreceptor Reflex Sensitivity (BRS), BP and Sinus arrhythmia (SA)	No inter-group significant difference in any variable
Wilkinson et al, 2006 (23)	RCT + mixed methods	Weak	Moderate to severe COPD and under long-term follow-up	4 sessions of reflexology over 4 weeks	Style and foot map not identified; all areas of feet treated	Supportive discussion for same length of time	Pre & post-test BP, HR, respiratory rate, oxygen saturation rates per session	Pre to post-test HR significantly reduced in the intervention group per session (p = 0.01)
McVicar et al, 2006 (26)	RCT crossover	Weak	30 healthy volunteers 16-59 years	Reflexology applied to both feet	'Angela Ruskin University' reflexology style and caterpillar technique cited, gentle pressure used	Control group sat together quiet room for same length of time	Pre & post test sBP, dBP and HR	Significant Intervention group reduction in sBP (p = 0.001) and HR (p = 0.001)
Zhen et al, 2004 (22)	RCT crossover	Weak	Male/ females 17-20 years	Mechanical reflexology applied to right foot only	Style & foot map not identified as mechanical reflexology device used	Sit in chair, relaxed sitting position for session	Continuous ECG linear & non-linear components of Heart Rate Variability	Significant intervention group changes in correlation dimension (p = 0.0006) & sampling distribution of the means (p = 0.03)
Joseph et al, 2004 (24)	RCT crossover	Weak	30 Male/ females 17-21 years	Mechanical reflexology applied to area below toes on both feet	Style & foot map not identified; mechanical Reflexology Device used	Sit in chair, relaxed sitting position for session	Continuous ECG linear & non-linear components of Heart Rate Variability	Significant intervention group changes in HRV correlation dimension (p = 0.05) and entropy (p = 0.02)
Machi et al, 2000 (31)	Clinical trial	Weak	5 volunteers (2 male/ 3 female)	Massage started from right foot then changed to left foot, short massage, then longer massage	'United Kingdom Reflexology Style' cited – style not described, foot map not identified	No comparative control used	Continuous HRV linear R – R intervals, continuous BP, intra-treatment blood flow at neck and knee	No significant changes reported
Zhang et al (2009) (32)	Clinical trial	Weak	10 females	Reflexology to areas of left foot	Style & foot map not identified, treatment to 'wards' of sole, instep and lateral aspect x 5, moderate finger pressure	Right foot left untreated	Blood flow using laser blood flow meter	Blood flow in both feet significantly increased at post-treatment (p < 0.05), 10 min post-t (p < 0.01). Left foot significantly different 20 mins post-t (p < 0.05)

Table 2.2. EPHPP Methodological Quality Review Scores

Study	Selection bias	Study design	Confounders	Blinding	Data collection methods	Withdrawals & dropouts	Global rating
Yoshio et al, 2000	Weak	Weak	Weak	Weak	Strong	Weak	Weak
Wilkinson et al, 2006	Moderate	Moderate	Weak	Weak	Moderate	Moderate	Weak
Joseph et al, 2004	Weak	Weak	Weak	Weak	Weak	Weak	Weak
Zhang et al, 2010	Weak	Weak	Weak	Weak	Strong	Moderate	Weak
McVicar et al, 2007	Moderate	Strong	Weak	Moderate	Strong	Weak	Weak
Zhen et al, 2004	Weak	Strong	Weak	Weak	Strong	Moderate	Weak
Sudmeier et al, 1999	Weak	Moderate	Strong	Moderate	Strong	Strong	Moderate
Frankel, 1997	Weak	Strong	Strong	Moderate	Strong	Strong	Moderate
Mur et al, 2001	Weak	Strong	Strong	Moderate	Strong	Moderate	Moderate
Gunnersdottir, 2007	Moderate	Strong	Strong	Weak	Strong	Strong	Moderate
Hodgson & Anderson, 2008	Moderate	Moderate	Strong	Moderate	Strong	Strong	Strong
Mackereth et al, 2009	Moderate	Strong	Strong	Moderate	Strong	Strong	Strong

2.2.1. Type and duration of reflexology intervention

Reflexology technique and foot maps varied considerably, dependent on where, and with whom the reflexologist trained. Three papers quoted the 'Ingham' method as the reflexology intervention style used (88;91;93). As discussed in chapter one, the 'Ingham' style has its own standardised technique and foot map. In the UK, this method is taught exclusively by the British School of Reflexology, the largest IIR UK reflexology teaching provider (102). One paper specified 'Angela Ruskin University' reflexology as the intervention type (95) and one described the therapy style as "United Kingdom style reflexology" (87). Neither of these papers described how these techniques differentiated from other forms of reflexology nor indicated whether each had its own individualised foot map. Of the remaining papers, seven gave no indication of type of reflexology style or variation of foot map used (89;90;92;94;96-98). Only one specified the exact anatomical location for both the intervention and control areas of the feet (92) and only one provided a detailed protocol sequence for the reflexology intervention (90).

2.2.2. Methodological approaches to isolating specific versus non-specific effects

Ten of the 12 studies delivered the reflexology intervention as a 'whole system' complex treatment. No attempt was made to control for non-specific haemodynamic effects in order to isolate any active specific haemodynamic ingredient said to be inherent in the therapy. Control comparisons included 'friendly chat sessions' (90) or 'symptom discussion' sessions for the same duration as the reflexology intervention (94), progressive muscle relaxation training (91), foot massage (88), sitting in quiet room (95), sitting in a relaxing chair (96;97) and resting in bed (93). Only two studies attempted to isolate a specific haemodynamic effect by

contrasting massage to a specific area of the foot whilst measuring the associated organ perfusion rates compared with massage to 'non-active' areas of the feet as the control (89;92).

2.2.3. Dosage

Five studies used a single reflexology treatment as the intervention (88;95-98). Four used a series of reflexology treatment sessions to form a combined measurable intervention (90;91;93;94). One study used both a single visit and an aggregated series of treatments as two separate measurement points (91). Two used a mechanical reflexology device ("Massager-Scroller") to massage a single area of the foot only (96;97).

2.2.4. Duration

The length of the intervention also varied considerably, ranging between eight minutes treatment (92), ten minutes (98), "a short massage (10 minutes) and a long massage (20 minutes)" (87), 20 minutes (96), 30 minutes (90), 40 minutes (91), 45 minutes (88), 50 minutes (94), and 60 minutes (95) with no clear rationale offered in any paper as to how the treatment length was determined.

2.2.5. Common haemodynamic parameters

Blood pressure: Two studies found significant post-test reductions for the reflexology intervention group in systolic blood pressure (sBP) but not for diastolic blood pressure (dBp), ($p = 0.001$) (95) and ($p = 0.05$)(89). One study found post-test significant reductions in sBP in both the intervention group ($p = 0.014$) and control group ($p = 0.048$) (92). One found a significant post-test difference irrespective of treatment type ($p = 0.0016$) (91). Four studies

failed to show any pre to post significant haemodynamic effect on systolic (sBP) or diastolic (dBP) blood pressure arising from a reflexology intervention (87;88;90;94). Heart Rate (HR): One study found significant post-test HR reductions for both the treated ($p = 0.008$) and control group ($p = 0.018$) (effects size not given) (92). One reported significant post-test HR changes for the intervention group irrespective of reflexology treatment vs. comparison intervention (Wilks $\lambda = 0.312$, $df = 1, 48$, effect of 1.12 units, 95% CI 0.162 – 2.081; $p = 0.01$) (91). And one study found significant post-test HR reduction for the intervention group ($p = 0.01$) (94) (effects size not given). Three studies failed to show any specific effect on heart rate for the intervention groups (89;90;93). Heart rate variability (HRV): Two non-linear HRV parameters, the estimate of the standard deviation of the sampling distribution of the means (SENN) of R-R intervals and correlational dimension (CD) analysis, were found to be significantly different (SENN $p = 0.03$; CD $p = 0.0006$) in favour of the reflexology group, when compared to a control group (96). One study found significant pre to post intervention group changes in HRV entropy, which is a thermodynamic quantity describing the amount of disorder in a system ($p = 0.025$) (97). Baroreceptor reflex sensitivity and sinus arrhythmia: Analysis of baroreceptor reflex sensitivity data and sinus arrhythmia rates revealed no significant difference when a reflexology intervention group were compared with a foot control massage group (88). Blood flow rates: Analysis of post-test pedal blood flow recovery rates found a significant 20 minute post-treatment difference for the intervention group (98). Two studies attempted to measure the relationship between massage to specific areas of the feet and changes in localised vascular resistive index rates using colour Doppler sonography. Both these studies reported positive findings for the intervention treatment, one reporting a significant intra-treatment change in resistive index of the renal artery when the 'kidney' are of the foot was massage ($p \leq 0.001$) (92). The other found significant resistive index changes in the superior mesenteric artery ($P=0.021$) when the "intestinal" reflex point on the foot was stimulated (89).

2.2.6. Risk of bias across studies

The majority of reflexology RCT's appear to lack sufficient blinding, either because the data collector seemed to be aware of the group conditions during the study (87;91;94;96;98) or because the data collector delivered the intervention reflexology itself (88;93;95). This can, in some instances, lead to selective reporting within the study and potentially affect the cumulative evidence (103). Only two studies were double-blinded, designed so that neither the data collector nor examined subjects were aware of which group they belonged to (89;92). There was no systematic attempt to uncover unpublished studies although searches of reference lists of published studies and systematic analysis did not identify unpublished material. As some of the studies were carried out by reflexology therapists who measured the outcomes as well as delivering the treatment, this could have led to bias. Finally, the 'dose', duration and type of reflexology varied considerably between studies, which could have influenced their findings.

2.3. Discussion

The review found that out of the 12 RCT's reviewed that used haemodynamic outcomes, there were seven whose findings suggested that reflexology massage had some kind of effect on blood pressure, heart rate, non-linear components of HRV and vascular resistive index rates. Of these seven, two studies reported beneficial reductions in systolic blood pressure for the intervention group and two reported a reduction in the intervention groups mean heart rate (89;91;92;95). However, five of these seven studies reviewed delivered the reflexology intervention as a whole complex treatment, with the data collector often delivering the intervention themselves. This meant that the study design was not able to provide an experimentally inert reflexology comparison which could differentiate between non-specific

haemodynamic effects - such as the compassion of the therapist, treatment environment, the act of lying supine - and the effects of simple foot massage that would be equally present in both intervention and control. Therefore the blood pressure and heart rate reductions were insufficient as evidence to suggest the existence of a specific change in the haemodynamic status of an individual organ. Overall, 10 of the 12 RCT's reviewed did not systematically control for non-specific effects in order to isolate any specific active component. The reasons for this were not clear. Only two reflexology researchers attempted met the design challenge regarding the distinction of specific versus non-specific effects by using a double-blind randomised method purposefully designed to allow a specific effect to reveal itself. Intriguingly, both studies demonstrated what appeared to be a specific, haemodynamically beneficial effect on localised organ perfusion rates. This effect appeared to correspond with reflexology massage to related areas of the feet, a haemodynamic effect that by virtue of their novel design strategy, appeared distinct from systemic non-specific massage effects (89;92).

Sudemeier et al (1999) reported statistically significant changes in resistive index of the renal arcuate artery when the 'kidney' foot area was massaged (92). Mur et al (2001) reported significant changes in the mesenteric artery resistive index when the 'intestinal' area was massaged (89). The precise mechanism which caused the changes in resistive index in both intervention groups remains uncertain although the direction of the change in resistive index allowed the inference to be made that the change was therapeutically beneficial in both cases, as reflexologists claim it would be. Furthermore, in both studies, no such change in resistive index occurred when control or unrelated points were massaged, implying that the effect was indeed specific as reflexologists claim. However these two studies still demonstrate the research challenges involved in any attempt to measure haemodynamic changes to specific organs without having to adopt invasive and potentially risky measuring methods. The researchers used non-invasive colour Doppler sonography technology to infer arterial resistive

index as an indication of organ blood flow velocity. This was certainly a move in the right direction, but the technology of colour Doppler sonography has yet to be widely validated as a reliable method from which to infer perfusion flow rates. Furthermore, neither paper defined the organ-associated foot reflexology map location used which makes it difficult to reproduce their methods and findings even if the technology was more robust. As discussed in chapter one, the lack of consensus in many of the published reflexology foot maps means that it remains unclear which part of the feet the researchers used to represent the 'kidney' or 'intestinal' reflex point.

This systematic analysis of the literature found that none of the reflexology researchers acknowledge the issue of reflexology foot chart inconsistency and the effect that this can have with regards to a rigorous standardisation of the intervention and reproducibility of findings. The map inconsistency is one of the most challenging aspects of reflexology research. Some published maps appear to have evolved from Traditional Chinese Medicine meridian maps, other charts derived from the personal empirical or intuitive experiences of therapists or individual schools of reflexology (104). The lack of reflexology foot map standardisation presents a serious research challenge in terms of how to tease out evidence of a specific haemodynamic effect on the internal organs quite distinct from the haemodynamic effects of conventional foot massage. To further compound the problem, the vast majority of published reflexology studies do not give details of which reflexology map the intervention is founded upon, which means that some of the studies may be, in theory, using relatively different reflexology charts on which to base the specific reflex-point intervention. If this is the case, there is a lack of consistency in active intervention approach which arguably invalidates the validity, generalisability and model validity of research findings.

The evidence also suggested that scientific study of specific effects within reflexology is further complicated by the challenge of finding a suitable control which can allow any active ingredient in the intervention to reveal itself. One of the four existing systematic review of reflexology efficacy (105) listed 10 studies (90;106-114) which used general foot massage as the experimental control. Yet in the majority of cases, the study design was not clear as to how the sham foot massage treatment can be differentiated from reflexology foot massage treatment. Six of these studies described the sham treatment as either gentle foot massage or foot massage that simply avoided pressure on the reflex areas of the foot (90;110;112-115). However generalised foot massage across the planter foot area could arguably 'contaminate' the control by stimulating individual organ points along the way. In other words, within the reflexology model, foot massage is not a passive and ineffectual form of adequate control for the special case of reflexology research. It is therefore unsuitable as a control treatment. In addition, reflexology 'dosage' appeared to differ considerably, suggesting an overall lack of intervention dose standardisation.

2.4. Conclusion

The literature review findings suggested that there was no suitable experimental protocol in existence which could be adapted to support the thesis aim. Primarily because very few studies attempted to control for non-specific effects in order to isolate any specific haemodynamic component. And most lacked a suitable form of experimental control. Furthermore none of the researchers appeared to have acknowledged or addressed the issue of the inconsistent reflexology foot maps. The review also showed that only one study had recruited participants from the cardiac patient population, but had not controlled for any specific haemodynamic effect. Which meant that the research challenge of developing a reflexology intervention that was able to compromise between the conflicting '*therapy specific*

benefit' and *'therapy specific risk'* beliefs evident in reflexology educational literature had not been addressed. The lack of recruitment from cardiac patient groups also meant that there was little data available to determine whether reflexologists were treating cardiac patients, regardless of the uncertainties about indication.

Therefore the results of the literature search verified that there was a clear need for research using a more rigorous experimental protocol and double-blind randomised controlled trial design, which could allow a specific haemodynamic effect to reveal itself. This was needed in order to provide high quality evidence for cardiac patient purchasers of reflexology to help them make a more informed decision about the safety and product quality of reflexology claims. Without the hypothesised active two-way haemodynamic connection, it could be argued that reflexology is completely indistinguishable from simple foot massage. It is this claim for a specific effect (17), manifesting as an increase in circulation to the corresponding organ (61), which this thesis set out to investigate, being one of the few empirically testable specific components that reflexology can offer. To meet this aim, it was decided to experimentally focus on one reflex point. The purpose of this was to see if reflexology massage to this particular point would specifically affect the haemodynamic status of the corresponding mapped organ. Given the reflexology product safety concerns amongst the cardiac population, it seemed appropriate to pick the heart reflex point itself in order to determine whether causal links exist between the application of reflexology massage techniques to the heart reflex point and specific beneficial changes in the haemodynamic status of the heart. On this basis, the thesis research aims and experimental questions will now be outlined.

2.5. Thesis aims

Aim 1: To develop a reflexology treatment protocol for use in the three experimental studies; consisting of healthy volunteers, patients with chronic heart failure and patients with coronary artery disease patients.

Aim 2: To conduct an internet based survey of AoR reflexologists to identify whether they are treating cardiac patients and to determine which area of the feet is being used as the heart reflex point in current reflexology practice, to help inform the development of the reflexology treatment protocol.

Aim 3: To use the reflexology treatment protocol to examine whether there are any specific haemodynamic benefits, product quality or safety issues associated with reflexology treatment to the area of the feet thought to be associated with the heart in healthy volunteers and cardiac patients, using double blind randomised controlled trials.

2.5.1. Thesis research questions

The following research question was devised in order to address research aim 1.

Q1. Can an experimental method be devised which controls for non-specific effects associated with reflexology treatment of the heart reflex point in order to isolate any specific haemodynamic effect?

The following two research questions were devised in order to address research aim 2.

Q2. What are the perceptions of UK reflexologists regarding the safety and efficacy of treating cardiac patients?

Q3. Is there a consistency in the location of the heart reflex point as identified by reflexologists?

The following four research questions were devised in order to address research aim 3.

Q4. Does reflexology applied to discreet areas of the feet thought to correspond to the heart result in specific changes in the haemodynamic parameters of healthy volunteers?

Q5. If a specific haemodynamic effect is detected, are there any risks or benefits associated with reflexology treatment to the area of the feet through to be associated with the heart in healthy volunteers?

Q6. Does the reflexology intervention developed for healthy volunteers, using a double blind randomised control trial, result in specific changes in the haemodynamic parameters of cardiac patients?

Q7. If a specific haemodynamic effect is detected, are there any risks or benefits associated with reflexology treatment to the area of the feet through to be associated with the heart in cardiac patients?

Chapter 3

Methods

Jones J, Thomson P, Lauder W, Leslie SJ. A Proposed Reductionist Solution to Address the Methodological Challenges of Inconsistent Reflexology Maps and Poor Experimental Controls in Reflexology Research: A Discussion Paper. *Journal of Alternative and Complementary Medicine*. 2012; (doi:10.1016/j.ctcp.2012.04.001)

Chapter 3

3.1. Method

Aim 1 of the thesis was to develop a reflexology treatment protocol for use in the three experimental studies; consisting of healthy volunteers, patients with chronic heart failure and patients with coronary artery disease patients.

The following research question was devised in order to address research aim 1.

Q1. Can an experimental method be devised which controls for non-specific effects associated with reflexology treatment of the heart reflex point in order to isolate any specific haemodynamic effect?

In order to satisfactorily address this research question, the protocol design had to enable the acute (immediate) haemodynamic effects of reflexology treatment applied to specific areas of the feet which are thought to correspond to the heart, to be measured. And to be compared with treatment applied to other areas which are not. The development of such a protocol would then allow research questions one to four to be successfully addressed. Therefore as the experimental aim of the thesis was to measure the haemodynamic effects of reflexology, the underlying assumption for the protocol development was that there was an objectively measurable haemodynamic component in reflexology that could be measured. This was despite the fact that there was little real contextual understanding how the effect might work. With this objective in mind, the chapter identifies the methodological framework assumptions

inherent in the research methods used to meet the thesis aim of developing a suitable protocol.

3.2 Thesis methodology

The principle of applying the best available scientific evidence to assess the safety and quality of specific treatment effects is now referred to as evidence-based medicine (EBM). In this framework, any intervention that makes claims for a specific effect should be able to demonstrate a causal relationship between the intervention and hypothesised outcome that can be attributed solely to the intervention itself. Furthermore, the intervention should be able to demonstrate intrinsic safety and therapeutic usefulness in its application (116). An assessment of risk/benefit ratio is perceived as the soundest way for uncovering knowledge about any specific treatment effects (117-119). As reflexology has many components which can contribute to the overall treatment effect, its complex nature presents particular research challenges within the evidence-based framework. Particularly in terms of distinguishing the specific effect of the intervention from any non-specific effects (120).

In complex interventions, specific effects are defined as the 'active' ingredient unique to the practice. Whereas non-specific effects are thought to have weak causal links and involve factors such as the therapeutic effect, patient expectation, placebo effect and aspects of social conditioning. These are all thought to contribute to any perceived or measured therapeutic benefits (116;121). The Medical Research Council (2008) provided an updated framework for EBM researchers planning to evaluate the effects of complex interventions, regardless of type or origin. These guidelines advised researchers to be clear about experimental outcomes, give detailed descriptions of the interventions to enable replication and to use experimental

designs if practicable (101). The Kings Fund report (2009) also acknowledged the research challenges involved in evaluating complex interventions. These included the variability in CAM skills, the interrelation between the active physical intervention and the context for the practice that makes measuring intervention-related outcomes difficult (116). From the EBM methodological perspective, the highest value is placed on the randomised controlled trial (RCT) for the detection and measurement of direct causal relationships (122). Other forms of evidence such as observation, ethnographical analysis or subjective (qualitative) interpretation are seen as less rigorous in this respect (123).

Some CAM researchers argue against the hierarchical value-based EBM research framework. They believe that the RCT appears to singularly favour the cause and effect relationship between pharmacological interventions and bio-marker outcomes (124). Also, that the perception of the casual relationship is more easily predicted in conventional medicine research. This is because there is usually a theoretical understanding of how an intervention causes change, which enables biomedical researchers to predict and identify steps in the causal links (116;125). Furthermore, that the RCT favours single instance treatment options for particular conditions (124). Moreover, that it is too limited in terms of being only able to determine whether an intervention has a statistical effect - not how that effect might work or what the participants experience in the context of the intervention (126).

Based on these factors CAM research theorists have called for consideration of alternative research approaches. These include 'whole systems', pragmatic or factorial evaluation methods for evaluating complex CAM interventions, rather than the RCT design (127;128). Within the CAM research framework, model validity requires that researchers remain sensitive to the context of the therapy. Also how it is delivered in normal practice. Researchers should

attempt to represent the practice as authentically and accurately as possible (128). From this perspective, many aspects of a therapeutic intervention are regarded as inherently culture-specific (128;129). This interpretation means that the researchers do not attempt to translate the context of the therapy into the experimental framework of the RCT study design, in order to eliminate any non-specific components, such as placebo, therapeutic or environmental effects (120). However although the whole systems framework allows for more sensitive evaluation of complex health care interventions (129), in the case of the specific claims of reflexology, there are ethical considerations that need to be addressed. Primarily because the specific value of reflexology relies predominantly on placebo or non-specific effects. The key issue here being whether researchers can provide evidence for the specific haemodynamic claims of reflexology in order to justify cost effectiveness for its purchasers over simple foot massage (130).

Therefore for this thesis, the whole systems or pragmatic concept of 'bundling' together the evaluation of multivariate components was rejected. This was because the assessment of reflexology as a whole system in a pragmatic manner would render it impossible to isolate any specific active haemodynamic effect. Whole systems research was also rejected because the key concept of this research framework allows for evaluation of a practice in its 'real world setting' in order to determine the effect of the overall package of care. Again, this 'bundles' together any inherent specific effect with other non-specific effects of the therapy which means it would be impossible to isolate any specific component (129). As the aim of the thesis concerns the experimental observation of the specific haemodynamic effects of reflexology, it was assumed that there was an objectively measurable entity that could be measured, even though the effect was not thought to be using any known biological pathways. CAM therapies are not unique in this respect. Specific causal relationships are evidenced in RCT's of conventional interventions such as drug therapies. However there is often little real contextual understanding of how the majority of pharmaceutical drugs induce effects such as

pain relief or anti-inflammatory effects, other than the empirical experience that they do (131). Therefore the research investigation of the reflexology specific effect appeared fundamentally no different than conventional medicine research, and on this basis, the RCT seemed the most appropriate research method to adopt.

3.2.1. Method

The RCT research design is an experimental design where the independent variable (such as reflexology massage applied to a reflex point) causes, or produces a measurable change in the dependant variable (e.g., an objective pre-defined biological marker). This design uses the process of randomisation to strengthen its experimental integrity. In a randomised trial, participants and experimenters are deliberately kept unaware of which subject has been randomised to receive the intervention or control in order to minimise bias (132). The process of randomisation of subjects and blinding of both subjects and experimenters ensures that groups are comparable on all factors that can influence the experimental outcome except for the effects of the intervention itself (45). As a design, it relies on concepts of causal relationships. Specifically, any change to the dependant variable must be attributed to the experimental independent variable alone, and not to any other contributing (confounding) influence (133;134). This quality made the RCT seem like the obvious choice to help realise the primary thesis aim of examining whether there were any specific haemodynamic effects associated with reflexology treatment to the area of the feet thought to be associated with the heart, as the design would help eliminate the non-specific effects of reflexology by the use of randomisation, adequate control methods and double blinding strategies.

3.3. Methodological challenges

There is presently no proven biological pathway which could explain how reflexology massage applied to distinct areas of the feet could be causally connected with a haemodynamic change. Local paracrine mediators involved in arterial dilation e.g. nitric oxide, endothelin, angiotensin (usually produced by smooth muscle and endothelial cells in the vessel wall) (135;136), could be one potential mechanism that reflexologists could appeal to. However the assumption of an active paracrine stimulating signal transmission from foot reflex point to localised arterial endothelial cells is biologically implausible. Nevertheless, as stated earlier, reflexology is not unique in this respect. For example, despite the fact that not a single piece of evidence exists to prove that neural tissue is even capable of creating a conscious thought, we accept the existence of consciousness without any proven biological pathway or mechanism (137). Therefore, regardless of the current biological implausibility of the haemodynamic claim, four key methodological research challenges had to be addressed in order to allow the hypothesised specific effect to reveal itself. First, how to overcome the issue of inconsistent reflexology foot maps (figure 3.1). Second, how to develop a simple standardised reflexology intervention that could compromise the ‘therapy-specific risk’ and ‘therapy-specific benefit’ approaches evident in contemporary reflexology? Third, how to devise a suitable form of experimental control and fourth, how to identify haemodynamic outcome measures that can be objectively measured and are relevant to the study population? In response to these distinct challenges, an experimental solution was devised which addressed both the map inconsistency problem and enabled a standardised reflexology control to be developed. It was assumed that if both of these methodological challenges were resolved, any specific haemodynamic treatment effect unique to reflexology should be able to experimentally reveal itself. The solution was to adopt a reductionist approach to the reflexology foot map design. This approach will now be explained.

3.4. Reductionist solution

The reductionist approach to the reflexology foot map design relied on the fact that despite considerable variations, all reflexology charts appear to have one consistent design condition. This is the idea that three transverse zone lines can be transposed across the foot map (138). In the reflexology model, these lines are used to further refine reflex point location by dividing up the map into three gross areas or zones called the 'shoulder girdle', 'abdominal region' and 'pelvic region' (138;139). Within this transverse map construct, the shoulder girdle area is said to represent the thoracic cavity. This area corresponds to the ball of the foot. In anatomical terms, the shoulder girdle area covers the region of the five metatarsal bones on either foot and is bounded by Lisfranc's point line. This line represents the articulation between the mid-foot and forefoot (138;139) (figure 3.2).

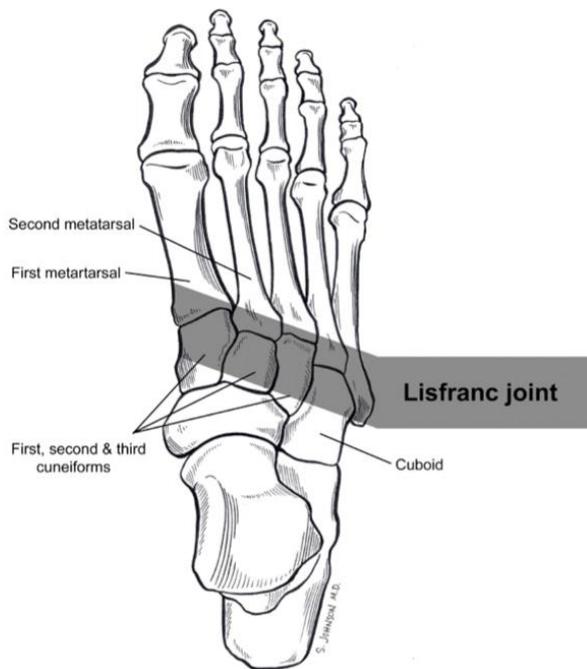


Figure 3.1 Lisfranc's joint line

This design feature proved to be highly relevant to the experimental aim of the study. Primarily because regardless of map origin, it was noted that all reflexology maps consistently place the heart reflex point somewhere within the shoulder girdle area on one or both feet. Whereas reflex points associated with organs below the thoracic cavity are consistently mapped in the abdominal or pelvic zone regions. Which means that these two lower zones contain no major organ reflex points associated with specific regulation of the heart. The gross division of the planter foot area between the shoulder girdle area and other two areas allowed a novel reductionist approach to be developed. The purpose of the reductionist approach was to isolate the general area of the heart reflex point, regardless of its unknown precise location and in doing so, address the methodological challenge of identifying the 'true' heart point region. Therefore the reductionist map approach 'reduced' the complexity of the overall map into three gross areas in order to overcome the variation problem and allowed the development of an intervention and control treatment. This novel approach will now be described.

3.4.1. The intervention

The intervention treatment involved reflexology massage (using touch techniques unique to reflexology) applied solely to the areas on both feet known as the shoulder girdle within the reflexology foot map construct. This 'reduced' area treatment served as the active 'heart point' intervention. The intervention will now be referred to as the 'forefoot'. It was reasoned that treatment to the forefoot area on either foot would, at some point, treat the heart reflex point, regardless of the fact that its precise location was unknown. Therefore if present, the 'true' heart point should reveal itself either during the left foot forefoot, or right foot forefoot treatment.

3.4.2. The control

The control treatment consisted of reflexology massage (using touch techniques unique to reflexology) applied solely to the areas on both feet known as the pelvic and abdominal areas within the reflexology foot map construct. This reduced area treatment (from now on referred to as the 'heel') served as the study control. It was reasoned that this area contained no organs specifically associated with regulation of the heart or the heart reflex point itself. By using the heel treatment as the control, an experimentally inert reflexology comparison was achieved. Which meant that non-specific effects such as the compassion of the therapist, the treatment environment, the act of lying supine, expectation of the receiver, and the relaxing effects of simple foot massage (111;140) should be equally present in both intervention and control.

The key aim of the study was not simply to compare crude foot massage applied to either half of the foot with massage applied to the other half, but to examine whether reflexology treatment applied to the forefoot area of either foot corresponded with specific measurable haemodynamic changes *across time* under the *same* condition (intervention). On this basis, if no significant change occurred in any heart-related haemodynamic variable during the intervention, this would suggest that there is no specific haemodynamic effect associated with the heart point, distinct from the effects of general foot massage, therapeutic effect or placebo. However if a specific haemodynamic effect was detected at any time during treatment to *either* forefoot area, this would indicate the existence of a region on one or both feet that corresponds with haemodynamic changes in the heart itself. The use of the heel area as the control would provide data to assess the effects of general foot massage, therapeutic effect or placebo, in order to distinguish any specific haemodynamic effect that might reveal itself in either the left or right foot forefoot area.

3.4.3. Standardised method of experimentally defining the two areas

Hypoallergenic tape was used to define and mark the demarcation line along the border of the shoulder girdle and mid transverse section at every experimental session. This was done to ensure that the treatment stayed within the boundaries of the designated forefoot (intervention) or heel (control) area (figure 3.3).



Figure 3.2. **Line of demarcation between the forefoot intervention and heel control area, marked by hypoallergenic tape**

3.4.4. Reflexology style and techniques

As one of the main aims of the thesis was to develop a reflexology protocol for use in the experimental studies, it was important to ensure that both the intervention and control treatments maintained the validity of Ingham-style reflexology in order to represent the therapy as accurately as possible. And at the same time, be standardised sufficiently to be documented, and reproducible, as required. The intervention and control also had to compromise between the 'therapy-specific risk' and 'therapy-specific benefit' approaches evident in contemporary reflexology. In order to achieve these requirements, a short review of selected texts from the 'core curriculum' reflexology literature was referenced. The purpose of this was to determine what common reflexology treatment sequences and massage techniques were commonly used. The brief review found that as with the inconsistent maps, detailed reflexology treatment sequences and massage techniques appeared to vary, dependant on author referenced.

For example, Marquardt (1983) recommends a sequence which begins with massage to the reflex zones of the head (which in her model, relates to the five toes). She then follows this with massage to the "*musculo-skeletal*" system (the medial and lateral aspects of both feet). Finally, massage to the shoulder girdle and pelvic regions, finishing with massage of the ankle and upper part of the feet (141). She does not suggest which foot should be used to start the sequence. The reflexology massage techniques are described as a "*grip sequence*", which involves the thumb(s) exerting either passive or active manual pressure as they move along the planter skin. The only other technique described is a "*sedation grip*". This is done using "*a firm hold*" with fingers and thumbs to maintain an even pressure. This technique, reminiscent of Fitzgerald's sustained pressure theory, is used to treat acute pain, therefore is regarded as a "first aid" technique by Marquardt (142). Dougans (1996) recommended treatment sequence also begins with the 'head' and 'neck' areas found on the toes. Her sequence then moves to the "*arch of the foot*", which in her model can be seen to relate to the

'abdominal region' transverse zone. She then recommends treating the pelvic girdle region. And like Marquardt, she completes the sequence with treatment to the ankle and upper part of the feet. However Dougans approach uniquely treats the same area on each foot as the sequence progresses. In other words, if the toes and shoulder girdle are treated on the right foot, she believes they should then be treated on the left foot before the practitioner moves on to the next transverse zone area. Furthermore, she suggests that treatments always start with the right foot. Dougans offers descriptions of a number of moving massage techniques. A rotating thumb movement is used to apply pressure on reflex areas. Fingers are used to rub, massage or pinch the plantar skin. The finger knuckles are used to knead the plantar flesh (143). Hall (1992) acknowledges that various forms of treatment structure exist and that different training schools teach different versions. She does not see this as a problem and believes the end results will still be beneficial regardless. She does not outline a treatment sequence or a particular foot to start the sequence. However like Dougans and Marquardt, she advises using the thumb to apply moving pressure to reflex point areas. She also incorporates finger techniques for massage and finger knuckles for kneading (144).

Kunz and Kunz (2005) appear inconsistent in their sequence recommendations. In their publication "Reflexology: Health at your fingertips" (145), they advise practitioners to begin the treatment on the right foot. However in "The complete guide to foot reflexology" (146) they contradict this by stating that treatment can start with either foot, as it is a "*matter of personal preference*" (147). In common with the other authors, they advise starting the treatment sequence with the toes. Their recommended sequence then moves to the 'shoulder girdle' region and the 'abdominal region' transverse zone area. They then move to the 'pelvic region', ankle region and finish with treatment to the top of the feet. The principle massage technique is described as "thumb walking". This is said to be the application of constant steady pressure to the surface of the foot, whilst the thumb moves along the foot

skin surface as pressure is applied, then released. The authors advise using the fingers to achieve the same effect. The thumb is also used to work individual reflex point areas. This technique for treating reflex points appears similar to Inghams original technique of applying pressure on a point using the thumb, which is then pulled back to create moving pressure (148).

Regardless of the apparent inconsistencies in strategies and techniques of these four authors, one consistent theme emerged. This was the general treatment sequence. The common reflexology treatment sequence to all authors started with the toes, then went to the 'shoulder girdle' region, then the 'abdominal' region and concluded with the 'pelvic' girdle zone and ankle. Therefore this general flow of treatment acted as the guide for the intervention and control sequence. Essentially, it was decided to simply use the first 50% of the typical treatment sequence as the intervention (in effect, treatment to the toes and shoulder girdle zone). Then use the remaining 50% of the treatment sequence to the abdominal, pelvic and ankle region as the control. In order to ensure that the reflexology treatment protocol developed for use in the three experimental studies retained sufficient model validity, Tracey Smith, Research Support Manager from the Association of Reflexologists (AoR), flew up to Inverness to oversee the reflexology treatment standardisation. She collaborated with the two reflexologists recruited for the study. Both therapists were recruited from the AoR list of registered members for the study and trained at the International Institute of Reflexology (IIS). Therefore both used standard Ingham touch techniques throughout the intervention and control. Although the reductionist foot map and shortened treatment sequences were not typical of reflexology treatments, the involvement of the reflexologists in the shortened treatments design and the therapists use of standard Ingham techniques ensured that the intervention and control treatments could still be distinguished as being reflexology, rather than simple foot massage.

The intervention and control sequences were carefully documented to aid standardisation and replication (table 3.1). There did not appear to be an internationally agreed or defined reflexology 'dosing' method to guide duration of treatment or depth of applied massage pressure. Therefore both treatments compromised between the '*therapy specific risk*' belief and '*therapy specific benefit*' beliefs by being timed to last just under 5 minutes. This was so that the intervention did not over, or under treat the heart reflex point at any time. Although cautious, based on previous research, it was thought that 5 minutes would be sufficient to allow a specific haemodynamic effect to reveal itself. Sudemier et al (1999), reported significant changes in renal blood flow during organ associated foot reflexology in a double blind RCT using a pre / intra / post-test comparison ($p < 0.001$). The reflexology massage to the kidney reflex point lasted for 8 minutes; however the intra-test measurement was taken 2 minutes into the treatment, which suggests that the effect appeared within the first 2 minutes. Furthermore, Mur et al (2001) found a significant reduction in resistive index in the superior mesenteric artery during the first four minutes of reflexology massage applied to the 'intestinal' reflex point ($p = 0.021$). On this basis, it was assumed that a five minute treatment period should be sufficient to allow a significant effect to be detected if the selected haemodynamic parameters, if present. Both therapists attempted to standardise massage depth by restricting treatment pressure (light to medium) and by modifying depth of touch techniques (shallow). The therapists practised for several hours on the researcher, each therapist treating one foot simultaneously, until the pressure and depth on both feet felt equal and standardised. No existing reflexology research has considered standardising depth of touch but as one of the thesis questions asked whether an experimental method could be devised which controls for non-specific effects associated with reflexology, it was felt important to standardise as many factors involved in the intervention and control treatment as possible. In summary, the key difference between the intervention and control is that they

were applied to two different areas of the feet. On this basis, the standardisation of both treatments ensured adequate comparisons could be made between the two treatment conditions. The AoR Research Support Manager and the two IIR trained therapists believed the reductionist map approach and reductionist treatment sequence continued to authentically represent reflexology, rather than foot massage, even though the experimental requirements forced a degree of treatment length compromise.

Table 3.1. **Reflexology Treatment Protocol using Ingham style touch techniques** (An explanation of these terms is given in the thesis glossary)

FOREFOOT (Intervention) Right Foot	HEEL (Control) Left & Right Foot
<ol style="list-style-type: none"> 1. Greet the feet by cupping around forefoot 2. Right foot, dorsal and plantar massage/relaxation 3. Big toe thumb walk up 5 zones medial to lateral 5 x 1 4. Thumb crawl neck medial to lateral 5 x 3 5. Finger roll the brain reflex x 3 6. Pituitary hold 7. Shoulder reflex finger roll and walking x 3 8. Lung reflex thumb crawl 4 x 3 9. Thyroid roll and finger walk x 3 10. Trachea/Chest 2 rows x 3 11. Plantar/dorsal massage 12. Plantar/dorsal kneading 13. Toe feathering 	<ol style="list-style-type: none"> 1. Greet the feet by cupping under heels 2. Cat tail pulls 3. Finger walk up chronic sciatic/reproductive reflexes x 3. Slide back down 4. Finger walk pelvic/hip area, uterus, ovaries etc. medial aspect 4 rows x 3 5. Medial pelvic/hip area walking from underside 4 strips x 3 6. Thumb walk plantar heel medial to lateral 4 x 3 7. Lateral pelvic/hip area walking from underside 4 rows x 3 8. Thumb walk plantar heel lateral to medial 4 x 3 9. Knuckle massage upwards around the ankle bones x 3 10. Heel Kneading 11. Hold and release
FOREFOOT (Intervention) Left Foot	
<p>LEFT FOOT</p> <p>Left foot: (identical to the right foot Treatment with the addition of) -</p> <ol style="list-style-type: none"> 1. Lateral to medial thumb walk the chest area 3 rows x 3 2. Heart reflex - press and hold 3. Plantar/dorsal massage 4. Plantar/dorsal kneading <p>Toe feathering</p>	

The development of a reductionist reflexology foot map helped to overcome the problem of experimental reproducibility in the face of inconsistent point location, and provide an inert control which for the first time, could allow a specific treatment-related two-way haemodynamic effect between reflex points in either half of the foot and their associated haemodynamically measurable organs to experimentally reveal itself. Now that valid and appropriate intervention and control treatment strategies had been established, the next step was to identify the populations of interest.

3.5. Population characteristics

In order to address the research aim to examine whether there are any specific haemodynamic benefits, product quality or safety issues associated with reflexology treatment to the area of the feet thought to be associated with the heart, it was decided from the start to recruit study participants from the cardiac patient population for the experiment. As coronary artery disease (CAD) is most common cause of death in the western world (149;150) and cardiovascular disease will affect the majority of the Scottish population at some point in their lives (151), this patient population was considered to be the most relevant to the investigation. However, as the number of people with CAD who go on to develop heart failure continues to increase (152) and more than 900,000 people are already thought to have chronic heart failure (CHF) in the UK (153), it was decided to recruit for a second separate experiment from this distinct population also. However as little was known about the magnitude of the effects of impact of reflexology on cardiovascular parameters, there was insufficient data to predict the smallest detectable or safe treatment effect or size in these two populations when designing the study. Therefore the thesis experiments started with a pilot study using healthy volunteers before moving on to the CAD and CHF phases. This was done for the following

reasons. First, it was assumed that a pilot study would enable the standard deviation of the size of the intervention treatment effect to be calculated based on actual results rather than assumption. This would provide the data necessary to inform the power calculation for the two cardiac patient phases of the study and to provide treatment related healthy volunteer standard deviation data for other reflexology studies. Second, running a pilot study would enable a 'stress'-test to be carried out of the actual study design and all protocols using the least vulnerable volunteer group. This would allow any design gaps or problems to be revealed before the cardiac patient studies took place. Furthermore, a refinement of criteria for the cardiac patient studies could be carried out if necessary with no wastage of further healthy volunteer or future cardiac patient data. Third, a pilot study would allow a proper risk assessment of the treatment effect to take place using healthy volunteers. Although it was thought to be harder to detect any potential treatment effect in a group of healthy volunteers with a wider range of age (the healthy volunteer males ranged from ≥ 18 years but it was not anticipated to recruit any males cardiac patient younger than ≥ 50 years of age, giving a more homogenous cardiac patient group), if a treatment effect was detected that was sufficiently powerful enough to reveal itself even amongst the background age variation of a healthy sample group wider age-range variation, it would enable a safer and more accurate risk assessment to take place for the cardiac patient studies.

3.6. Study design

All three studies (healthy volunteers, CHF patients and CAD patients) used a randomised controlled double blind repeated measures design – effectively one group of subjects, observed over a continual time period under two conditions (intervention and control), with a restabilisation period of at least 48 hours between first and second treatment. Using a repeated measures design meant that each recruited volunteer received both the active and

control reflexology treatments in either random order, with a restabilisation or washout period in-between. Therefore the study participants acted as their own control, which allowed within-subject comparisons of treatment differences with potentially less variability. This design also meant that fewer subjects were required to detect a treatment difference (154). The main limitations with this type of research design were taken into account and addressed wherever possible. The inconvenience to subjects in a repeated measures trial was not estimated to be too significant, as subjects were only asked to attend twice and all lived within 25 miles of the hospital location where the study took place. Subjects were also re-imbursed for all transport costs. With regards to the cardiac patients, they all had stable chronic disease symptoms which meant that they were stable and therefore it was less likely that there would be major haemodynamic changes between the two visits. Furthermore, as the subjects were randomised to receive either the control or intervention treatment at either visit, and to have at least a 48 hour 'washout' period, it was not anticipated that any lingering or 'carryover' effect from the shortened experimental reflexology treatment would continue into the second visit. Overall, it was assumed that the reflexology intervention and control treatments would both have a short-lived effect and as all the subjects were reflexology naive, and as the recruitment letters and posters did not reveal the true intent of the experimental aim, this design would fit the aim of the experiment (154).

3.6.1 Randomisation

The equal group random allocation was performed by a third party not involved with the study, using computer generated random numbers. Subjects were randomly allocated to either receive the intervention treatment at the first visit, followed by the control treatment at the second visit, or to receive the treatment schedule in the opposite way round. The allocation list was handed directly to the two reflexology therapists in sealed opaque

envelopes. The researcher did not have access to the allocation list until data analysis was complete.

3.6.2. Blinding

The study was double-blinded. None of the study volunteers knew in which order the intervention or control treatment was delivered, only the reflexologists were aware. The reflexologists worked behind a screen when delivering the reflexology so the researcher was not aware of the treatment order for each subject (figures 3.4 / 3.5). The researcher audibly monitored all treatment sessions from behind the screen to ensure that there is no undue influence in the form of verbal variation or cueing by the reflexologist which could unmask the blinding allocation and allow bias. The reflexologists restricted all conversation during the session and no talking took place during the session treatment periods. It was not intended to assess the degree to which the blinding was maintained after the study was complete as the volunteers received reflexology treatments for both the active and control intervention.



Figure 3.3. The therapists working area was screened from view at all times



Figure 3.4. One of the study reflexologists working behind a screen during a treatment session

3.7. Outcome measures

3.7.1. Haemodynamic variables

A number of relevant objective haemodynamic and subjective experiential outcomes were considered. As the thesis aim was to detect and measure a specific haemodynamic effect related to reflexology treatment applied to the area on the reflexology foot map thought to be associated with the heart, the most obvious measurable haemodynamic components related to the study aim was the blood supply and performance of the heart itself. The method of measurement had to be able to detect any haemodynamic effects related to changes in the heart or coronary circulation, even though these might be very subtle and transient in nature. Furthermore, the method had to be ethically appropriate by minimising risk to the participants. The most ethical form of measurement being a non-invasive form of measurement that could be operated within the clinical skills limitations of the researcher's general nursing background. Within these clinical limitations, it was also clear that the experimental haemodynamic outcomes had to be measured on a frequent intra-treatment basis throughout the intervention and control treatment sessions, rather than simply pre and post-test, so as not to miss a transient effect. And although non-invasive, the methods of measurement had to overcome the challenge of detecting subtle transient haemodynamic cardiac changes, even though the heart is buried deep inside the thoracic cavity.

Although it seemed the most obvious component to measure in the experiment, localised coronary circulation is particularly difficult to evaluate either globally or regionally, as the coronary circulation has two inflows and multiple outflows. Absolute coronary artery blood flow is clinically assessed using one of two invasive methods, depending on diagnostic aim. The first method is coronary angiography, which is used to locate stenosed or occluded

sections of the arteries. The second is coronary thermodilution method, which measures coronary flow reserve (the change in blood flow in coronary arteries above the normal resting volume). This procedure is often used to determine the efficacy of treatments such as vasodilators (155). Although thermodilution would have been ideal to measure changes in coronary artery blood flow reserve under the different conditions of the reflexology intervention and control in the experiment, this method is invasive and requires a high degree of cardiovascular surgical skill to administer, which rendered it both ethically and technically unsuitable as an experimental method for this thesis. There is currently no non-invasive method of measuring coronary artery blood flow. However derived measurements of global cardiac haemodynamic performance, such as cardiac output, stroke volume, pulsatile pressure and autonomic nervous system innervation of the heart, determined as relative derived values, could be measured using more basic, non-invasive methods (156). Therefore although not offering absolute localised data on individual coronary artery perfusion rates, indirect methods of using globally derived measurements which offered an ethically acceptable and technically achievable means of detecting transient specific haemodynamic effects were assessed for suitability.

Heart rate: The most basic method of assessing heart rate and rhythm is through the palpation of the peripheral radial pulse at the wrist. This method detects the expansion of the artery as systolic pressure rises. Pulse rate can be affected by neurological influence, (sympathetic or parasympathetic innervations), chemical influence in the form of hormones (thyroxine, adrenaline) and electrolytes (calcium, sodium and potassium) or physical factors such as age, sex and physical exercise (157). The palpation of the pulse is also a simple way of determining cardiac stroke volume, although as the pulse is determined by the difference between systolic and diastolic pressures, these could both be very high or very low and give you the same 'pulse' (158).

Brachial blood pressure: The measurement of arterial blood pressure in the brachial artery in the arm can be measured by manual sphygmomanometer. Vessel length, vessel diameter and blood viscosity affect the flow of blood moving from the heart through the body and although viscosity is typically fairly constant, vessel diameter changes frequently in response to neurohormonal mechanisms (158). However although blood pressure measurement is a cheap and effective means of assessing changes in force of pressure exerted by the circulating blood flow against the walls of the arterial vessels (159) the basic manual sphygmomanometer approach was thought inappropriate. This was because operation of this approach would involve a standard bladder cuff being manually inflated at regular intervals. This would need to be done in order to restrict blood flow sufficiently to allow the attached manometer to measure both the arterial pressure responses and the peripheral pulse. Therefore the manual method was thought to be too operator intensive and lacking in any beat-to-beat data generating capabilities.

Doppler method: Haemodynamic monitoring can also be done by pulsed Doppler method (echocardiography), which measures the left ventricular stroke volume. Although this method has an advantage in that it is non-invasive, the ultrasound beam needs to be as parallel to the blood flow as possible, which means it requires specialised training and is operator intensive (160). On this basis, it too was deemed unsuitable as a measuring tool.

Pulse wave analysis: Arterial compliance, which is a measure of arterial stiffness, can be measured non-invasively by transcutaneous recording of the radial artery pressure waveform. Data is obtained by using a Tonometer transducer placed on the skin surface at the point of the radial artery pulse (161). The advantage of this system is that it is non-invasive, however data recording and quality is highly operator dependent. On consideration, this method did not

offer the beat-to-beat data capabilities or operator independence as required because in order to gain enough data to estimate arterial compliance, the radial pulse waveform needed to be recorded for a set interval before a calculation of the central aortic pressure waveform was possible.

The Electrocardiogram (ECG): The ECG measures the transthoracic interpretation of the electrical activity on the heart on a beat-to-beat basis. Deviations from the standard waveform can be used to diagnose ischaemic heart damage. Furthermore, analysis of the data can allow assessment of the effects of devices such as pacemakers or interventions such as drugs that regulate the hearts performance (162). For this reason, ECG recording seemed highly appropriate to the study aim as it offered the possibility of allowing any transient effect on the haemodynamic status of the heart to reveal itself.

Impedance cardiography (ICG): As an adjunct to ECG technologies, ICG appeared to offer the additional non-invasive global cardiac performance capabilities that the study required. The electrical conductivity of blood means that the electrical impedance of the thorax fluctuates with each cardiac oscillating cycle. From this, a wide range of haemodynamic data related to the heart can be estimated or inferred from the impedance variation (163). The clear benefit of this technology is that like ECG technology, it is non-invasive. The limitation of ICG rests on the fact that measurements are derived from impedance data so are not absolute values. However for the purposes of the study, it's non-invasive nature and large number of derived haemodynamic data about the heart made it the obvious choice for the experiment.

The cardiorespiratory department of the Raigmore hospital offered the use of their Task Force® Monitoring (TF®M) impedance cardiography unit for the study. This equipment had been in use in the Raigmore Cardio-respiratory department for some years and is one of their regular diagnostic tools in use with patients who attend the department for syncope tilt table testing. The researcher completed a one-day Task Force® Monitor (TF®M) operator training course held at the cardiovascular unit, Cross Hospital, Edinburgh, Scotland. This was important to ensure that the equipment was used correctly according to the manufacturer's instructions. The course was designed and delivered by the APC Cardiovascular Ltd in-house clinical specialist. APC Cardiovascular Ltd supplied and maintain the Task Force® Monitor (TF®M) unit at Raigmore hospital.



Figure 3.5. **The Task Force® Monitor (TF®M)**

The TF[®]M is a haemodynamic monitor which provides continuous measurement and automated analysis of several derived parameters. These include blood pressure, stroke volume (SV), stroke index (SI), cardiac output (CO), cardiac index (CI) and total peripheral resistance (TPR). The TF[®]M software calculates blood pressure measurement with automatic correction to oscillometric blood pressure (absolute values) for every heartbeat. This is achieved using the vascular unloading technique, which is explained shortly. It also non-invasively evaluates beat-to-beat stroke volume, cardiac output and total peripheral resistance using derived values from impedance cardiography (164). The TF[®]M also analyses real-time sympathetic and parasympathetic tone, derived from heart rate variability (164). The haemodynamic components measured by this equipment appeared highly relevant to the study purpose as recording of this data on a beat-to-beat basis fitted with the experimental aim, which was to detect any transient and potentially subtle effect on the haemodynamic status of the heart, therefore the TF[®]M was used to measure the physiological outcomes for the experiment. The haemodynamic parameters associated with each category of the TF[®]M technology will now be briefly described in more detail.

3.7.2. ECG - Electrocardiography

Heart rate and autonomic nervous system monitoring using ECG derived heart rate variability

The TF[®]M ECG is used to measure heart rate (beats per minute), PQRST complex waveform and heart rate variability (HRV). The TF[®]M ECG conducts using the bipolar principals of EINTHOVEN, with two channels included, EINTHOVEN I and EINTHOVEN II and samples at a frequency of 1000Hz. It meets the EN 60601-1 standards. The EN 60601-1 international standards relate to medical electrical equipment (165). The TF[®]M has an internal calibration generator which calibrates the ECG before every single measurement automatically (166).

ECG derived Heart rate variability (HRV) is the measurement of the subtle changes in heart rate that occur in the variation between the heart's 'beat-to-beat' intervals. This component was ideal for the experimental purpose of monitoring potentially transient changes as the regulation of heart rate is a dynamic process of changing innervation by the autonomic nervous system (ANS). Emerging research into autonomic system dysfunction has found that reduced parasympathetic influence is a powerful and independent predictor of progressive heart failure mortality (167-169). For example, without the 'calming' influence of the parasympathetic system, there is reduced beat-to-beat rate variation and an increase in heart rate (167-170). Analysis of HRV data can reveal autonomic system dysfunction, marked by a reduction in the instances of higher parasympathetic frequencies or increase in lower sympathetic frequencies found within the total frequency domain of the HRV data. By the mathematical analysis of variation data, the changes in speed and their assigned frequencies are plotted on a frequency scale and this allows very low frequency (VLF), low frequency (LF) and high frequency (HF) components to be identified. In HRV, sympathetic tone is represented by the LF band of 0.04 – 0.15 Hz and vagal tone is represented by the HF band (HF band 0.15 – 0.4 Hz) (169).

Changes in heart rate variability are controlled by the autonomic nervous system and occur within the scope of a few thousandths of a second, which means that the ECG hardware has to provide a very fast sampling rate in order to measure the small differences accurately. A minimum sampling rate for precision of measurement of R-R interval of 1000 times per second is the basis of accurate HRV analysis (170). The TF[®]M performs a power spectra analysis of HRV and blood pressure variability in order to estimate the changes in sympathetic and parasympathetic tone over a given period of time at a frequency rate of 1000Mhz times per second (166). HRV can be obtained from ECG recordings over shorter or longer periods. Although 24 hour ambulatory ECG recordings give clinical useful information of ANS activity

over a longer period, the required recorded data editing corrections for ectopic beats, arrhythmic events, signal loss, noise effects and baseline drift (often inherent in 24 hour ambulatory ECG recordings) can alter the power spectral density of HRV (167;171). The European Society of Cardiology and the North American Society of Pacing and Electrophysiology guidelines suggest that short-term recordings of two to five minutes allow the LF and HF components to be adequately identified (171) and research has demonstrated that continuous five minute collection of HRV frequency domain data allowed the power spectral densities of both HF (sympathetic ANS cardiovascular influence) and LF (parasympathetic ANS cardiovascular influence) and low to high ratio frequency components (LF-HF) to be identified during the five minute intervention time period (172). For this reason, HRV frequency domain recording seemed highly appropriate to the study aim as it offered the possibility of allowing any transient ANS effect on heart rate to reveal itself.

3.7.3. Continuous and oscillometric blood pressure

Continuous blood pressure using vascular unloading technique: The vascular unloading monitor (continuous blood pressure finger cuff device) has a measurement range of 50mmHg to 250mmHg, with detectable heart rate up to 150 beats per minute. The absolute values recorded are automatically calibrated against the oscillometric device with an accuracy of +/- 5mmHG (166). As blood pressure in the circulatory system is primarily due to the pumping action of the heart against the resistance presented by the blood vessels, continuous systolic, diastolic and mean arterial blood pressure seemed an ideal component to measure on a beat-to-beat basis as an indicator of changing cardiac haemodynamic status. The TF[®]M does continuous measurement of blood pressure by the use of the finger cuff method. The finger cuff method measures continual blood pressure on a small artery of the finger, using the vascular unloading approach. This technique uses an occluding cuff attached to the finger,

which has a photoelectric plethysmograph consisting of light-emitting diodes and phototransistors, used to detect the volume changes in the artery (158). This method of using a continuous calibration of finger blood pressure against brachial blood pressure values recorded in a larger artery has been validated against intra-arterial recordings of BP and shown to be a reliable method of accurately recording BP on a beat-to-beat basis (173). The TF[®]M oscillatory blood pressure recording method has been validated against two international standards. First, the American national standard for electronic or automated sphygmomanometers (ANSI AAMI SP10-1992) and second, the Quality Requirements of the German Hypertension League (164). It has a measuring accuracy of +/- 5mmHg and a measuring range of 50mmHg to 250mmHg. The measuring interval can be adjusted individually through the software interface, with the shortest interval of one minute possible (166). For the experiment, the interval was set at 5 minutes, in order to allow one oscillatory measurement to be taken per data block for regular calibration.

Baroreceptor reflex sensitivity (BRS): The TF[®]M measures baroreceptor reflex sensitivity by analysing beat-to-beat rising sequences (rising systolic blood pressure and extended R – R HR intervals) and falling sequences (decreasing systolic blood pressure and extended R – R intervals). The slope of the linear regression line between these two components indicates the strength of the baroreceptor reflex or sensitivity (174). This method of non-invasive baroreceptor reflex sensitivity measurement has been shown to correlate well with the invasive method of intra-arterial blood pressure monitoring (175).

3.7.4. ICG – Impedance cardiography

Stroke volume (SV), cardiac output (CO) and total peripheral resistance (TPR) using impedance cardiography

This technology was used because it offered effective means of monitoring haemodynamic parameters such as cardiac output and stroke volume. A meta-analysis of studies using non-invasive technique of thoracic bioimpedance found a good correlation of impedance and other reference techniques such as thermodilution ($r=0.82$), radionuclear angiography ($r=0.65$) and the Fick technique ($r = 0.80$), supporting its use in measuring trends in cardiac output (176). Less accuracy has been found in patients with pulmonary oedema and on mechanical ventilation in intensive care units (176;177), however all the volunteers in this study were in sinus rhythm and were stable on treatment. And although absolute values appear to be underestimated when derived using thoracic bioimpedance compared to absolute values obtained from thermodilution (177), as this study aimed to identify haemodynamic changes over a period of time, this technique seemed to offer the most appropriate ethical means of detecting changing haemodynamic trends in volunteers (178).

The TF[®]M short band impedance cardiography electrodes use a unique signal processing tool to eliminate the electrical influence of breathing (164). The electrodes have been compared against other intra-arterial invasive measurements such as thermodilution, in the detection of cardiac output in patients with heart failure. The findings suggest that the TF[®]M impedance measurements correlate well with intra-arterial invasive techniques, particularly when detecting changes in CO levels after pharmacological intervention (164;179). Transthoracic ICG has also been demonstrated to be an effective method of measuring SV and SI in CAD and CHF patients (164). The TF[®]M ICG allowed continuous measurement of SV, CO, TRP and BRS, highly relevant haemodynamic components for beat-to-beat monitoring in the experiment as they are all physiological mechanisms directly involved in the control of the blood volume and blood output of the heart itself. The TF[®]M short band impedance cardiography electrodes on the skin pass a small current through the thorax from the chest and neck leads, to measure cyclically changing electrical impedance in the thorax cavity through the cardiac oscillating

cycle. From this, stroke volume, cardiac output, total peripheral resistance and baroreceptor reflex sensitivity data is estimated or inferred from cyclical impedance variations using the following formulae (174):

Stroke volume / stroke index: Stroke Index [ml/m²] is indexed to the Body Surface Area (BSA) of the patient by the TF®M. The BSA is calculated by the TF®M from the input of the patients height and weight data. SV and SI are then calculated using the following formula:

$$SI = \frac{SV}{BSA}$$

Cardiac output / Cardiac index: Cardiac Index [l/(min*m²)] is the TF®M measurement of cardiac output, indexed to the BSA of a patient and is therefore a cardio-dynamic measure based on cardiac output. Cardiac output can be indexed to a patient's body size by dividing by the body surface area (called the BSA) to yield the cardiac index.

$$CO = SV \times HR \text{ (Heart rate)}$$

$$CI = \frac{CO}{BSA}$$

Total peripheral resistance / total peripheral resistance index: Total peripheral resistance is measured by the TF®M as [dyn*sec/cm⁵]. Total peripheral resistance index is indexed to the BSA of the patient.

$$TPR = \frac{(*MABP - CVP) .80}{CO} \quad (*\text{Mean arterial blood pressure})$$

$$TPRI = \frac{(*MABP - CVP) .80}{CI}$$

3.7.5. Baseline haemodynamic stabilisation period

Impedance cardiography methodological guidelines vary in recommend stabilisation periods between times of electrode attachment to beginning of data collection, from 0 minutes (start recording data as soon as clear signals produced), to 10 minutes prior to data collection (180;181). Pre-reflexology treatment stabilisation in the Mur et al (2001) and Sudemier et al (1999) studies consisted of the subjects laying supine for a period of 10- minutes prior to the reflexology treatment. It was decided to err on the side of caution in the present study, and allow a 20 minute pre-stabilisation period before data recording began. Therefore, after all the measuring equipment was attached to subjects and the headphones put in place and the lights dimmed, the subjects would be left to lie in a supine position for 20 minutes before the actual baseline haemodynamic data recording began.

3.7.6. Summary of haemodynamic outcomes chosen

The following outcomes were measured and recorded in the experiment:

Haemodynamic parameter	Abbreviation	Method of measurement
Heart rate	HR	Task Force Monitor (TF [®] M) impedance cardiography system
Diastolic blood pressure	dBp	TTF [®] M impedance cardiography system
Systolic blood pressure	sBP	TTF [®] M impedance cardiography system
Mean arterial blood pressure	mBP	TTF [®] M impedance cardiography system
Stroke index	SI	TTF [®] M impedance cardiography system
Stroke volume	SV	TTF [®] M impedance cardiography system
Cardiac output	CO	TTF [®] M impedance cardiography system
Cardiac index	CI	TTF [®] M impedance cardiography system
Total peripheral resistance	TPR	TTF [®] M impedance cardiography system
Baroreceptor up events	BarUpEv	TTF [®] M impedance cardiography system
Baroreceptor down events	BarDwEv	TTF [®] M impedance cardiography system
Low-frequency component of heart rate variability	LF-RRI	TF [®] M 2 channel electrocardiogram function (ECG)
High-frequency component of heart rate variability	HF-RRI	TF [®] M 2 channel electrocardiogram function (ECG)

3.8. Subjective outcomes

In order to develop an experimental method which controls for non-specific effects associated with reflexology treatment of the heart reflex point in order to isolate any specific haemodynamic effect, the standardisation of the intervention and control reflexology treatments was assessed using two subjective analysis measurement tools. These tools

measured the perceptions of how relaxing or painful each treatment was in order to ensure that the study subjects did not perceive either treatment as being inherently 'more relaxing' or 'more painful' than the other. These two potentially confounding factors were important to address as either could spuriously affect the haemodynamic outcome data. In effect, if either the control or intervention treatment was consistently experienced as being more relaxing or more painful than the other, then the haemodynamic effects could be misinterpreted as evidence of a specific effect relating to the reflexology haemodynamic effect claim, as opposed to a non-specific effects related to the experience of receiving general foot massage.

3.8.1. Measurement of transient state anxiety

In order to assess whether the relaxation states induced by the intervention and control treatments were equal, the subjects were asked to complete pre & post-test State Anxiety Inventories (SAI) at each session. The SAI is a self-report scale consisting of 20 statements that has been extensively validated to be a sensitive psychometric indicator of changes in transitory anxiety or tension states (182;183). The inventory measures how people feel at a particular time and has been used in medical, surgical and psychometric situations across a variety of cultural and clinical practice procedures to assess how people feel "right now" (184). The SAI is designed to be self-administered, with no time limit for completion. Approximately 50% of the questions are designed to inquire about negative characteristics, such as feeling upset or tense, and the other half of the questions inquire about more positive characteristics, such as feeling content or relaxed. Scores are weighted from 1 – 4 for all questions, a higher overall score indicating greater anxiety and a lower score suggesting a more relaxed state (183;185). It was hoped that by comparing the pre and post-test scores for both the intervention and control treatments, it could be demonstrated that both treatments were equally as relaxing as one another, meaning that the non-specific effects related to the foot massage relaxation

component would not be mis-interpreted as evidence of a specific reflexology effect in either condition. The SAI has previously been successfully used to record transient state anxiety in reflexology studies (93) and amongst cardiac patients (186).

3.8.2. Measurement of transient pain discomfort

As well as the relaxation standardisation assessment tool, a visual analogue scale (VAS) tool was used post-treatment to measure the peak physical massage pressure pain experienced during the reflexology massage, in order to determine whether the levels of pressure-related pain inherent in both treatments was equal. The VAS used was a 10 cm standard line, labelled “no pain” at one end and “worst pain experienced” at the other (appendix 6). Subjects were requested to mark the line with a vertical mark at the point which indicated the most intense pain or discomfort experienced during the actual treatment itself, at the end of the treatment session. Subjects were informed that the discomfort or pain related to the reflexology treatment only, not to any perceived discomfort related to lying supine or any other aspects of the experimental environment or procedures. This simple visual method of assessing subjective discomfort and pain assessment has compared well to verbal rating assessment of perceived pain and discomfort, so appeared to offer a reliable form of pain-state measurement tool suitable for the experimental purpose of measuring perceived transient treatment-related discomfort (187;188). VAS tools have previously been successfully used in cardiac patients to measure pain and other subject transient measures (189;190).

3.9. Potential risks and safeguards for subjects

3.9.1. Inconvenience

In order to minimise participant inconvenience, the researcher aimed to schedule the sessions at convenient times for the subjects. Participants were asked to confirm their attendance beforehand by confirming preferred times & dates to suit them, however for circadian haemodynamic uniformity, they were asked to attend at the same time on both days in the study information letter. This was done as evidence suggests that heart rate, blood pressure and ECG indices demonstrate circadian rhythms (191).

3.9.2. Potential cardiovascular risk of treatment intervention

As the study took place in a hospital and cardiac measurements were taken before during and after the procedure, it was anticipated that should any related or unrelated cardiac event occur as a result of the intervention or simply concurrent with the intervention, the lead researcher would be able to make an immediate nursing assessment of care requirements and call for immediate assistance according to hospital protocols.

3.9.3. Consent and other ethical issues

The researcher is a trained nurse and therefore experienced in gaining verbal, implied and written consent for various interventions and processes from patients. The study subjects did not have any standard procedure withheld as a result of voluntary participation in this study as reflexology treatment is not currently provided by the NHS or other public bodies as a part of routine clinical or commercially available free care. The risks of reflexology for both the healthy volunteer and subsequently for the cardiovascular patient were thought to be minimal and as the potential effects of the intervention were not thought to be dangerous nor cause large changes in haemodynamic parameters, it was not anticipated that the study subject

would be at any undue risk over and above that of visiting a reflexology therapist in the context of private practice.

3.9.4. The volunteer subjects relationship with healthcare professionals

The researcher was professionally uninvolved with any of the participants outside the research program. It was made clear in the patient information sheet (appendix 1) that there were no obligations to volunteer for the study and that any decline to participate would not affect any existing or future potential relationship they may enter into with Stirling University, NHS Highland, NHS Highland Heartbeat Centre or future treatment options. The participants were informed in the information letters that they were free to leave the study at any time.

3.9.5. Potential acute emotional response to treatment intervention

Although there are many subtle factors involved in the therapist-client/nurse-patient/doctor-patient relationship, it was assumed that for the purposes of this study, the participants awareness that the treatment was a part of a research project would enable the participants to understand that on a practical level, the session was slightly altered from a conventional therapeutic exchange which would more freely allow for emotional expression (192). However provision was made for the participants to be referred following the treatment to other healthcare professionals for support if they so request.

3.9.6. Potential Benefits

It was hoped that volunteers benefited from participation because they all received a relaxing foot massage as a part of the therapeutic intervention. Research already supports the benefits

of relaxing massage (7;10), so it was anticipated that all participants benefited to some degree by virtue of receiving a physical therapy intervention (8). However as this study was a RCT and reflexology effects were not known then this could not be guaranteed. Also, it was hoped that the results would inform future research.

3.9.7. Confidentiality and anonymity

Each volunteer study subject was assigned a Participant Identification Number at the start of the trial. In line with the 'Caldicott Principles' (193) which provide an ethical framework for use of identifiable study data within the framework of the Data Protection Act 1998, the researcher ensured that confidentiality was maintained at all times. The use of data was justified in terms of the existing research gap. Access to the data was on a strict need-to-know basis and the researcher and academic supervisors were aware of the responsibility of storing such personal data and the relevant legislation that applied to the storage. A record was kept of participants names and their corresponding code list was kept separate from the data in a password protected document on a University computer. Only the researcher had access to the data. Names, addresses and any other personal details that might identify the participant were not used in any of the measures, including the cardiovascular measurement tools and recording. Once the study ended, all data was archived in a password protected file in a secure University computer, to be stored for a period of 10 years, after which the data will be destroyed.

3.10. Statistical analysis

3.10.1. Application of statistical models in order to examine study hypotheses

When recording data, the TF®M software offers the capability to divide real-time data into blocks for statistical analysis. Each block consists of beat-to-beat data for each haemodynamic parameter recorded throughout a stationary measuring phase. This phase is defined by two marked points, a manually created start point and end point. Each statistical block contains the data from the time the recording started to the first operator-defined end point. Each subsequent block contains the data recorded from the first operator-defined end point to the second operator-defined end point and so on. For each data block created, the proprietary TF®M software automatically calculates the number of detected events, minimum and maximum value, mean value, standard deviation and standard error of the mean. These statistical values are provided for HR, sBP, dBP, mBP, HRV RRI, SV, SI, CO, CI and TPR parameters. The same values are also calculated for HRV parameters such as low frequency R-R interval (LF-RRI) and high frequency RRI (HF-RRI).

The statistical analysis of baroreceptor reflex sensitivity is determined by the calculation of the number of instances where rising or falling sBP blood is detected within three consecutive heart beats, mapped against concurrent changes in RRI (194). As the comparable reductionist intervention and control treatments had been designed to last just under five minutes (in order to compromise between the *'therapy specific risk belief'* and *'no-therapy specific risk belief'* treatment of the heart reflex point during the intervention), the operator defined TF®M statistical block start and end points were manually set to five minutes per block throughout the actual data recording, regardless of treatment allocation. During each session, the subject

would first lie supine for a period of approximately 20 minutes in order to allow the cardiovascular system to gradually acclimatise to the reclined position. Once this time had elapsed, a five minute 'baseline' start and end point were manually created in the TF[®]M software interface as live data recording commenced. Once five minutes of baseline data had been recorded, another five minute start and end point were manually created. During the second block of data recording, the therapist delivered treatment of the right foot (either intervention or control as allocated). The same five minute start and end points were created for the treatment of the left foot, followed by the creation of three other separate statistical blocks, each one immediately after the other and each with its own start and end point. These post treatment blocks were created in order to detect any treatment-related 'lingering' effect. This meant that each intervention or control session produced six statistical blocks of data for comparison (figure 3.9).

DATA RECORDING SCHEDULE

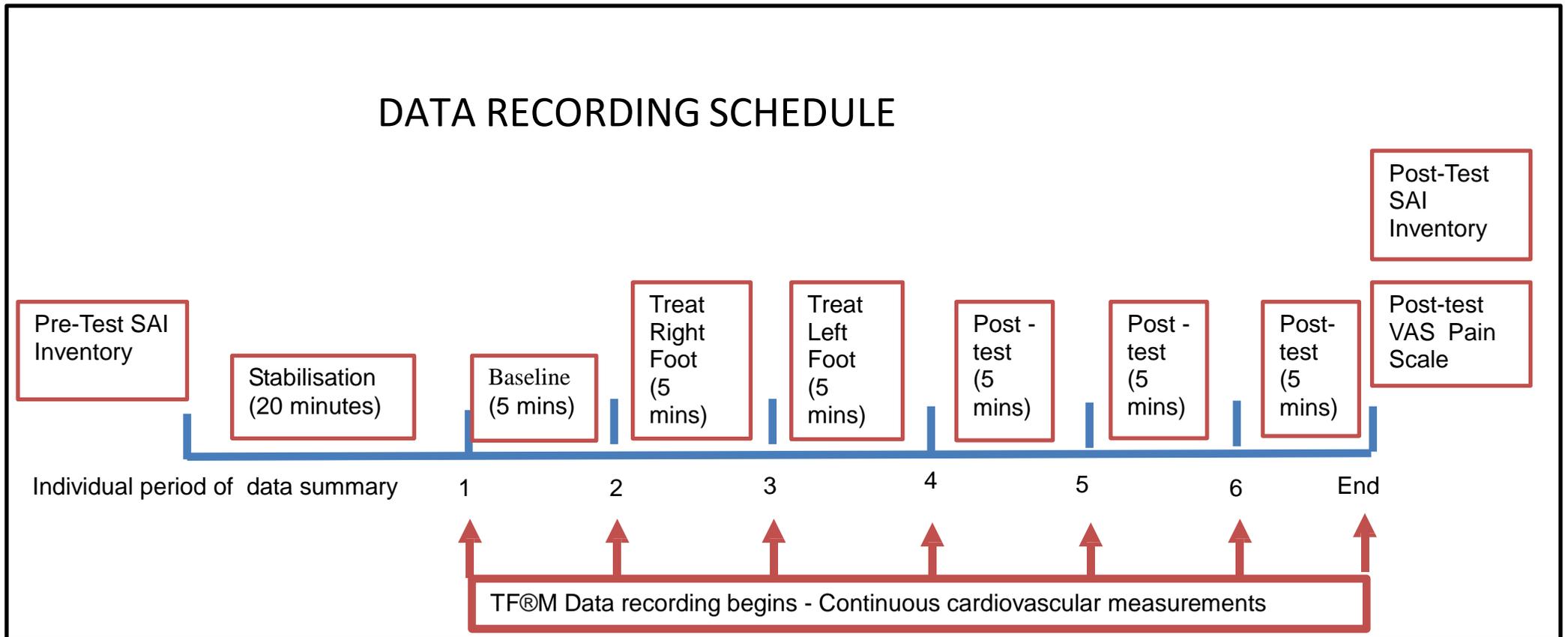


Figure 3.6. Session recording schedule

Therefore, as each subject was observed over six data blocks (time) periods under two conditions, (intervention and control treatment) in a repeated measures model, the statistical aim was to compare the means of multiple blocks of data for differences. Formal statistical advice on the correct analytical model for this design was sought from Ms Kate Howie, Statistical Consultant, Department of Computing Science and Mathematics, University of Stirling. She confirmed that Analysis of Variance (ANOVA) General Linear Model (GLM) was the correct choice of appropriate statistical model to process the data to meet the study aim (195). ANOVA GLM was used to investigate whether there was any interaction between condition and time or between the times or conditions using the hypothesis of Subject * Group * Time (196).

This query controlled for individual differences in reactions to the intervention and control treatment by testing the same subjects in all conditions of the experiment and produced an f-ratio value for each variable, which represented the ratio of the amount of systematic variance to unsystematic variance in the data (195). However GLM did not provide information about how the means between each data block varied, for example, whether the means of all six data blocks were significantly different from each other, or whether the difference detected came from one or more individual data block means. Which meant that ANOVA GLM was useful in determining whether one of the data block means was significantly different from the others, but limited as it did not reveal what the effect was, or in which data block it occurred in (197). Therefore in order to look more closely at any set of dependant variable data that demonstrated an overall significance under ANOVA GLM, Ms Howie confirmed that the choice of planned comparison analysis using Tukey significance tests to identify where any significant effect occurred (Minitab version 16.1.1.1, Microsoft, Redmond, Washington, USA) was also correct (195). She also confirmed that assumptions of normality and homogeneity of variance were validated and advised that an overall 5% significance level was used (198). This method

compared the mean of each data block for the variable against all the other blocks in the same variable, with each block acting as the control level for the variable in turn and is used when there are specific hypotheses to be tested (195). For this process, Tukey's method of significance test was used, which specified that all the comparison sets should have an error rate of 0.05 (equivalent to a 95% confidence interval) (196). In any data block where a significant Planned Comparison mean was identified, the values were transformed using omega squared effect process to reveal the true actual effect size (199). When trying to estimate an effects size in the population based on the variance explained by ANOVA, the effects size is typically reported as W^2 and values of .01, .06 and .14 are commonly presented as small, medium and large effects sizes (195).

The most appropriate statistical model to compare the post intervention and post control VAS data post-test data was a paired 't' test. This statistical test answers the question as to whether there is a significant difference between the means of two samples in the two different treatments. As the study used a repeated measures design, the two samples came from the same subjects who were measured twice, therefore the paired 't' test reduced the effects of confounding factors involved in comparing two different samples (200). As the comparison of pre and post-test STAI scores data also came from the same participants, the same statistical process was used on these data also. Ms Howie also confirmed that the choice to use same paired 't' test analysis model for data analysis for these two measurement comparisons was correct.

3.11. Summary

This chapter has described the study methods, haemodynamic and subjective outcomes and statistical analyses model used in the thesis experiments. The protocol design addressed the research aim to develop a reflexology treatment protocol for use in the three experimental studies. Furthermore, it enabled the acute (immediate) specific haemodynamic effects of reflexology treatment applied to specific areas of the feet which were thought to correspond to the heart, to be examined in both healthy volunteers and cardiac patients. And allowed this measurement to be compared with treatment applied to other areas which were not. Therefore the methods described in this chapter successfully addressed research question five, which asked if an experimental method could be devised which controls for non-specific effects associated with reflexology treatment of the heart reflex point in order to isolate any specific haemodynamic effect.

Having established a suitable research protocol for the experimental part of the thesis, the enquiry then addressed the second thesis aim. This was to investigate whether, in the face of inconsistent reflexology teaching literature regarding indication for cardiac patients, reflexologists were treating this patient group in clinical reflexology practice. Also, in the face of inconsistent published reflexology foot maps, to establish the degree of diversity in reflex point placement amongst practising reflexologists. The most direct method of finding out this information was to ask practicing reflexologists themselves whether they treat clients with any form of diagnosed heart disease. And to ask them to identify the precise location of one specific reflex point in order to determine the extent of reflex point location differences in current reflexology clinical practice. To address this aim, an internet based survey of AoR reflexologists was carried out to identify whether they are treating cardiac patients and to determine which area of the feet is being used as the heart reflex point in current reflexology practice. The purpose of the survey was to help inform the further development of the reflexology treatment protocol, prior to the RCT experiments.

The next chapter describes the methods and findings of the survey. Chapters five, six and seven then describe three RCT experiments in healthy volunteers, patients with chronic heart failure and patients with coronary artery disease. These RCT's were carried out in order to meet the primary thesis aim. The experiments demonstrated that the protocol described in this chapter could be used to investigate the acute (immediate) specific haemodynamic effects of reflexology. On this basis, the research aim to develop a reflexology treatment protocol for use in the three experimental studies; consisting of healthy volunteers, patients with chronic heart failure and coronary artery disease patients was successfully addressed.

Chapter 4

Internet-based Survey of UK AoR

Reflexologists

Jones J, Thomson P, Lauder W, Leslie SJ. Reported Treatment Strategies for Reflexology in Cardiac Patients and Inconsistencies in the Location of the Heart Reflex Point: A Survey. *Complementary Therapies in Clinical Practice*. 2012; Aug;18(3):145-50. Epub 2012 Jun 27

Chapter 4

Internet survey of UK AoR reflexologists

4.1. Survey aim and research questions

Aim 2 of the thesis was to conduct an internet based survey of AoR reflexologists to identify whether they were treating cardiac patients and to determine which area of the feet was being used as the heart reflex point in current reflexology practice, to help inform the development of the reflexology treatment protocol.

The following two research questions were devised in order to address research aim 2.

Q2. What are the perceptions of UK reflexologists regarding the safety and efficacy of treating cardiac patients?

Q3. Is there a consistency in the location of the heart reflex point as identified by reflexologists?

4.2. Methods

4.2.1. Participants and setting

The Association of Reflexologists (AoR) is the largest reflexology professional association in the UK. They only grant full membership status to therapists who have met minimum learning outcomes (77). Their registered database of full member therapists with World Wide Web access and active current email addresses provided the population framework for the data set. All full AoR members contactable by email were invited to participate, therefore it was a convenient sample. The opportunity to approach all AoR full members with online access and active email accounts meant that standardised data could be collected at one point from any therapists in the AoR population who responded, rather than using a cross-sectional sample. Although the AoR provided no details about their distribution process or methods of identifying respondents with active email accounts, it was hoped that this method would reduce bias sampling. As the AoR emailed their member therapists on the researcher's behalf, respondent characteristics were unknown.

4.2.2. Survey Design

An internet-based survey design using a variety of response formats seemed the most appropriate method to gather relevant statistical data. The questions aimed to evaluate current clinical practice amongst a wide representation of the AoR member population (45). By using the AoR to send out the survey link on the researchers behalf, respondents anonymity was protected, which has been shown to improve online survey response rates and reduce response biases, increasing reliability (201). The survey required dichotomous YES/NO answers to questions three to eight, and continuous numerical answers for questions one and two. Descriptive statistics were used to summarise the data. Relevant data were analysed in percentages.

4.2.3. Survey validity

As there was no existing validated previous questionnaire that could be used to identify whether reflexologists are treating cardiac patients and to determine which area of the feet is being used as the heart reflex point in current reflexology practice, a questionnaire was developed in several iterative stages in co-operation with the AoR. The AoR were aware that the researcher had broadly categorised reflexology educational literature into *'therapy specific benefit'* vs. *'therapy specific risk'* treatment approaches. They were also aware that some of the questions were devised in order to detect a true difference between these two broad approaches in treating cardiac patients in clinical reflexology practice. In other words, to identify whether the presence of cardiac disease influenced the therapist's treatment strategy.

Based on this understanding, the AoR helped to provide linguistic validity by co-scripting all 9 survey questions (table 4.1). This ensured that the language and phrasing used was familiar to reflexologists within the context of their own therapeutic framework. For example, the AoR advised using the term "Heart problems" as the broad definition for cardiac patients, as they were concerned that more specific terms such as heart failure may be misunderstood by some participants. Therefore the questionnaire content was assessed by reflexology experts during its construction. Although this assessment was subjective, it was hoped that the involvement of subject experts would ensure that the wording of the questions would be understood in the same way by all the therapists who completed the survey (202). This helped ensure that there were no ambiguities and that questions were clear and concise.

4.2.4. Survey reliability

Because of the AoR assessment of the survey content and their involvement in co-scripting the questions, it was assumed that the non-factual questions in the survey had an acceptable degree of reliability (202). The non-factual questions aimed to measure opinions that were categorised into two distinct themes (*'therapy specific benefit'* vs. *'therapy specific risk'*

beliefs). As the two beliefs were quite distinct, it was assumed that the responses would reflect true differences in opinion in repeated administration, as would be expected, given the variation in educational literature guidance.

4.2.5. Survey distribution

An invitation was sent out in email form by the AoR inviting all members to participate to all members as described above. The email stated that the researcher was interested in capturing a survey snapshot of how reflexologists approach cardiac patients in their practice. Recipients were asked to respond even if they had never treated any clients with cardiac disease. The email contained a hyperlink to the online survey (www.surveymonkey.com) for subjects to complete. By using the AoR to send out the survey link and diagram on behalf of the researcher, it was hoped to create the perception of anonymity for the respondent. This has previously been showing to improve online survey response rates and reduce the level of response biases that may have occurred (201). For example, if the therapist felt that their responses could have been identified by the researcher and/or AoR, they may have changed their responses to reflect the 'official' recommendations of their particular training provider rather than their own practice-derived beliefs.

The invitation also contained a graphical attachment. This was a diagram showing of a blank outline of a left and right foot. The background showed a semi-transparent anatomically accurate outline of the complete foot bone structure within each foot outline. The diagram had both horizontal and vertical labelled grid-lines superimposed over the top of the feet, rather like the grid on a map (figure 4.1). The email message explained that the diagram was linked to question 9 in the survey, which asked respondents to identify the grid box (or boxes) which would best represent where they would place the heart reflex point. As reflexologists

are taught to identify the location of various reflex points by anatomical bone structure landmarks, this template diagram appeared fit for purpose.

4.2.6. Survey data collection

Survey monkey (www.surveymonkey.com) is an online survey service and offers an easy-to-follow formatting. When the embedded hyperlink in the AoR email was clicked, it rendered the complete surveymonkey.com survey web page with no security login required. The web-based hosting ensured that the survey reached all AoR members with active email accounts. The user-friendly accessible format of SurveyMonkey.com placed minimum burden on the respondents. The survey website data collection was restricted to one response per computer (IP address restriction). This was done in order to prevent duplicate responses from individual practitioners. The questionnaire required the respondent to complete all fields in the required answer format in order to submit. SurveyMonkey.com does not store data about how many people started the survey but did not complete.

4.2.7. Statistical methods

Data were downloaded into the Excel spreadsheet (Microsoft Excel Version 10, Microsoft, Redmond, Washington, USA) to allow for statistical analysis. Data were expressed as actual and percentage or mean and standard deviation (SD), unless otherwise specified.

4.2.8. Ethics

This survey was designed and conducted to evaluate the extent of product safety and quality control issues in existing reflexology therapy services and involved no randomisation. According to the National Patient Safety Agency National Research Ethics Service guidelines for defining research, the survey purpose and design clearly fitted the description of service

evaluation only; therefore there were no ethical implications and thus ethics committee review was not required (203). Nevertheless, anonymity and confidentiality were assured throughout.

4.3. Results

A total of 3539 emails were sent out by the AoR. 235 were returned undelivered (reported as reason not known). This left a total of 3304 (93%) successfully delivered. Of these, 303 (9%) therapists responded on or before the six week cut-off date when the survey was closed to further data collection. The survey was closed at this point as no new responses had been registered for seven days. Responses to the questions are shown in table 4.1. Both 'yes' and 'no' data are included to show that there was no missing data. The reflexologists had a mean of 9.7 ± 6.6 years' experience and saw on average $20.0 (\pm 17.5)$ patients per month. Only 42 (14%) had referrals from doctors. The majority, 195 (64%) saw patients with diagnosed "heart problems". The majority of reflexologists 293 (97%) were happy to treat patients with "heart problems". However 94 (31%) of reflexologists would be concerned if their client reported stable angina or heart failure and 160 (53%) would limit treatment in these cases. 214 (71%) of therapists would expect treatment to improve heart condition symptoms. All respondents answered question 9, which asked them to identify which grid box (or boxes) would best represent where they would place the heart reflex point. Selected grid-boxes are displayed in figure 4.1, with a visual representation of actual 'votes' for each box and corresponding % gradation of shading. It should be noted that some practitioners identified more than one box (figure 4.1).

Table 4.1. **Survey Questions and Response Field Type**

Table 1. Questions	Response	
1. What year did you qualify as a reflexologist?	9.7 years (SD 6.6) ±	
2. On average how many individual clients do you see per month	20 (SD 17.5) ±	
3. Do you get referrals from doctors?	YES	42 (14%) *
	NO	261 (86%)
4. Do you ever see any clients with diagnosed heart problems?	YES	195 (64%)
	NO	108 (36%)
5. If your client had stable diagnosed heart problems, would you be happy to treat?	YES	293 (97%)
	NO	10 (3%)
6. If your client reported having stable angina or heart failure, would you be concerned about doing reflexology on them?	YES	94 (31%)
	NO	209 (69%)
7. Would you limit the treatment because of their heart condition?	YES	160 (53%)
	NO	143 (47%)
8. Would you expect the treatment to improve their heart condition symptoms?	YES	214 (71%)
	NO	76 (29%)
9. We are aware there are various reflexology foot charts and we are curious to investigate where most people put the heart reflex. Please look at the attachment sent with the original AoR email. It is a diagram showing the outline and bones of the feet. There is a 'grid' map superimposed behind. Which grid box (or boxes) would best represent where you would place the heart reflexology point. Please tell us by writing the grid box reference here (e.g. B2 or B2/B3)?	See figure 4.1	
± Data represented as mean and standard deviation (SD) ; *Data represents actual value or percentage (%) of responses unless specified		

T

4.4. Discussion

This was the first internet survey of UK AoR registered reflexologists to identify whether they are treating cardiac patients. Furthermore, it was the first survey to use a novel foot template diagram in an attempt to establish the degree of diversity in reflex point placement amongst practising reflexologists. The results revealed that cardiac patients are seeking reflexology treatment, with the majority of respondents claiming to have treated such clients. This finding alone justifies the need for further evidence in reflexology use in cardiac patients. The results also revealed that integration from conventional medicine in the form of referrals from medical staff appeared very low. The results also suggested that the vast majority of respondents reported feeling confident to deliver reflexology to cardiac patients when the term “Heart problems” was used. However when more specific diagnostic labels such as stable angina or heart failure were used, two thirds reported they would not be concerned about doing reflexology. This suggested that the medical diagnostic terms ‘stable angina’ and ‘heart failure’ may have been misunderstood by some participants.

This thesis survey was also the first to identify the concepts of *‘therapy specific benefit’* and *‘therapy specific risk’* in reflexology teaching literature and by doing so, make a theoretical contribution to future reflexology literature analysis. With regards to *‘therapy specific benefit’* vs. *‘therapy specific risk’* beliefs reported by participants, two thirds of respondents reported that reflexology would improve heart condition symptoms. This suggested that the majority of respondents regarded reflexology treatment as having an effect beyond that of simple foot massage. Therefore it appeared that the majority of respondents share Ingham’s *‘therapy specific benefit’* approach. However the results still mirrored the inconsistencies found in the educational training literature. One third of respondents reported feeling concerned about doing reflexology in cardiac patients. And evidence to suggest a *‘therapy specific risk’* was

further implied by the fact that over half of respondents reported that they would limit the treatment of a cardiac patient, implying that excessive treatment could have potentially adverse effects. As the survey confirmed that cardiac patients were using reflexology, these inconsistent therapeutic views indicated a lack of standardisation in reflexology educational and clinical practice that needed to be addressed.

The survey also investigated the degree of variation in the heart reflex point placement by reflexologists in clinical reflexology practice. Here, the findings suggested a significant quality control issue, with a marked level of inconsistency demonstrated in heart reflex point placement. Given the degree of reflex point variation in the survey responses, it seemed likely that other reflex points on the feet may be systematically prone to the same level of inconsistent placement in clinical practice too. This mirrored the inconsistencies found in published foot maps and therefore indicated a clear lack of standardisation in reflexology training and clinical practice standards. In future research, the foot template tool could overcome the reflex point reproducibility issue.

It is a concern that many variations of reflexology foot maps are publicly available, produced on a smaller scale by individual reflexology training providers and on a larger scale, by professional reflexology member organisations such as the International Federation of Reflexologists, the Association of Reflexologists, the British Reflexology Association and the British School of Reflexology. None of these organisations are regulatory bodies, but all four provide their own bespoke version of the reflexology foot map and with the exception of the AoR, all provide reflexology training. Most maps appear to be loosely based on the original Eunice Ingham reflexology chart but have evolved idiosyncratically. The majority appear to be based on little more than the beliefs of individual practitioners. The cost of purchasing a

copyrighted foot map from each provider varies considerably. It was suggested by the AoR that this may be a contributing factor to the diverse array available.

4.5. Conclusion

As a precursor to the thesis experimental RCTs, an internet based survey of AoR reflexologists was carried out in order to identify whether they are treating cardiac patients and to determine which area of the feet is being used as the heart reflex point in current reflexology practice. This survey identified that reflexologists are treating cardiac patients. For this client group, the inconsistent views regarding indication treatment limitation raised questions about the intrinsic safety of reflexology. The survey also identified that there is a marked lack of clarity and consistency in therapists reported treatment strategies for cardiac patient clients and the heart reflex point in this patient group. The results suggested that although most reflexologists appear happy to treat cardiac patients, the majority of therapists responded that excessive treatment to the heart reflex point could have potentially adverse effects. This data confirmed the need for the thesis enquiry. Furthermore, marked inconsistencies were found in heart reflex point placement. Therefore the survey foot template data helped inform the development of the reflexology reductionist foot map protocol described in Chapter three: Methods. The next chapter describes a pilot study carried out to investigate the acute (immediate) haemodynamic effects of reflexology in healthy volunteers using the protocol. The purpose of the pilot study was to test the protocol and to look for potential safety issues prior to using it in patient studies.

Chapter 5

Reflexology in healthy volunteers

Jones J, Thomson P, Lauder W, Howie K, Leslie SJ. Reflexology has an acute (immediate) haemodynamic effect in healthy volunteers: A double blind randomised controlled trial. *Complementary Therapies in Clinical Practice*. [<http://dx.doi.org/10.1016/j.ctcp.2012.03.006>]

Jones J, Thomson P, Lauder W, Howie K, Leslie SJ. Conference abstract -Double blind randomised controlled trial of the acute (immediate) cardiovascular effects of reflexology: A pilot study in healthy volunteers. *European Journal of Integrative Medicine*, June 2011; 3(2):c109

Chapter 5

Results of a double-blind randomised controlled pilot study in healthy volunteers

5.1 Pilot study aim and research question

This pilot study was the first in a series of three RCT's devised to address research aim 3. In this study, the aim was to use the reflexology treatment protocol developed for the thesis to examine whether there are any specific haemodynamic benefits, product quality or safety issues associated with reflexology treatment to the area of the feet thought to be associated with the heart in healthy volunteers, using a double blind randomised controlled trial design.

The following two research questions were devised in order to address research aim 3 in healthy volunteers.

Q4. Does reflexology applied to discreet areas of the feet thought to correspond to the heart result in specific changes in the haemodynamic parameters of healthy volunteers?

Q5. If a specific haemodynamic effect is detected, are there any risks or benefits associated with reflexology treatment to the area of the feet through to be associated with the heart in healthy volunteers?

5.2. Methods

5.2.1. Design

Randomised controlled double blind repeated measures design (as outlined in Chapter 3: Methods).

5.2.2. Study participants

Any healthy male > 18 years of age and post-menopausal women were assessed for eligibility. Only post-menopausal women were considered, as evidence suggests that circulating oestrogen and progesterone increase during the luteal phase of the menstrual cycle and these hormones have been found to affect arterial compliance and stiffness (204;205). The influence of these sex hormone changes during the menstrual cycle meant that there would have been a potential for a spurious hormonal-related haemodynamic influence on systolic and/or diastolic BP trends in pre-menopausal women which could have skewed the haemodynamic results. Therefore the following volunteer recruitment criteria were applied.

Inclusion/exclusion criteria

Inclusion criteria:

1. Able to give informed consent
2. Male patients aged >18 years old
3. Post-menopausal women
4. Normal lower limbs (no previous operations including varicose veins) in order to eliminate any potential contraindication to reflexology therapy pressure to the feet
5. No form of medication for 48 hours prior to study participation (to eliminate any confounding pharmaceutically induced haemodynamic effects)

6. Abstain from tobacco and caffeine-containing drinks for at least 12 hours prior to the study (to eliminate any confounding effects of caffeine or tobacco stimuli on the central nervous system)(206;207)
7. Abstain from food for 4 hours before the study in order to eliminate any effects of digestion on blood pressure rates (208)
8. Reflexology naïve (i.e. have never had training in or received reflexology therapy)

Exclusion criteria:

1. Participation in pharmacological study within the previous 3 months (in order to eliminate any spurious pharmaceutical effects on the cardiovascular system)
2. Clinical history of cardiovascular disease (in order to eliminate the effects of any cardiovascular abnormalities or medication)
3. Clinical history of neuropathy (in order to eliminate the effects of any neuropathic abnormalities)

5.2.3. Recruitment process

All eligible healthy volunteers were identified by having responded to a poster (Appendix 2) which was placed on the staff notice board in Raigmore hospital, Inverness. Each self-referred volunteer received a study enrolment pack containing 1) a Patient Information Sheet outlining the study purpose and design (Appendix 3) and 2) a Study Participant Consent form (Appendix 4). Informed consent procedures were strictly followed and written consent forms were signed at a minimum of 48 hours before the volunteers were enrolled into the study.

5.2.4. The intervention

Reflexology massage (as described in the Methods, Chapter 3), applied solely to the areas on both feet known as the shoulder girdle within the reflexology foot map transverse zones.

5.2.5. The control

Reflexology massage (as described in the Methods, Chapter 3), applied solely to the areas on both feet known as the pelvic and abdominal areas within the reflexology foot map transverse zones.

5.2.6. Reflexology style and techniques

Both therapists trained at the International Institute of Reflexology (IIS), therefore the intervention and control treatments were formulated using used standardised Ingham touch techniques and principles. The therapists standardised both intervention and control treatment times (both lasted for 5 minutes), treatment pressure (light to medium) and depth of touch techniques (light to medium) as described in Methods: Chapter 3.

5.2.7. Background music

Each subject wore headphones and listening to the same piece of instrumental music ("Ancient Canyons" by John Hurling) throughout both sessions. It was assumed to be an adequate balance between not being too relaxing to mask any treatment effect, yet sufficient to eliminate any far more potentially confounding sudden or distracting noise from the general environment (the study took place in a busy hospital-based cardiorespiratory department). As

both the control and active group listened to the same piece of music at the same volume level through the same headphones throughout both sessions, the music component was standardised as much as possible, therefore any non-specific relaxation effect arising from the music was thought to be equal across both groups.

5.2.8. Measurement of haemodynamics parameters

Table 5.1. Haemodynamic parameters used in the study (as described in Methods: Chapter 3)

Haemodynamic parameter	Abbreviation	Method of measurement
Heart rate	HR	TF [®] M impedance cardiography system
Diastolic blood pressure	dBp	TF [®] M impedance cardiography system
Systolic blood pressure	sBP	TF [®] M impedance cardiography system
Mean arterial blood pressure	mBP	TF [®] M impedance cardiography system
Stroke index	SI	TF [®] M impedance cardiography system
Stroke volume	SV	TF [®] M impedance cardiography system
Cardiac output	CO	TF [®] M impedance cardiography system
Cardiac index	CI	TF [®] M impedance cardiography system
Total peripheral resistance	TPR	TF [®] M impedance cardiography system
Baroreceptor up events	BarUpEv	TF [®] M impedance cardiography system
Baroreceptor down events	BarDwEv	TF [®] M impedance cardiography system
Low-frequency component of heart rate variability	LF-RRI	TF [®] M 2 channel electrocardiogram function (ECG)
High-frequency component of heart rate variability	HF-RRI	TF [®] M 2 channel electrocardiogram function (ECG)

5.2.9. Anxiety and pain assessment

Transient state anxiety: Pre & post measurement of the subject's self-reported perceived state of anxiety was assessed using The State Anxiety Inventory (SAI), as described in Methods, Chapter 3 (182).

Transient pain: A Visual analogue scale (VAS) was used post-treatment to measure the peak physical massage pressure pain experienced during the reflexology massage. The VAS was a 10 cm standard line, labelled "no pain" at one end and "worst pain experienced" at the other (appendix 6). Subjects were asked to make a mark anywhere along the line at a point which represented the peak level of perceived pain intra-treatment. The VAS is a well-validated method for measuring acute pain as described in Methods, Chapter 3 (187;188).

5.2.10. Sample size

For the pilot study of healthy volunteers, expert advice on the healthy volunteer sample size study design was sought from Dr raser I. Lewis BSc MSc PhD, Applied Statistician at the Epidemiology Research Unit, Scottish Agricultural College. The question was whether any intervention-related specific haemodynamic effect would be detectable against the background of naturally occurring physiological variations within the same hemodynamic parameters. However as little was known about the potential magnitude of the effects of reflexology on haemodynamic parameters, there was insufficient data to predict the smallest detectable treatment effect or size when designing the pilot study. Therefore, a pragmatic sample size of 16 was chosen. It was considered that this number would be sufficient to provide the data necessary to inform the power calculation for the cardiac patient phases of the study, and to provide treatment related healthy volunteer standard deviation data for

other haemodynamic-testing reflexology studies. Dr Lewis agreed that the rationale for the healthy volunteer pilot study sample size and study design were sufficient to meet the aims of the pilot study.

5.2.10. Location

The study took place at the Highland Heartbeat Centre, Raigmore Hospital. The treatments were conducted in a quiet, draught-free room maintained at a constant temperature of 22-24 °C. The lighting was dimmed throughout the session as this was thought to be optimum to the delivery of the intervention.

5.2.11. Randomisation

The equal group random allocation was performed by a third party not involved with the study, using computer generated random numbers. Subjects were randomly allocated to either receive the intervention treatment at the first visit, followed by the control treatment at the second visit, or to receive the treatment schedule in the opposite way round (table 4.2). For the second visit, the subject was automatically assigned to the other treatment in order to act as their own control. The subject remained unaware of group allocation criteria throughout the study. The allocation list was handed directly to the two reflexology therapists in sealed opaque envelopes. The researcher did not have access to the allocation list until data analysis was complete.

5.2.12. Blinding

The study was double-blinded. Neither the reflexology-naive subjects nor researcher knew in which order the intervention or control treatment was delivered. The reflexologists worked behind a screen when delivering the reflexology so the researcher was not aware of the treatment order for each subject (as described in Methods, Chapter 3).

Table 5.2. Treatment schedule random allocation list

Study Subject	Visit 1	Visit 2
1	Forefoot	Heel
2	Heel	Forefoot
3	Forefoot	Heel
4	Heel	Forefoot
5	Heel	Forefoot
6	Heel	Forefoot
7	Forefoot	Heel
8	Heel	Forefoot
9	Forefoot	Heel
10	Forefoot	Heel
11	Heel	Forefoot
12	Heel	Forefoot
13	Forefoot	Heel
14	Forefoot	Heel
15	Forefoot	Heel
16	Forefoot	Heel

5.2.13. Pre-study requirements

All volunteers were required to abstain from any form of medication for at least 48 hours prior to study participation, food for 4 hours beforehand and from tobacco and caffeine-containing drinks for at least 12 hours prior to attendance.

5.2.14. Protocol

Volunteers were asked to attend for two study visits, each lasting approximately 1 hour 20 minutes, so were observed under two conditions (the intervention and control), with a restabilisation period of at least 48 hours between first and second treatment. The same reflexologist treated the same subject at both visits to ensure uniformity of treatment approach. Subjects were asked to wear loose comfortable clothing to each session. Upon arrival and before the intervention took place, the procedure was explained to the subject. This repeated the information given to the participants previously in the patient information sheet prior to them consenting to be involved in the study. Subjects self-completed the state-anxiety inventory which was given to them when they arrived. Subjects then removed their socks and shoes and lay supine on the couch in the temperature-controlled experiment room (24-26). A blanket was placed over the subjects bare feet at all times until each foot was exposed for the reflexology treatment.

Depending on which part of the foot was to be treated, the demarcation line between the intervention and control treatment areas was defined using hypoallergenic tape in order to prevent the therapist from treating the non-designated area of the foot during the session irrespective of which part of the foot is being treated. The ECG and ICG leads were correctly placed on the peripherals and trunk and blood pressure cuff attached to the left arm at the beginning of the session and was left in place for the duration of the session. The TF[®]M finger cuff was placed over the middle two fingers of the right hand. The TF[®]M software was initiated to begin data monitoring and data capture quality evaluation, although actual data recording was not initiated until a 20 minute 'resting' phase had elapsed. Subjects were verbally advised that there would be no talking during the recording session and that the blanket would be removed from the right foot when the reflexology treatment was about to start. After 20 minutes had elapsed to allow for resting physiological parameters to stabilise,

the reflexologist began the treatment protocol when instructed to do so by the researcher. Dialogue between reflexologist, researcher and subject was kept to a bare minimum throughout, with no talking whatsoever during the data recording phase. The researcher remained behind the screen at all times so that the subject's legs and the reflexologist were hidden from view throughout the recording session. After six periods of data block recording had completed, the live monitoring was stopped and the electrodes and bladder cuffs removed. At the end of the session, the study subject completed the post-test SAI questionnaire tool for a second time and completed a VAS pain scale tool.

5.2.15. Ethics

The study was undertaken with the approval of the Research and Ethics Committee (DREC), University of Stirling (no DREC reference number issued) and the North of Scotland Research Ethics Committee (NOSREC 10/S0801/49) and in accordance with the Declaration of Helsinki. Written informed consent was obtained from each volunteer before entry into the study.

5.2.16. Statistical Methods

Summary descriptive data were collected as socio demographic characteristics. As the study aim was to investigate whether there was any interaction between condition and time or between the times or conditions using the hypothesis of Subject * Group * Time, rather than simply compare pre and post measurements between groups, Analysis of Variance (ANOVA) General Linear Model (GLM) was selected as the appropriate choice of statistical modelling to meet the study aim. ANOVA GLM could be used to investigate whether there was any interaction between condition and time or between the times or conditions using the hypothesis of Subject * Group * Time. In the event that a significant effect was identified by

ANOVA GLM, it was decided to further process the data using planned comparison analysis with Tukey significance tests to identify where any significant effect occurred (Minitab version 16.1.1.1, Microsoft, Redmond, Washington, USA). Data was correctly transformed. Assumptions of normality and homogeneity of variance were validated and an overall 5% significance level was used.

As the post-test VAS scores were normally distributed, it was decided to compare the subjects post intervention and post control data using a paired 't' test statistical model (as described in Chapter three: Methods) (Minitab version 16.1.1.1, Microsoft, Redmond, Washington, USA). This statistical test answers the question as to whether there is a significant difference between the means of two samples in the two different treatments. As the study used a repeated measures design, the two samples came from the same subjects who were measured twice, therefore the paired 't' test reduced the effects of confounding factors involved in comparing two different samples (200). As the comparison of pre and post-test STAI scores data were also normally distributed and came from the same participants, the same statistical process was used on these data also (Minitab version 16.1.1.1, Microsoft, Redmond, Washington, USA).

5.3. Results

Eleven healthy men (mean age 21.1 years, \pm 17.3) and 5 post-menopausal women, (mean age 53.4 years, \pm 7.3) with an overall group mean BMI 27.1 (\pm 4.9) were recruited between July and August 2010 (table 5.3). All sixteen participants completed both arms of the study (attended twice) (figure 5.1). The data from one patient was discarded from final statistical analysis as the fire alarm went off during the second session reflexology treatment, potentially affecting the reliability of the recorded haemodynamic response data.

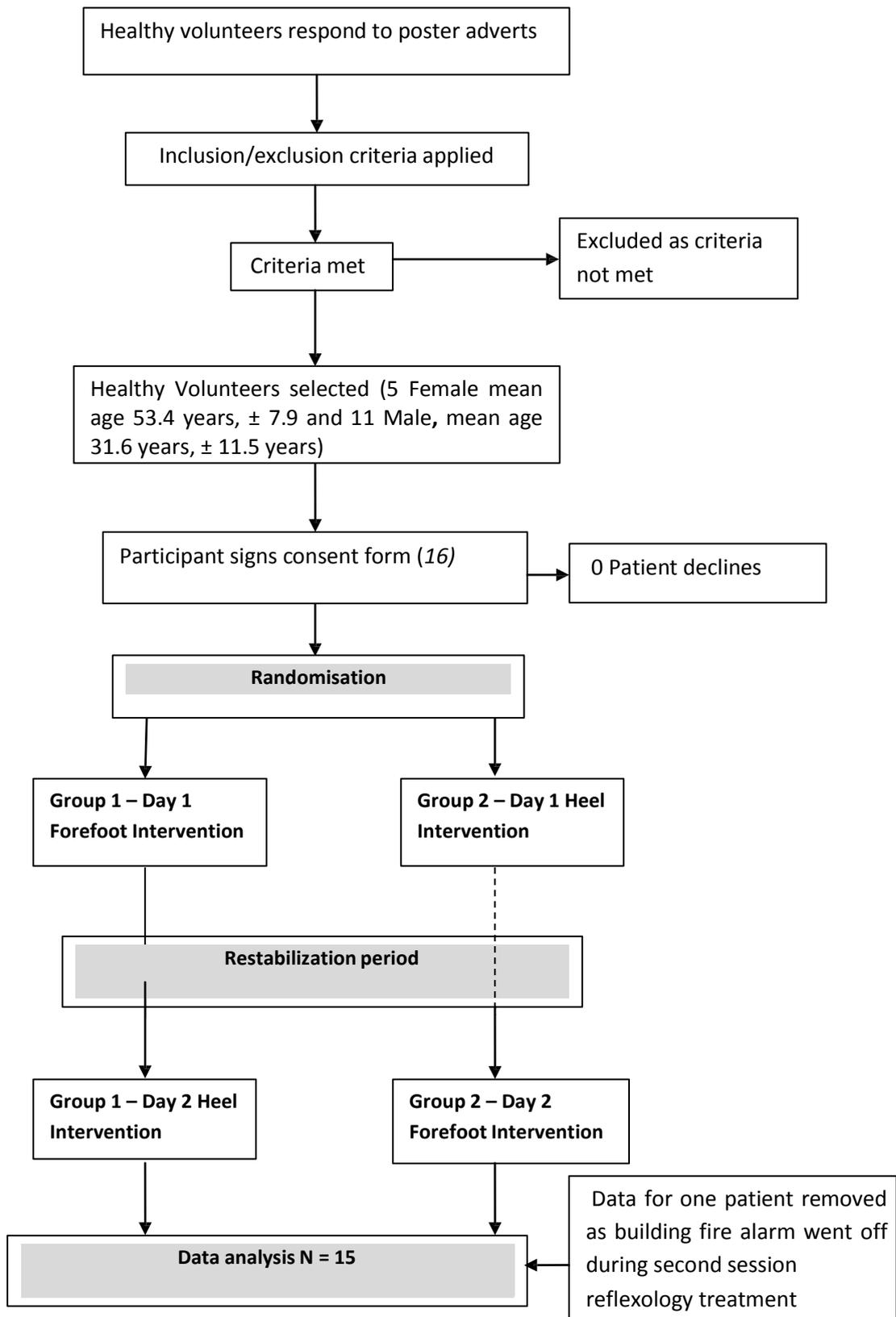


Figure 5.1: Healthy volunteer recruitment and research study procedures

Table 5.3 Study participant characteristics

Participant ID	Sex	Age (years)	Height (cm)	Weight (kg)	BMI (kg/m ²)
1	F	58	165	88	32.3
2	M	19	170	74	25.6
3	F	50	188	85	24
4	F	48	169	98	34.3
5	M	28	176	66	21.3
6	F	47	167	69	24.7
7	M	20	157.5	68	27.4
*8	M	44	160	57	22.3
9	F	64	160	63	24.6
10	M	47	170	68	23.5
11	M	20	183	83	24.8
12	M	20	175	110	35.9
13	M	38	172	105	35.5
14	M	35	176	72	23.2
15	M	45	176	89	28.7
All data expressed as actual values					
* Data for this participant was excluded from the final analysis					

5.3.1. Haemodynamic outcome results

Systolic blood pressure (sBP), diastolic blood pressure (dBP), mean arterial blood pressure (mBP), stroke volume (SV), stroke index (SI), baroreceptor up events (BarUpEv) / baroreceptor down events (BarDwEv), heart rate variability (LHRRV or HFRRV).

There was no statistically significant difference or overall trend noted in sBP, dBP, mBP, SV, SI, BarUpEv, BarDwEv or HRV LHRRV or HFRRV in either the Forefoot (intervention) or Heel (control) conditions (all $p > 0.05$). Furthermore, sub-group analysis found no individual significant outcome differences in these variables between the two therapists. Stroke volume in the Forefoot (intervention) group baseline was significantly different from the Heel (control) group baseline ($p = 0.003$), as was stroke index ($p = 0.002$), cardiac output ($p = 0.001$), cardiac index ($P = 0.002$) and total peripheral resistance ($p = 0.002$) (table 5.4).

Table 5.4. **Baseline variable differences between the intervention and control groups**

Outcome	Intervention	Control	p value
HR	66.7 (9.9)	66.3 (9.4)	0.999
dBp	84.9 (13.9)	84.1 (9.4)	0.602
sBP	132.9 (16.4)	129.8 (10.7)	1.000
mBP	99.1 (13.5)	97.4 (9.0)	0.990
SV	74.0 (18.7)	78.2 (12.2)	0.003**
SI	39.6 (11.3)	41.9 (8.5)	0.002**
CO	4.8 (1.1)	5.2 (1.0)	0.001**
CI	2.6 (0.75)	2.7 (0.6)	0.001**
TPR	1703.1 (592.7)	1534.5 (407.85)	0.002**
BarUpEv	22.4 (16.6)	22.9 (20.1)	1.000
BarDwEv	20,5 (13.7)	20.9 (13.9)	1.000
LF-RRI	115281 (132211)	127607 (172482)	1.000
HF-RRI	161908 (196096)	143872 (198767)	1.000
<p>*All data expressed as mean, standard deviation (SD)</p> <p>* * indicates significance at the p < 0.05 level</p>			

All haemodynamics results are reported in table 5.5. Heart rate was recorded in beats per minute (bpm). There was no significant difference between the Forefoot (intervention) right

foot treatment (RFT) (64.2; standard deviation (SD) 9.1; 95% CI +/- 4.6; p=ns) or Forefoot (intervention) left foot treatment (LFT) (63.7; SD 8.6; CI +/- 4.3; p=ns) vs. Heel (control) RFT (65.4; standard deviation (SD) 10.8; 95% CI +/- 5.5; p=ns), or Heel (control) LFT (65.5; SD 10.4; CI +/- 5.3; p=ns) response. However an overall trend was noted during the Forefoot (intervention) treatment. HR dropped by 2.6 bpm from baseline during the Forefoot RFT and 3.1 bpm during the Forefoot LFT vs. 0.9 bpm Heel control RFT and 0.8 Heel control LFT. This drop occurred intra-treatment only and HR regained baseline rates post treatment. Cardiac output was affected in the Forefoot (intervention) condition intra-treatment with a borderline significance in interaction overall ($p = 0.051$), and a statistically significant Planned Comparisons difference ($p = 0.007$) between the baseline block using when compared with the Forefoot LFT block (baseline mean 4.83; SD 1.07; CI +/-0.54 vs. LFT mean 4.57; SD 1.06; CI +/- 0.54). The Heel (control) LFT (2.7; SD 0.6; CI +/- 0.3; p=ns) showed no comparable response. Cardiac index was found to be significant overall ($p = 0.035$). Planned comparison analysis using Tukey simultaneous tests identified that cardiac index decreased significantly in the Forefoot intervention group during the left foot treatment (LFT) block by $0.15 \text{ l/min}\cdot\text{m}^2$ (Baseline mean 2.6; standard deviation (SD) 0.75; 95% CI +/- 0.38 vs. LFT mean 2.45; SD 0.68; CI +/-0.35). This data was transformed using omega squared effect (w^2) to reveal the effects size of the interaction ($w^2 = 0.002$; t-contrast 1.18; $w = 0.045$). There were no significant difference between the mean of the Forefoot (intervention) right foot treatment (RFT) (1782.5; standard deviation (SD) 606.5; 95% CI +/- 610.1; p=ns) or Forefoot (intervention) left foot treatment (LFT) (1842.9; SD 610.1; CI +/- 308.7; p=ns) vs. Heel (control) RFT (1584.2; standard deviation (SD) 435.5; 95% CI +/- 220.4; p=ns), or Heel (control) LFT (1565.4; SD 404; CI +/- 204.5; p=ns) response. However an overall TPR trend occurred in the Forefoot (intervention) treatment. From baseline, TPR increased by 139.8 dyn*sec/cm⁵ during the Forefoot RFT and 139.8 during the Forefoot LFT, then fell back to baseline levels post treatment. No comparable trend was

noted in the Heel (control) treatment blocks. Figures 5.2 – 5.18 give graphical representations of the study results.

Fig 5.2

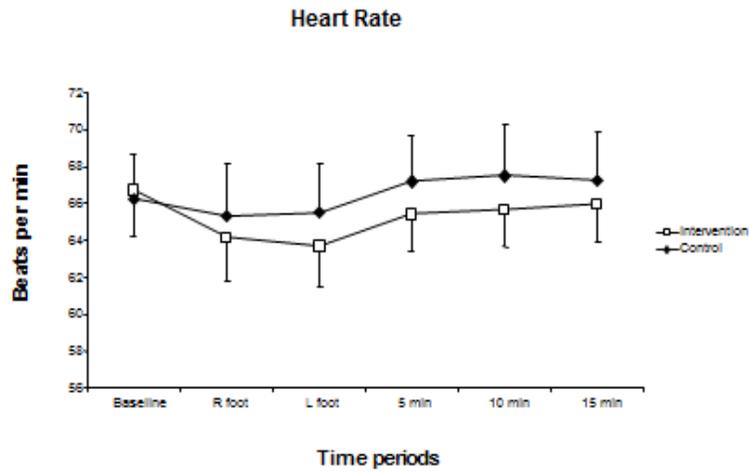


Fig 5.3

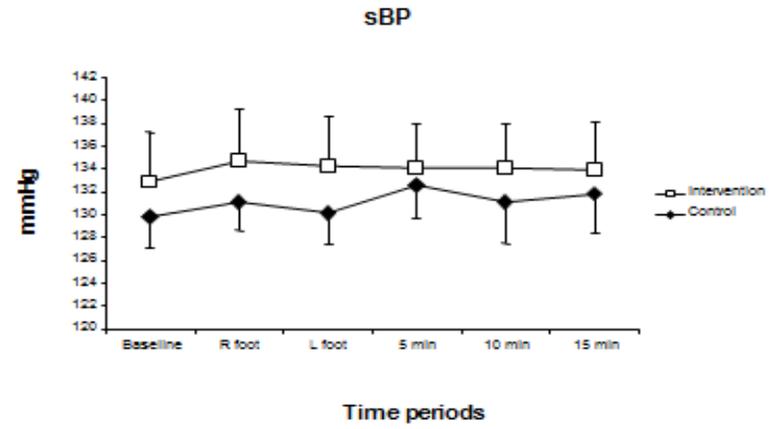


Fig 5.4

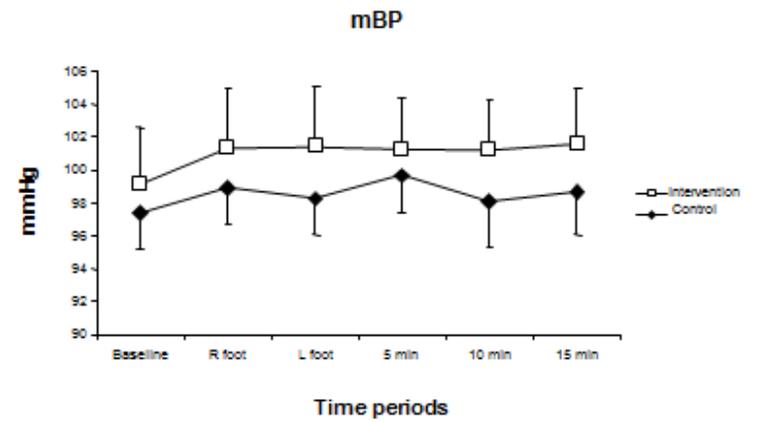
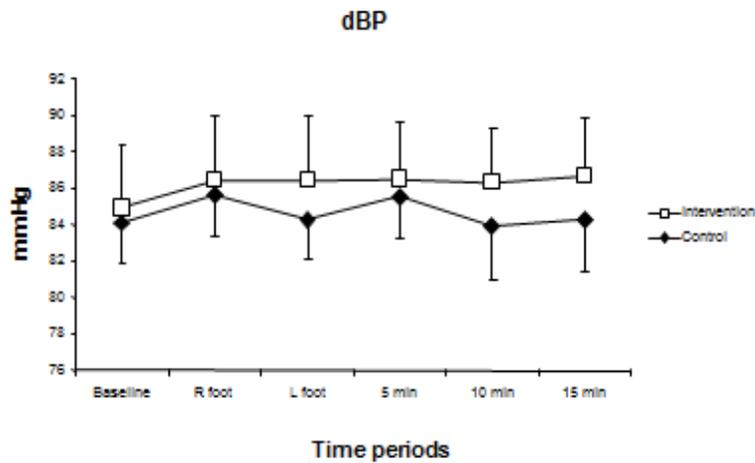


Figure 5.2 – 5.5. ANOVA GLM comparison of HR, sBP, dBP and mBP across the six recorded data blocks. The white square points are the intervention group means, the diamond black points are the control group means for each period. The error bars show Standard Error of Mean (SEM)

Fig 5.6

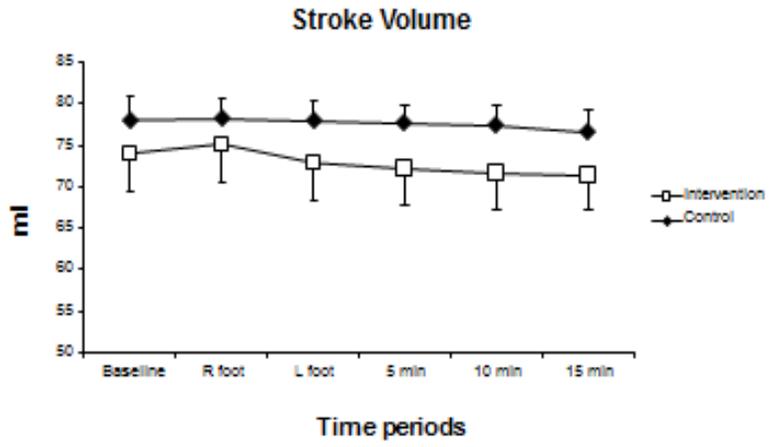


Fig 5.7

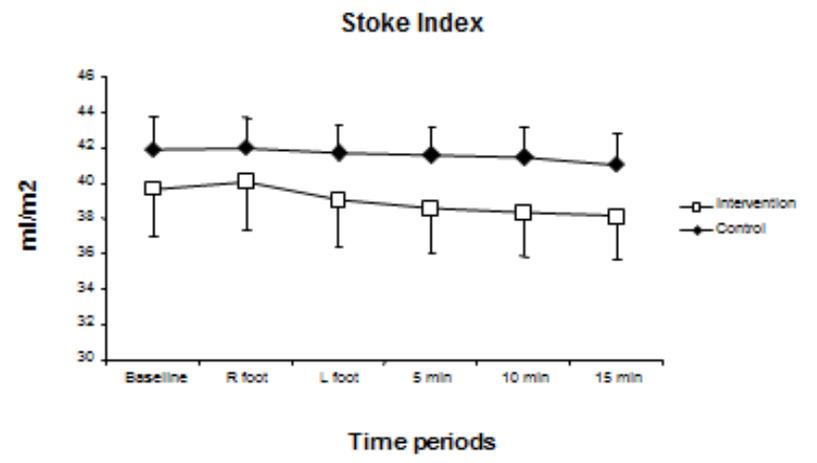


Fig 5.8

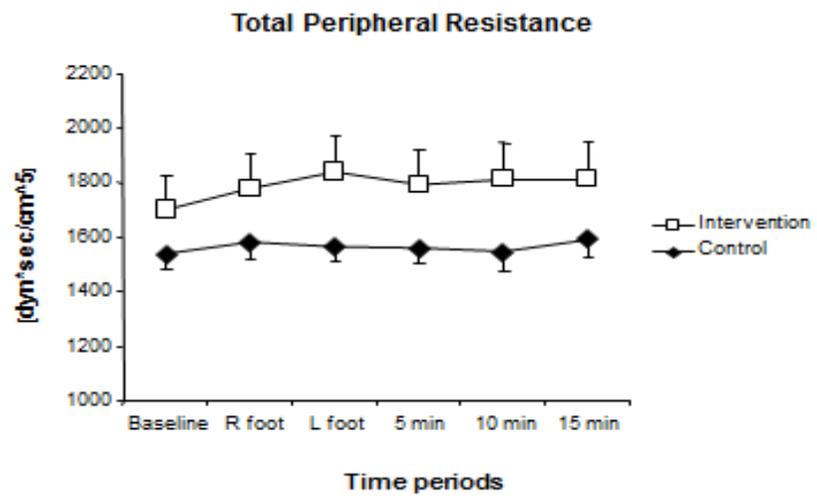


Fig 5.9

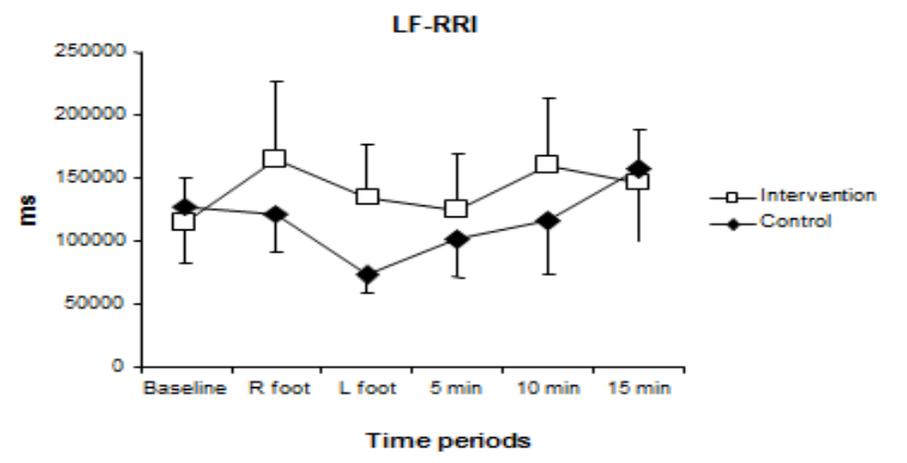


Figure 5.6 – 5.9. ANOVA GLM comparison of SI, SV, TPR and LF-RRI across the six recorded data blocks. The white square points are the intervention group means, the diamond black points are the control group means for each period. The error bars show Standard Error of Mean (SEM)

Fig 5.10

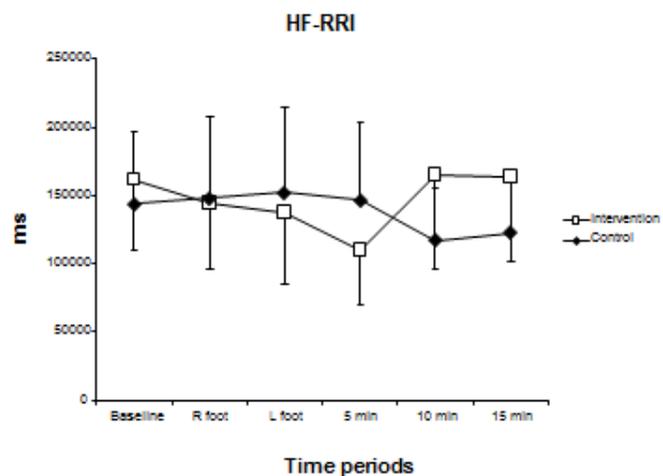


Fig 5.11

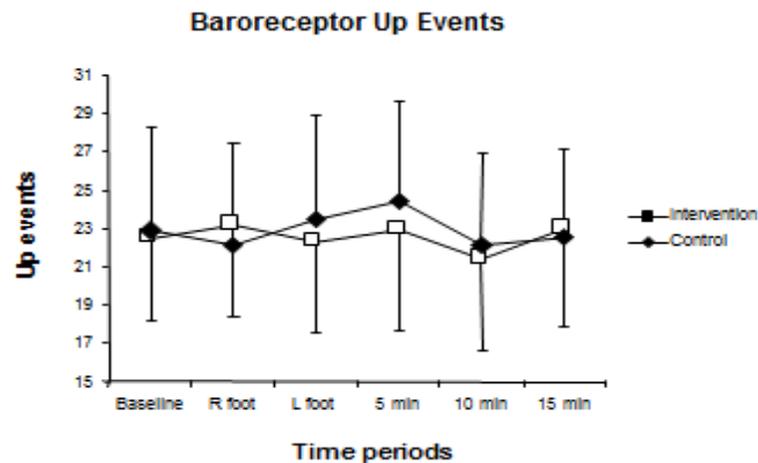


Fig 5.12

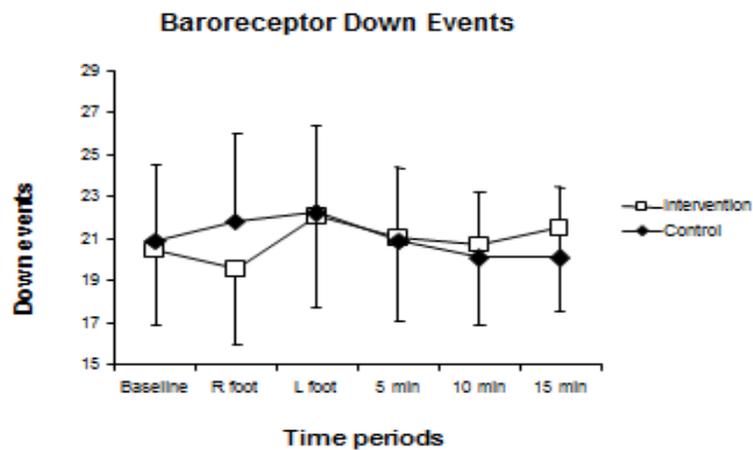


Figure 5.10 – 5.12. ANOVA GLM comparison of HF-RRI, BarUpEv, BarDwEv, across the six recorded data blocks. The white square points are the intervention group means, the diamond black points are the control group means for each period. The error bars show Standard Error of Mean (SEM)

Fig 5.13

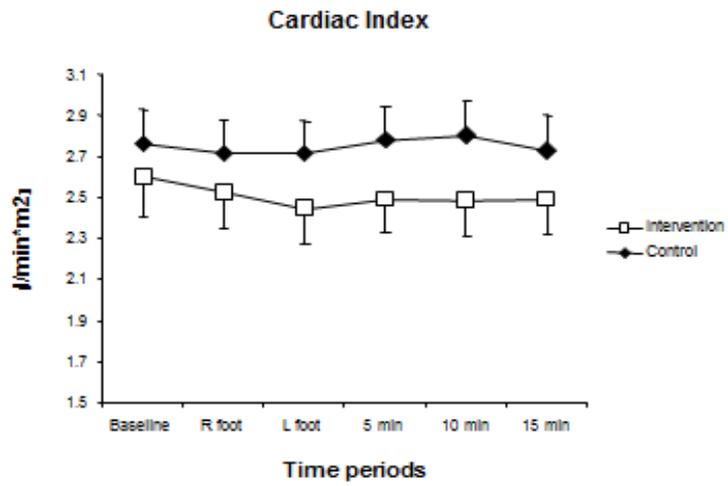


Fig 5.14

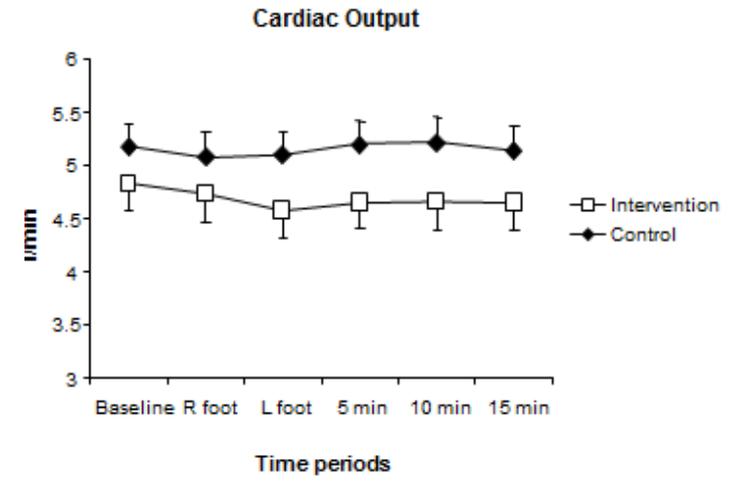


Figure 5.13 – 5.14. ANOVA GLM comparison of Cardiac Output and Cardiac Index across the six recorded data blocks. The white square points are the intervention group means, the diamond black points are the control group means for each period. The error bars show Standard Error of Mean (SEM)

5.3.2. Subjective outcome results

State anxiety: Transient state anxiety was assessed by the SAI tool (figures 5.15. and 5.16). Results suggest that the reflexology treatment reduced post treatment state anxiety in both the intervention group (pre-test mean 33.5; SD 5.34; CI = +/- 2.7 vs. post-test mean 24.3; SD 4.3; CI +/-2.17, $p = 0.0001$) and control group (mean 33.8; SD 7.3; CI =/- 3.7 vs. mean 24.1; SD 3.9; CI +/- 2.0, $p = 0.0001$) with no significant post-treatment difference between the two groups. This suggested that the two treatments were adequately standardised in terms of relaxation effect. Furthermore, sub-group analysis found no individual significant outcome differences in STAI pre and post-test scores between the two therapists indicating adequate standardisation of relaxation effects of massage between the two therapists.

Transient pain: Transient pain was assessed using a Visual Analogue Scale (VAS) (figure 5.17). The subjective VAS levels of treatment discomfort were very similar for both groups, intervention group (post-test mean 3.9 mm; SD 4.2; CI +/- 2.1) and control (mean 2.8 mm; SD 3.4; CI +/- 1.7). Furthermore, sub-group analysis found no individual significant outcome differences in VAS scores between the two therapists, indicating that the pressure of massage was adequately standardised between the two therapists and between the two treatments.

Fig 5.15

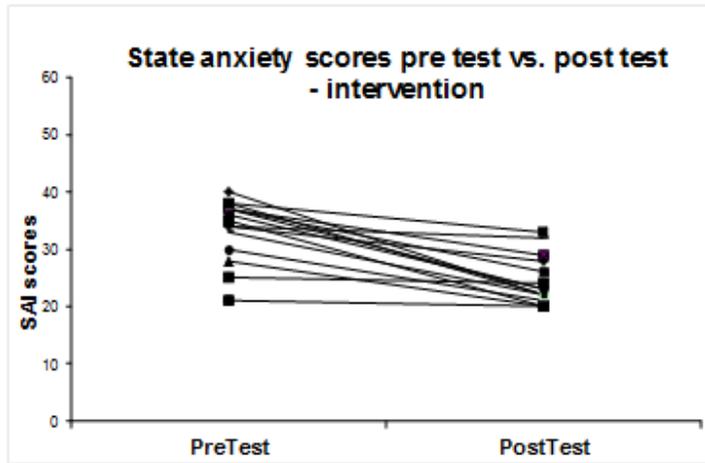


Fig 5.16

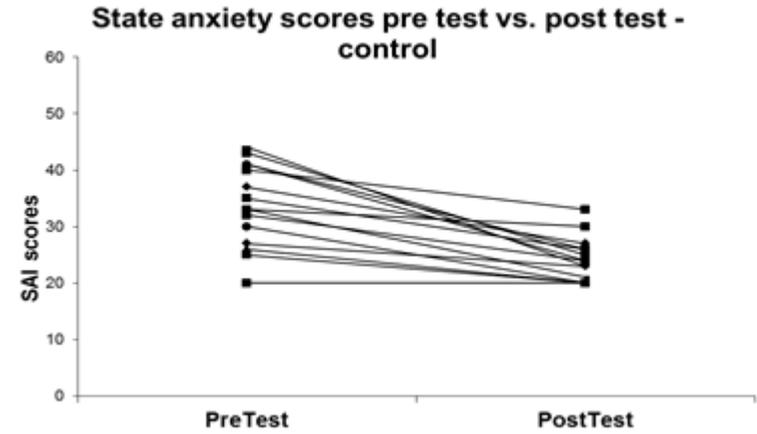


Fig 5.17

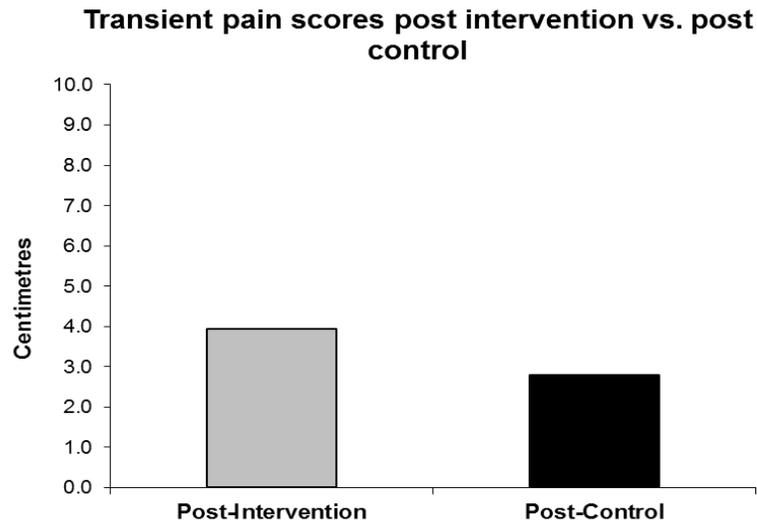


Figure 5.15 – 5.16. Transient anxiety pre and post-test scores as measured by the SAI for the intervention and control group

Figure 5 17. Comparison of transient pain pre and post-test visual analogue scale scores

Table 5.5. This table shows the mean and standard deviation (SD) data for each five minute recording period.

Results								
Cardiovascular measurement	Baseline	Right foot	Left foot	5 mins	10 mins	15 mins	GLM F value (Group * Time) overall	GLM P value (Group * Time) overall
HR Forefoot	66.7 (9.9)	64.2 (9.1)	63.7 (8.6)	65.5 (7.8)	65.7 (7.7)	66.0 (7.9)	1.81	0.123
HR Heel	66.3 (9.4)	65.4 (10.8)	65.5 (10.4)	67.2 (9.8)	67.5 (10.8)	67.3 (10.1)		
sBP Forefoot	132.9 (16.4)	134.7 (17.2)	134.3 (16.8)	134.1 (14.9)	134.0 (14.6)	133.9 (16.0)	0.40	0.847
sBP Heel	129.8 (10.7)	131.2 (10.2)	130.2 (10.9)	132.6 (11.1)	131.1 (14.3)	131.8 (14.8)		
dBp Forefoot	84.9 (13.9)	86.4 (14.1)	86.5 (13.9)	86.5 (12.4)	86.3 (12.0)	86.7 (12.6)	0.32	0.897
dBp Heel	84.1 (9.4)	85.6 (9.6)	84.3 (9.7)	85.6 (10.0)	83.9 (13.1)	84.3 (14.3)		
mBP Forefoot	99.2 (13.5)	101.4 (14.4)	101.5 (14.2)	101.3 (12.4)	101.2 (12.0)	101.7 (12.7)	0.21	0.958
mBP Heel	97.4 (9.0)	98.9 (9.1)	98.3 (9.6)	99.7 (9.4)	98.1 (12.3)	98.7 (13.4)		
SV Forefoot	74.0 (18.7)	75.1 (18.3)	72.9 (18.1)	72.3 (17.7)	71.7 (17.9)	71.4 (17.3)	1.24	0.299
SV Heel	78.2 (12.2)	78.3 (10.9)	78.1 (10.3)	77.7 (10.9)	77.5 (11.4)	76.7 (12.8)		
SI Forefoot	39.6 (11.3)	40.1 (11.2)	39.0 (11.0)	38.5 (10.4)	38.3 (10.3)	38.1 (10.2)	1.33	0.261
SI Heel	41.9 (8.5)	42.0 (8.0)	41.7 (7.5)	41.6 (7.8)	41.5 (8.0)	41.1 (8.5)		
CO Forefoot	4.8 (1.1)	4.7 (1.1)	4.6 (1.1)	4.6 (1.0)	4.7 (1.1)	4.6 (1.1)	2.33	0.051
CO Heel	5.2 (1.0)	5.1 (1.0)	5.1 (0.9)	5.2 (1.0)	5.2 (1.0)	5.1 (1.0)		
CI Forefoot	2.6 (0.7)	2.5 (0.7)	2.4 (0.7)	2.5 (0.6)	2.5 (0.7)	2.5 (0.7)	2.56	0.035
CI Heel	2.8 (0.6)	2.7 (0.6)	2.7 (0.6)	2.8 (0.6)	2.8 (0.7)	2.7 (0.7)		

TPR Forefoot	1703.1 (592.7)	1782.5 (606.5)	1842.9 (610.1)	1797.3 (548.8)	1812.7 (597.3)	1816.3 (585.1)	1.15	0.342
TPR Heel	1534.5 (407.9)	1584.2 (435.5)	1565.4 (404.0)	1562.3 (431.1)	1546.4 (505.7)	1594.6 (591.5)		
RRI Forefoot	925.1 (146.5)	959.0 (143.1)	964.4 (136.6)	935.8 (117.0)	932.9 (120.5)	928.7 (124.3)	0.96	0.449
RRI Heel	926.7 (131.2)	947.7 (161.2)	943.1 (153.0)	916.6 (137.0)	915.1 (147.0)	917.2 (143.6)		
*BarUpEvForefoot	22.4 (16.6)	23.2 (18.1)	22.3 (18.1)	22.9 (19.9)	21.4 (18.2)	23.0 (19.7)	0.33	0.893
BarUpEvent Heel	22.9 (20.1)	22.2 (19.8)	23.5 (20.4)	24.4 (19.8)	22.1 (18.1)	22.5 (17.6)		
BarDwEv Forefoot	20.5 (13.7)	19.6 (13.9)	22.1 (16.7)	21.0 (15.4)	20.7 (14.6)	21.5 (15.3)	1.06	0.392
BarDwEvHeel	20.9 (13.9)	21.8 (15.9)	22.3 (15.8)	20.9 (13.4)	20.1 (11.7)	20.1 (12.8)		

*All data expressed as mean, standard deviation (SD)

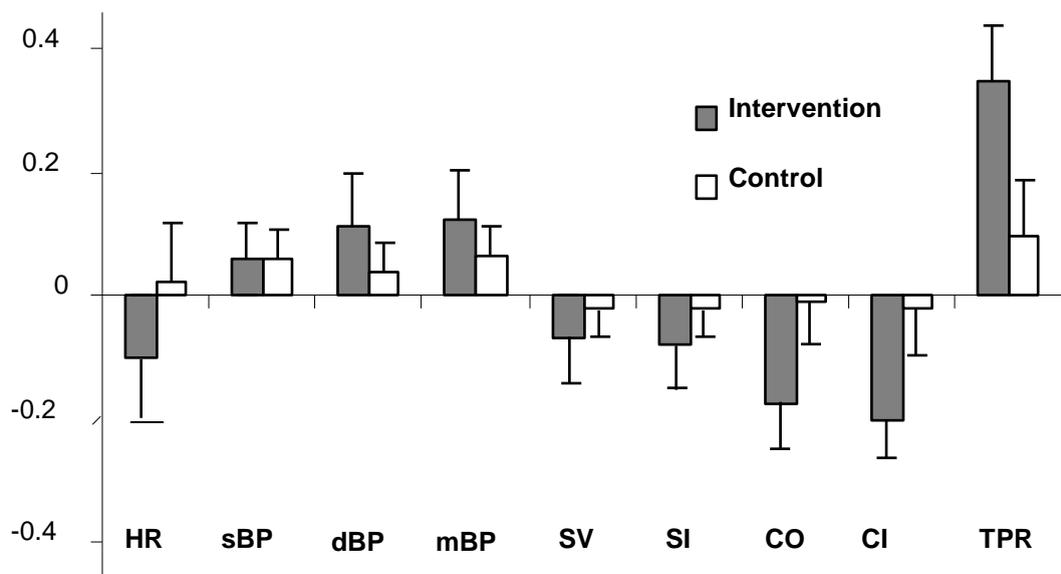


Figure 5.18 **Area under the curve graph**

Area under the curve histogram for main hemodynamic parameters, heart rate (HR);, systolic blood pressure (sBP), diastolic blood pressure (dBP), mean blood pressure (mBP), stroke volume (SV), stroke index (SI), cardiac output (CO), cardiac index (CI), total peripheral resistance (TPR); comparing forefoot reflexology (grey bars) (control) and heel reflexology (white bars) (intervention). This graph shows the overall trend direction in each haemodynamic parameter.

5.4. Discussion

This is the first double-blind randomised controlled study to examine whether there are any specific haemodynamic benefits, product quality or safety issues associated with reflexology treatment to the area of the feet thought to be associated with the heart in healthy volunteers. There were no adverse events and the study was well tolerated by all participants. This study showed that there is a small change in cardiac index when reflexology massage is applied to the upper part of the left foot (intervention). In contrast, there was no difference in cardiac index when the lower half of either foot (control) or the upper half of the right foot was massaged using the same reflexology techniques. There were no significant changes in any other parameters. During the intervention left foot treatment (LFT), 10 subjects had a reduction in CI compared to baseline, one subject increased CI and four maintained the same CI as baseline. In contrast, during the control LFT, five subjects had a reduction in CI compared to baseline, six subjects maintained the same CI as baseline and four subjects increased CI compared to baseline. The precise mechanism which caused the drop in CI during the intervention remains uncertain. The normal range of cardiac index is 2.6 - 4.2 l/min per square meter (m²) (209). The mean reduction in the Forefoot group was 0.15 l/min*m² during the left foot intervention.

In this study, the reduction in CI seems to be associated with an increase in total peripheral resistance and a drop in heart rate. The drop in heart rate is not a typical compensatory mechanism for falling cardiac output. And if an increase in total peripheral resistance was due to an increase in sympathetic stimulation (e.g. due to noxious stimulus) then one would expect an increase in heart rate which did not occur. In extreme cases of increased afterload (e.g. cross clamping of the aorta) there is a reflex reduction in heart rate and cardiac output (210)

but it seems unlikely that similar mechanisms are involved in this volunteer group. Measurement of anxiety and pain (SAI and VAS respectively) indicated that both treatments were similar in terms of perceived effect by the subject, neither being significantly more relaxing (anxiety reducing) or painful than the other. Thus, the apparent trend towards a reduction in heart rate in the context of reduced cardiac output and a trend to raised total peripheral resistance was not caused by a noxious experience or adverse clinical event. Therefore reflexology massage to the upper half of the left foot was associated with a specific change in cardiac index of the heart. And the global location where the effect was measured appeared to be consistent with the claims of the majority of the most popular published reflexology foot maps, which put the heart reflex point somewhere within this same region. Although the precise locations vary, this original Ingham map heart positions the heart reflex point in the left foot forefoot region (211), as does the AoR foot map (212) and the BRA map (213). Therefore, the study findings suggest that specific changes did occur in selected haemodynamic parameters, quite distinct from non-specific massage components, such as physical touch, therapeutic exchange and placebo effects, in volunteers receiving reflexology treatment applied to discrete areas of their feet which are thought to correspond to the heart (intervention) compared with reflexology applied to other areas of the foot which are not (control).

It was not clear why the baseline differences occurred between the two groups. Impedance cardiography methodological guidelines recommend stabilisation periods between times of electrode attachment to beginning of data collection, from 0 minutes (start recording data as soon as clear signals produced), to 10 minutes prior to data collection (180;181). On this basis, it was assumed that allowing 20 minutes from attachment of electrodes and establishment of clear signals, to beginning of data recording, would be sufficient to allow the subjects haemodynamic parameters to stabilise within typical ranges. However as ANOVA

GLM analysis was run on each group data separately in order to evaluate differences between patterns of treatment *across time* under the *same* condition, the consultant statistician Ms Howie confirmed that the chance baseline differences between the three conditions at baseline did not affect the intra-group analysis for specific haemodynamic differences in linear trends across time periods pre, during of post the left or right foot forefoot treatments (195;214).

The study findings are consistent with two other short-term studies which also suggest a specific haemodynamic effect in reflexology, related to changes associated with organ reflex points. Sudemeier et al reported statistically significant changes in resistive index of the renal arcuate artery when the kidney foot point was massaged (92). Mur et al found significant changes in the mesenteric artery resistive index when the intestinal point was massaged (89). No such change in resistive index occurred when control or unrelated points were touched in either study. One recent study suggested a somatotopic relationship between distinct reflex point treatment and corresponding cortical activity using fMRI techniques (4;215). However the cortical activity was recorded in the left hemisphere even though the operator delivered the stimulation to the reflex point areas on the right foot. This, appears to contradict the fundamental reflexology tenet that assumes that the left foot affects the left side of the body and the right foot, the right side

With regards to Inghams claim that reflexology massage to the heart reflex point specifically and beneficially increases blood supply to the heart (6), the study results are inconclusive. The coronary blood supply comes from the left and right coronary arteries. The coronary circulation through these arteries delivers a much higher level of oxygen to its tissues due to the high metabolic demands of the heart. This is achieved by the coronary blood flow being

around ten times larger per gram of tissue than the rest of the body (156;216). This ratio of workload to coronary blood flow rates increases proportionally as and when the heart tissue increases its workload, mainly through the action of vasodilators released by the myocardium tissues (156). Heart tissue perfusion is at its lowest during systole as the coronary blood vessels are compressed by the contracting heart muscle, which means that perfusion occurs primarily during diastole, when the heart muscle is relaxed (216). At rest the vascular tone of these arteries is maintained through innervation by the sympathetic nervous system. In this study, there was no change in sympathetic or parasympathetic tone indicated by heart rate variability and baroreceptor variability suggesting autonomic parasympathetic involvement leading to increased vasodilation of the arterial tone. And although peripheral resistance appeared to increase during the intervention LFT, the study findings showed no systemic change in sBP, dBP or mBP to indicate compensatory vessel compliance changes. However there was a trend towards a reduction in heart rate during the LFT intervention which did not occur in the RFT intervention or control groups. Therefore as perfusion occurs primarily during diastole and there was an uncompensated, transient fall in cardiac index and trend indicating a transient reduction in heart rate, it is possible to speculate that the coronary arteries had an increased arterial perfusion refill time which corresponded with reflexology massage being applied to the area thought to contain the heart reflex point.

The pilot study addressed the methodological limitations of previous research by using validated measuring equipment and adequate control for non-specific placebo response with a randomised double blind controlled reproducible study design. Several other reflexology studies have used cardiovascular outcomes, but these studies used a whole systems approach to the reflexology intervention (with the author often delivering the treatment) and delivered reflexology as a complex, multi-component intervention with the control being either foot massage, resting supine, or usual care, which did not allow any specific cardiovascular effect to

reveal itself (88;95). One of the most common criticisms of complementary and alternative medicine (CAM) is that any beneficial therapeutic effect is largely due to a placebo response (217;218). The House of Lords Select Committee report (21) and the King's Fund report (25) recommend that any CAM treatment claim should be evaluated by controlled trials in order to determine evidence of clinical and cost-effectiveness beyond that of placebo. And the recent ASA Cap Code change requires that any specific therapeutic claims advertised on websites be validated. Like many complex CAM interventions, reflexology research presents methodological challenges if the intention is to isolate a specific, clinically relevant and cost-effective ingredient as a distinct component. Non-specific components such as the compassion of the therapist, the treatment environment, the act of lying supine and expectation of the receiver also potentially contribute to the overall treatment effect, as does the relaxing effects of simple foot massage (111;140). This study intentionally compared reflexology treatment to one area of the foot in comparison to another using a repeated measures double-blinded design and reflexology naïve subjects, so that all the non-specific components would be present in both interventions.

5.5. Conclusion

In conclusion, this double-blind randomised controlled study was extremely useful in examining whether there are any specific haemodynamic benefits, product quality or safety issues associated with reflexology treatment to the area of the feet thought to be associated with the heart in healthy volunteers. Reflexology has not been previously rigorously tested for any specific hemodynamic effect during treatment. This is despite the reflexology claim that massage to specific points of the feet increases blood supply to referred or 'mapped' organs in the body. This study showed that there is a small change in cardiac index when

reflexology massage is applied to the upper part of the left foot (intervention). There did not appear to be any potential risk of adverse effects associated with the intervention effect and the specific haemodynamic effects and trends were small. The study also enabled the novel protocol developed for this thesis to be tested, including the subjective measurement tools used to ensure that both treatments were standardised between both therapists for treatment related transient relaxation and pain effects. The pilot study findings justified the thesis purpose of studying the acute (immediate) specific haemodynamic effects of reflexology in patients with chronic heart failure and coronary artery disease, to see if the specific effects on cardiac index and the trend in cardiac output, heart rate reduction and peripheral resistance increase would be repeated in these two patient groups. As the specific and non-specific haemodynamic effects and trends were small and therefore unlikely to be harmful, it was assumed to be safe to examine the effect in the two cardiac patients groups. The next two chapters report on the two subsequent studies undertaken in patients with chronic heart failure and patients with coronary artery disease.

Chapter 6

Reflexology in patients with chronic heart failure

Jones J, Thomson P, Howie K, Lauder W, Leslie SJ. Reflexology has no acute (immediate) haemodynamic effect in patients with chronic heart failure: a double blind randomised controlled trial (*Submitted to European Journal of Cardiovascular Nursing, Nov 2012*)

Chapter 6

Reflexology in patients with chronic heart failure

6.1. Study aim and research questions

This experiment was the second in the series of three RCT's devised to address research aim 3. In this study, the aim was to examine whether there are any specific haemodynamic benefits, product quality or safety issues associated with reflexology treatment to the area of the feet thought to be associated with the heart in patient with chronic heart failure (CHF) due to left systolic ventricular dysfunction (LVSD), using a double blind randomised controlled trial design.

The following two research questions were devised in order to address research aim 3.

Q6. Does the reflexology intervention developed for healthy volunteers, using a double blind randomised control trial, result in specific changes in the haemodynamic parameters of cardiac patients with CHF due to LVSD?

Q7. If a specific haemodynamic effect is detected, are there any risks or benefits associated with reflexology treatment to the area of the feet through to be associated with the heart in cardiac patients with CHF due to LVSD?

6.2. Methods

6.2.1. Design

Randomised controlled double blind repeated measures study.

6.2.2. Study participants

Model-validity requirements involved the development of clear selection criteria for the CHF patients with LVSD for this study. The methodology took into account comparable disease categorisations from both the medical and reflexology perspective in order to meet reflexology model validity requirements, reduce error variance and to ensure homogeneity within both constructs (219). Model validity requires that the participant disease categorisation is congruent with the context of the CAM therapy under investigation so that the diagnosis and outcomes accurately represent the practice being investigated (128). On this basis, the group selection criteria will now be described, and the disease classification from both the medical and reflexology perspective given. It was important to understand the pathophysiology of CHF due to LVSD in order to anticipate how the compensatory mechanisms inherent in this condition could affect the study outcomes.

6.2.2.1. Disease categorisation from the medical perspective

Chronic heart failure (CHF) is a complex syndrome, characterised by the chronic inability of the heart to maintain adequate tissue perfusion at a normal filling pressure (220). The heart fails when any structural or functional disorder impacts on the heart muscle to the degree that it becomes unable to maintain a sufficient arterial output to meet the demands of the body, regardless of whether the venous pressure is normal or not. This reduction in myocardial contractility results in a higher filling pressure and end-diastolic volume being required in order to maintain stroke volume (221). Left ventricular failure is commonly caused by ischaemic heart disease, either due to chronic ischemia or previous myocardial infarction. Other causes of left ventricular systolic dysfunction include dilated cardiomyopathy, (mediated by toxins, drugs, viral or familial), or end stage aortic or mitral valve disease. Heart failure can occur due to diastolic dysfunction most commonly secondary to excessive afterload due to hypertension

(222). Right ventricular failure is most commonly caused by pulmonary hypertension due to lung disease, or by chronic failure of the left ventricle which persistently increases the workload of the right ventricle until it too loses contractility (221). CHF patients with LVSD experience symptoms of exertional breathlessness, fatigue and signs of fluid retention (222) and the severity of these symptoms is stratified according to the New York Heart Association (NYHA) classification. The NYHA functional classes are used as symptom severity classification guidelines in the National Institute of Clinical Excellence guidelines for diagnosis and management of chronic heart failure in primary and secondary care (223) (table 6.1).

Table 6.1. **New York Heart Association Classification of heart failure symptoms** (223)

Class	Symptoms
I	No limitations. Ordinary physical activity does not cause fatigue, breathlessness or palpitation. (Asymptomatic left ventricular dysfunction is included in this category).
II	Slight limitation of physical activity. Such patients are comfortable at rest. Ordinary physical activity results in fatigue palpitation breathlessness or angina pectoris (symptomatically “mild” heart failure)
III	Marked limitation of physical activity without discomfort. Although patients are comfortable at rest, less than ordinary physical activity will lead to symptoms (symptomatically “moderate” heart failure)
IV	Inability to carry out any physical activity without discomfort. Symptoms of congestive cardiac failure are present even at rest. With any physical activity, increased discomfort is experienced (symptomatically “severe” heart failure)

As heart failure progresses, various complex neuro-humoral responses occur in order to maintain cardiac output (220). These mechanisms maladaptively respond to the reduction in

myocardial contractility that occurs in heart failure by increasing fluid retention and raising venous pressure through various means. The renin-angiotensin-aldosterone hormonal system attempts to compensate for reduced left ventricular ejection fraction by increasing systematic pressure in order to maintain vital organ perfusion (224). When a reduced circulating blood volume is detected by the kidneys, renin is secreted into the circulating bloodstream. Following the conversion of angiotensinogen and angiotensin I, the vaso-active peptide angiotensin II is produced. This acts as a power vasoconstrictor, resulting in increased blood pressure. Angiotensin II also stimulates the secretion of aldosterone hormone, which in turn, increases the renal reabsorption of sodium and water into the blood in order to increase circulating fluid volume (225). Chronic heart failure is also often associated with an excessive sympathetic nervous system venomotor response. As the sympathetic nerves attempt to innervate blood vessels to compensate for the reduced left ventricular ejection fraction, norepinephrine diffuses from nerve cells into the blood and epinephrine is released by the adrenal medulla (226). Circulating norepinephrine and epinephrine cause a beta-adrenoceptor mediated increase in heart rate and arterial vasoconstriction (227). The anti-diuretic hormone vasopressin, a peptide hormone formed in the hypothalamus and released from the posterior pituitary gland, acts on the kidneys and blood vessels to decrease urine formation. This in turn maintains circulating fluid volumes in compensation for the reduced cardiac output (228). Vasopressin also binds to V1 receptors in the smooth muscle of the vascular walls to cause vasoconstriction (229). Increasing levels of circulating angiotensin II, vasopressin and shearing forces act on the vascular endothelium and lead to Endothelin being released from endothelial cells. Endothelin is a powerful vasoconstrictor (230). Although Endothelin is normally kept in balance by other mechanisms, increased circulating levels have been associated with chronic hypertension and heart failure (220). Furthermore, recent evidence suggests that variants in neuro-hormonal genes may be involved in the pathophysiology of heart failure (231). For

example, genetic polymorphisms of the renin-angiotensin-aldosterone system may mean that each individual responds to heart failure in a unique way (232).

6.2.2.2. Disease categorisation from the reflexology perspective

The five reflexology educational texts sampled made reference to 'chronic heart disease' (43;82), 'heart disease' (44) and 'angina' (233). No further sub-group disease treatment stratification was given for any specific cardiovascular symptom within the reflexology construct, except for one mention of tachycardia (43). Therefore the reflexology construct appeared to have no further sub-groups within the cardiac disease classification that would render the study recruitment criteria for CHF patients with LVSD non-homogenous in terms of reflexology. On this basis, the following recruitment criteria successfully maintained a degree of homogeneity of the patients from both the conventional medical and reflexology perspectives.

6.2.3. Patient population

Any CHF patient attending the Raigmore Hospital cardiology department at any time during the past five years for diagnosis and/or treatment of LVSD and who fulfilled the criteria listed below, were considered appropriate to approach for recruitment to the study. However for female volunteers, only post-menopausal women were approached, as evidence suggests that circulating oestrogen and progesterone increase during the luteal phase of the menstrual cycle and these hormones have been found to affect arterial compliance and stiffness (204;205). The influence of these sex hormone changes during the menstrual cycle meant that there would have been a potential for a spurious hormonal-related haemodynamic influence on systolic and/or diastolic BP trends in pre-menopausal women which could have skewed the haemodynamic results. Strict medication exclusion criteria for the chronic heart failure

patients were deliberately not applied. This was because it was anticipated at the start that despite certain cardiovascular pharmacological therapies in the cardiac patients potentially diluting or masking a potential specific reflexology haemodynamic effect. However, as the aim of the study was to examine whether there are any specific haemodynamic benefits, product quality or safety issues associated with reflexology treatment to the area of the feet thought to be associated with the heart in patient with chronic heart failure (CHF), it was hoped to be able to generalise the results as widely as possible to include those on standardised drug regimes. With this 'real-world' generalisability, the study findings could then provide new scientific data to enable a large proportion of chronic heart failure patient purchasers of reflexology and their clinicians to finally assess reflexology safety. On this basis, the following recruitment criteria were applied:

Recruitment criteria for patients with chronic heart failure

Inclusion criteria:

1. Able to give informed consent
2. Patients diagnosed with Heart Failure due to LV systolic impairment
(as identified in patients notes)
3. Documented left ventricular dysfunction by echo-cardiogram
(mod/severe or EF <35%) (as identified in patients notes)
4. Able to give informed consent
5. Male >18 years old or post-menopausal women
6. Symptoms of heart failure (breathlessness or fatigue) NYHA Grade II
or III (as identified in patients notes)
7. Clinically stable for 3 months
8. Normal lower limbs (no previous operations including varicose veins)

9. Abstinence from tobacco and caffeine-containing drinks for at least 12 hours prior to the study (to eliminate any confounding effects of caffeine or tobacco stimuli on the central nervous system)
10. Abstain from food for 4 hours before the study (in order to eliminate any effects of digestion on blood pressure rates)
11. Reflexology naive (i.e. have never had training in or received reflexology therapy)

Exclusion criteria:

1. Permanent, persistent or paroxysmal atrial fibrillation (AF) (The TFM manufacturer instructions state that patients with AF will not produce reliable results)
2. Pacemaker in situ (contraindicated with the TFM)
3. Admission to hospital within the previous 3 months for cardiology care
4. Participation in pharmacological study within the previous 3 months

6.2.4. Recruitment process

All eligible patient volunteers were identified by replying to a letter of invitation sent via their clinician. The letter of invitation process was as follows. The researcher gave a number of study recruitment letter packs and an outline of the study aims, protocol and inclusion/exclusion criteria to the Raigmore cardiology consultant team. The packs contained 3 documents, 1) a letter of introduction, explaining the reason for contact (Appendix 5), 2) a Patient Information Sheet outlining the trial purpose and design (Appendix 3) and 3) a "Consent to Contact" form (Appendix 4).

Each letter had the name of the relevant cardiology consultant as sender and the patient name field blank at this point. Participating cardiology consultants identified a number of suitable potential prospective volunteers from their clinic lists using the study eligibility criteria list and posted the appropriately addressed letters bearing their own name as sender. The letter explained to the recipient that there was a reflexology study taking place in the cardiology department of the Raigmore hospital and enquired as to whether the recipient was interested in obtaining any further information about participation in the study. If interested in receiving further information, the potential volunteer was directed to sign the "Consent to Contact" form and return it in the stamped addressed envelope provided. This form and the pre-paid envelope included were addressed to the researcher. Only upon receipt of the response letter did the researcher then approach the patient to discuss participation further and, if agreeable, gain informed consent from the volunteer. Informed consent procedures were strictly followed and written consent forms were signed before the volunteers were enrolled into the study (figure 5.1). As the cardiology team confidentially screened the patients for inclusion, to maintain patient confidentiality, it was not known how many were approached or screened for eligibility or the refusal rate. Only basic socio-demographic characteristics and clinical data (NYHA and medication data) were passed to the researcher.

6.2.5. The intervention

As described in Chapter 3 Methods, reflexology massage (using touch techniques unique to reflexology) applied solely to the areas on both feet known as the shoulder girdle within the reflexology foot map construct.

6.2.6. The control

As described in Chapter 3: Methods, reflexology massage (using touch techniques unique to reflexology) applied solely to the areas on both feet known as the pelvic and abdominal areas within the reflexology foot map construct.

6.2.7. Reflexology style and techniques

As described in Chapter 3: Methods, both therapists were trained at the International Institute of Reflexology (IIS), therefore the intervention and control treatments were formulated using used standardised Ingham touch techniques and principles. The therapists standardised both intervention and control treatment times (both lasted for 4.5 minutes), treatment pressure (light to medium) and depth of touch techniques (light to medium) – (as described in Chapter 3).

6.2.8. Background music

Background music was introduced in this experiment as previously described in Chapter 5, Healthy volunteer pilot study.

6.2.9. Outcomes measurements

See table 6.2.

Table 6.2. **Haemodynamic parameters used in the study** (As described in Chapter 3: Methods)

Haemodynamic parameter	Abbreviation	Method of measurement
Heart Rate	HR	Task Force Monitor (TF [®] M) impedance cardiography system
Diastolic blood pressure	dBp	TF [®] M impedance cardiography system
Systolic blood pressure	sBP	TF [®] M impedance cardiography system
Mean arterial blood pressure	mBP	TF [®] M impedance cardiography system
Stroke index	SI	TF [®] M impedance cardiography system
Stroke volume	SV	TF [®] M impedance cardiography system
Cardiac output	CO	TF [®] M impedance cardiography system
Cardiac index	CI	TF [®] M impedance cardiography system
Total peripheral resistance	TPR	TF [®] M impedance cardiography system
Baroreceptor up events	BarUpEv	TF [®] M impedance cardiography system
Baroreceptor down events	BarDwEv	TF [®] M impedance cardiography system
low-frequency component of heart rate variability	LF-RRI	TF [®] M 2 channel electrocardiogram function (ECG)
high-frequency component of heart rate variability	HF-RRI	TF [®] M 2 channel electrocardiogram function (ECG)

6.2.10. Anxiety and pain assessment

As described in Chapter 3: Methods, pre & post measurement of the subject's self-reported perceived state of anxiety and transient intra-treatment pain were assessed using The State Anxiety Inventory and a visual analogue scale (VAS) (182).

6.2.11. Sample size

Formal statistical advice on the power calculation for the study was sought from Ms Kate Howie, Statistical Consultant, Department of Computing Science and Mathematics, University of Stirling. As little was currently known about the magnitude of any specific effects of reflexology in CHF patients with LVSD, data were extracted from the pilot study for the power calculation. The pilot study data showed that cardiac index (a cardio-dynamic measure based on cardiac output that is indexed to the BSA of a patient) decreased significantly in the intervention group during the left foot treatment (LFT) block by $0.15 \text{ l/min}\cdot\text{m}^2$ (Baseline mean 2.6; standard deviation (SD) 0.75; 95% CI +/- 0.38 vs. LFT mean 2.45; SD 0.68; CI +/-0.35; $p = 0.003$). So in order to detect the recorded cardiac index difference of $0.15 \text{ l/min}\cdot\text{m}^2$ (Alpha = 0.05; assumed SD of paired differences = 0.14 with 0.8 power) a sample size of 9 would have been sufficient for the heart failure patients. Cardiac output, the actual clinical value from which cardiac index is derived, also decreased to a highly significant level in the intervention group during the LFT block (4.83; SD 1.07; CI +/-0.54 vs. 4.5; SD 1.06; CI +/- 0.54: $p= 0.007$) with a mean difference of 0.26 litres per min; (SD 0.32). As cardiac output represents the amount of blood the left ventricle ejects into the systemic circulation in one minute, and is the haemodynamic parameter from which cardiac index values are derived – the paired mean and SD data from this parameter was used to calculate both this study and the study involving patients with coronary artery disease. The power calculation (Minitab version 16.1.1.1,

Microsoft, Redmond, Washington, USA) determined that in order to detect a difference of 0.29 litres per min with 80% confidence and significance level of 0.05, 12 subjects would be required.

6.2.12. Location

As described in Chapter five, the study took place at the Highland Heartbeat Centre, Raigmore Hospital. The treatments were conducted in a quiet, draught-free room maintained at a constant temperature of 22-24 °C. The lighting was dimmed throughout the session.

6.2.13. Randomisation

As described in Chapter 3: Methods, the equal group random allocation was performed by a third party not involved with the study, using computer generated random numbers. Subjects were randomly allocated to either receive the intervention treatment at the first visit, followed by the control treatment at the second visit, or to receive the treatment schedule in the opposite way round (table 6.3). For the second visit, the subject was automatically assigned to the other treatment in order to act as their own control. The subject remained unaware of group allocation criteria throughout the study. The allocation list was handed directly to the two reflexology therapists in sealed opaque envelopes. The researcher did not have access to the allocation list until data analysis was complete.

Table 6.3 Treatment schedule random allocation list

Study Subject	Visit 1	Visit 2
1	Forefoot	Heel
2	Forefoot	Heel
3	Heel	Forefoot
4	Heel	Forefoot
5	Heel	Forefoot
6	Forefoot	Heel
7	Forefoot	Heel
8	Forefoot	Heel
9	Forefoot	Heel
10	Heel	Forefoot
11	Heel	Forefoot
12	Forefoot	Heel

6.2.14. Blinding

As described in Chapter 3: Methods, the study was double-blinded. Neither the reflexology-naive subjects nor researcher knew in which order the intervention or control treatment was delivered. The reflexologists worked behind a screen when delivering the reflexology so the researcher was not aware of the treatment order for each subject.

6.2.15. Pre-study requirements

As described in Chapter three: Methods, all volunteers were required to abstain from food for at least 4 hours beforehand and from tobacco and caffeine-containing drinks for at least 12 hours prior to attendance.

6.2.16. Protocol

An identical protocol was followed for this study as described in Chapter five: Healthy volunteer pilot study.

6.2.17. Ethics

The study was undertaken with the approval of the Research and Ethics Committee, University of Stirling, the North of Scotland Research Ethics Committee (NOSREC 11/AL/0009) and in accordance with the Declaration of Helsinki. Written informed consent was obtained from each patient before entry into the study.

6.2.18. Statistical analysis

Summary descriptive data were collected as socio demographic characteristics and clinical data (NYHA and medication data). Analysis of Variance (ANOVA) General Linear Model (GLM) statistical model to analyse the haemodynamic study data in order to determine whether there was any interaction between condition and time or between the times or conditions using the hypothesis of Subject * Group * Time. Furthermore, as also described in Chapter 3: Methods, planned comparison analysis using Tukey significance tests was used to identify in which part of the data a significant effect occurred (Minitab version 16.1.1.1, Microsoft, Redmond, Washington, USA). As in the analysis of the healthy volunteer data, assumptions of normality and homogeneity of variance were validated and an overall 5% significance level was used. As the post-test VAS scores were normally distributed, it was decided to compare the subjects post intervention and post control data using a paired 't' test statistical model (as described in Chapter three: Methods) (Minitab version 16.1.1.1, Microsoft, Redmond,

Washington, USA) (200). As the comparison of pre and post-test STAI scores data were also normally distributed and came from the same participants, the same statistical process was used on these data also (Minitab version 16.1.1.1, Microsoft, Redmond, Washington, USA).

6.3. Results

Three post-menopausal women, (mean age 64 ± 6.1 years) and 9 men, (mean age 71 ± 7.6) years with established CHF were recruited between July and September 2011 (table 6.4). All twelve completed both arms of the study (figure 6.1).

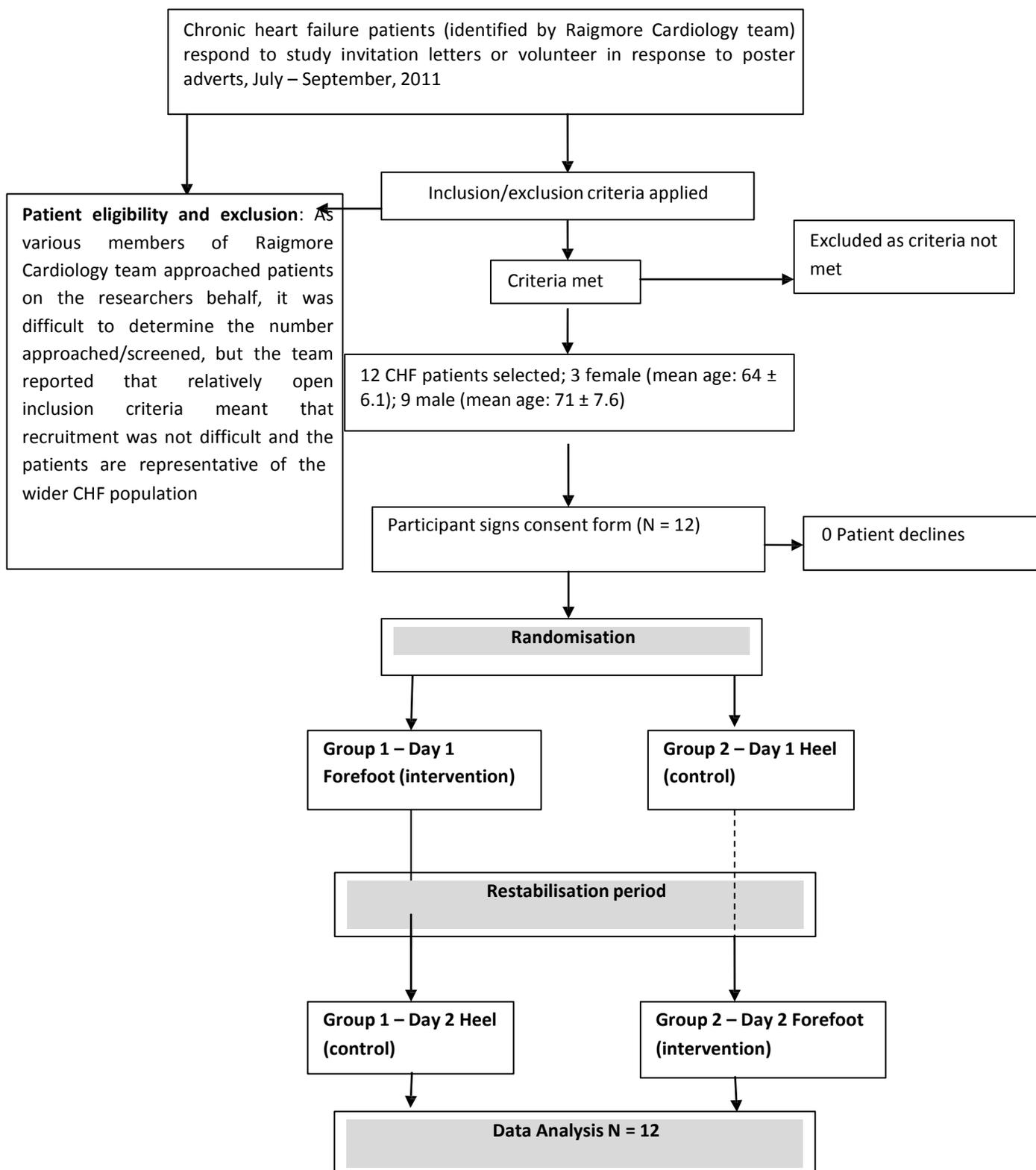


Figure 6.1. Summary flow chart

Table 6.4- Patient characteristics and medications

Patient	Sex	Age (years)	BMI	Cause of HF	NYHA	Drugs and dose *	Relevant co-morbidities†
1 1	M	65	37	Ischaemic	II	ASA75, Ator80, Bis5, Frus20, Met1000, FerS300	CAD, NIDDM, MI
2 4	M	63	32	Ischaemic	II	Per8, Frus40, Aml5, Bis2.5	EH, CAR
3 5	M	78	25	Ischaemic	II	Bis2.5, Frus40, Ator80, ASA300	CAD, CABG, NIDDM, MI
4 13	F	60	32	Idiopathic	II	Per8, Bis10, ASA75, Sim40, Frus40	HBP, CAR, CAD
5	M	58	30	Ischaemic	III	Ator80, Clo75, ASA75, Per4	MI, CAD, OB
6	M	77	21	Idiopathic	III	Warf, Nic20, ISM50, Frus80, Per2, Clo75	NI, HBP, PH, RHF, HBP
7 19	F	71	28	Ischaemic	III	ASA75, Nic40, ISM60, Bis1.25, Per8, Frus80, Ator80	CAD, HBP, VD, CABG
8 20	M	81	37	Ischaemic	III	Los75, Sim40, ASA75, Aten25, Frus40	COPD, CKD, ANG, HBP, CABG, OB
9 21	M	73	36	Ischaemic	III	ISM50, Spir25, ASA75, Bis1.25, Sim40, Nic10, Los50, Frus120	HC, HBP, MI, VS, ST
10	F	61	40	Idiopathic	II	ASA75, Ros5, Lis2.5, Ben2.5, Nic20	EH, ANG, ST

11	M	74	30	Ischaemic	II	ASA75, Clop75, Ator80, Per4, Aten25	MI, HBP, ANG, CAD
12	M	70	25	Ischaemic	II	ASA75, Ator80	MI,CAD

*Doses in mg except for digoxin (ug): Aspirin (ASA) , amlodipine (Aml), atenolol (Aten); Atorvastatin, (Ator); Bendrofluazide (Ben); Bisoprolol (Bis); Body mass index (BMI); Digoxin (Dig); Ferrous sulphate (FerS); Furosemide (Frus); Isosorbide mononitrate (ISM); Lisinopril (Lis); Losartan (Los); Metformin (Met); New York Heart Association (NYHA); Nicorandil (Nic); Simvastatin (Sim), Perindopril (Per); Rosuvastatin (Ros); Spironolactone (Spir); Warfarin (Warf).

†Angina (ANG); Coronary artery bypass graft (CABG); Cardiomyopathy (CAR); Coronary artery disease (CAD); Chronic kidney disease (CKD); Chronic obstructive pulmonary disease (COPD); Essential hypertension (EH); Hypercholesterolemia (HC); Hypertension (HBP); Pulmonary hypertension (PH); Previous MI (MI); Right sided heart-failure (RHF); Stent (ST); Type 1 Diabetes Mellitus (IDDM); Type 11 Diabetes Mellitus (NIDDM); Valvular heart disease (VD); Vasovagal syndrome (VS);

6.3.1. Results of outcome measurements

There was no statistically significant difference or overall trend noted in and of the haemodynamic parameters (table 5.6) in either the Forefoot or Heel conditions (all $p > 0.05$). The sub-group analysis found no individual significant outcome differences between the two therapists suggesting that the therapists' treatment deliver was adequately standardised. The forefoot LF-RRI baseline was significantly different from the heel group baseline ($p = 0.02$) (table 6.5).

Table 6.5. **Baseline variable differences between the intervention and control groups**

Outcome	Intervention	Control	p value
HR	67.5 (9.5)	68.3 (21.3)	0.797
dBP	76.3(11.6)	80.1(11.9)	0.155
sBP	122.4(15.8)	126.7(16.2)	0.382
mBP	93.8(13.1)	97.7(14.1)	0.163
SV	58.4(13.0)	56.5(11.7)	0.205
SI	31.9(6.5)	32.4(7.7)	0.254
CO	3.8(0.6)	3.7(0.6)	0.999
CI	1.8(0.2)	1.8(0.2)	0.844
TPR	2002.3(299.5)	2118.7(298.9)	0.054
BarUpEv	15.0 (11.9)	13.2 (10.6)	0.999
BarDwEv	16.3 (12.2)	13.1 (11.3)	0.799
LF-RRI	596.8 (649.4)	281.8 (309.4)	0.017* *
HF-RRI	614.2 (809.41)	466.3 (628.6)	0.913
*All data expressed as mean, standard deviation (SD)			
* * indicates significance at the $p < 0.05$ level			

Fig 6.2

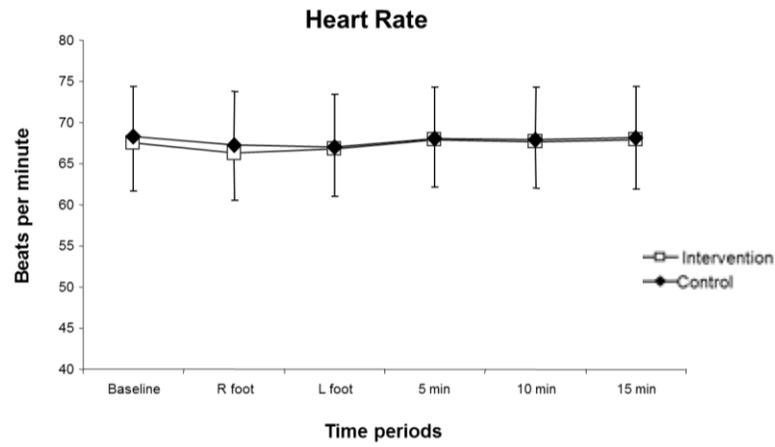


Fig 6.3

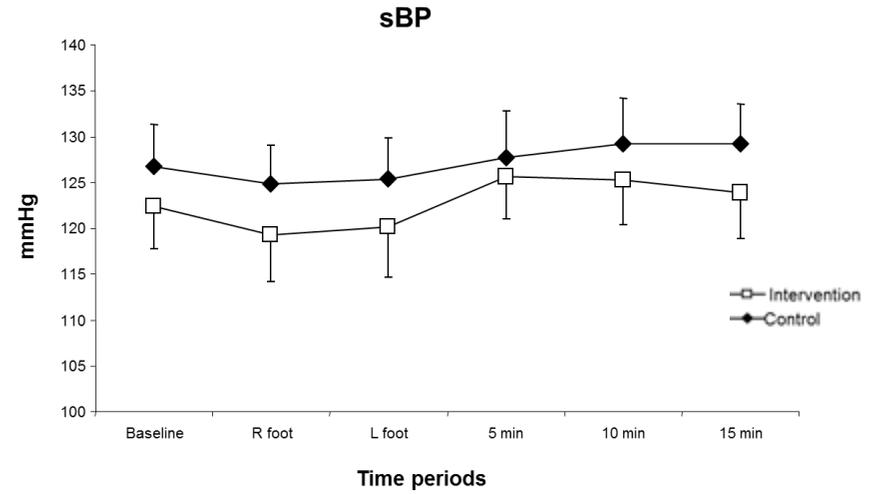


Fig 6.4

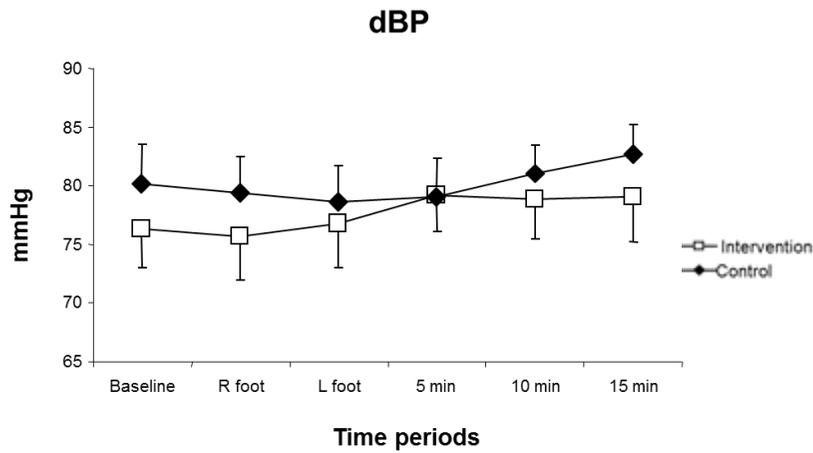


Fig 6.5

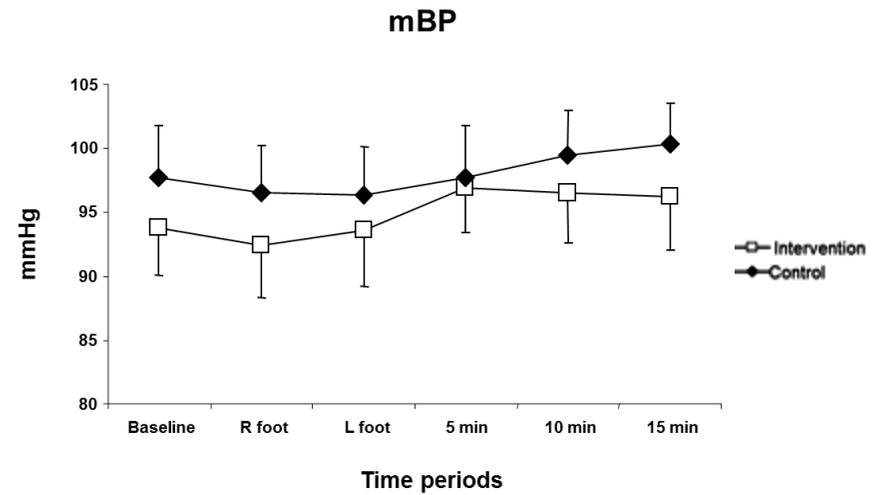


Figure 6.2 – 6.5. ANOVA GLM comparison of HR, sBP, dBP and mBP across the six recorded data blocks. The white square points are the intervention group means, the diamond black points are the control group means for each period. The error bars show Standard Error of Mean (SEM)

Fig 6.6

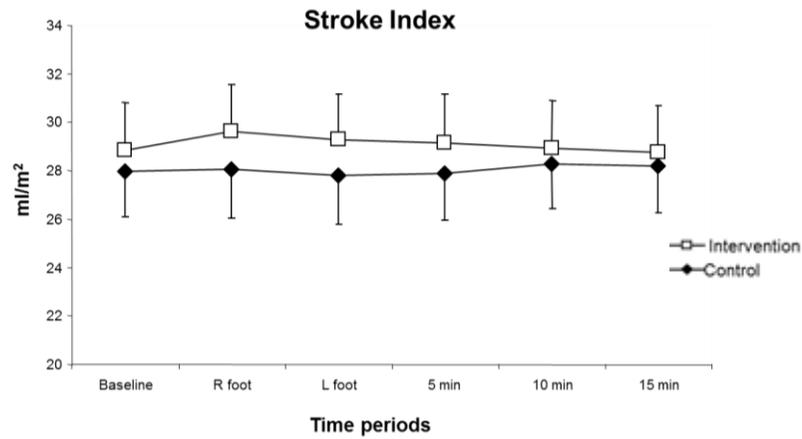


Fig 6.7

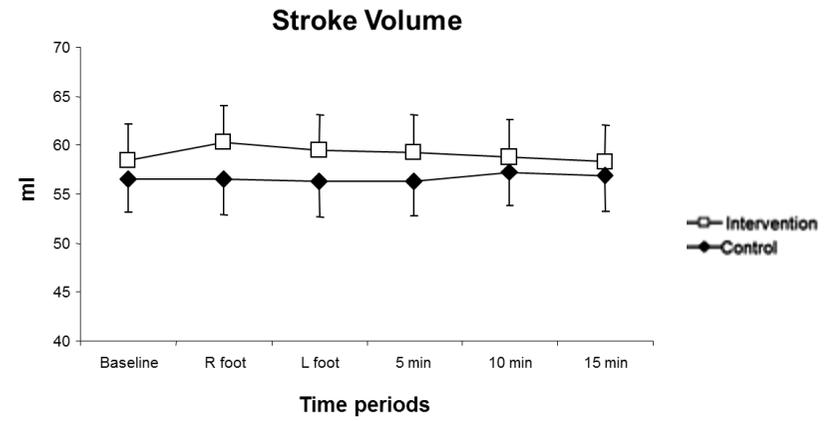


Fig 6.8

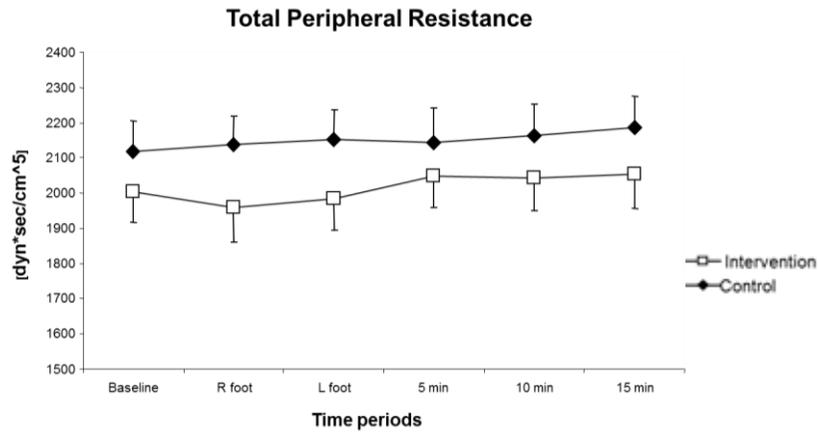


Fig 6.9

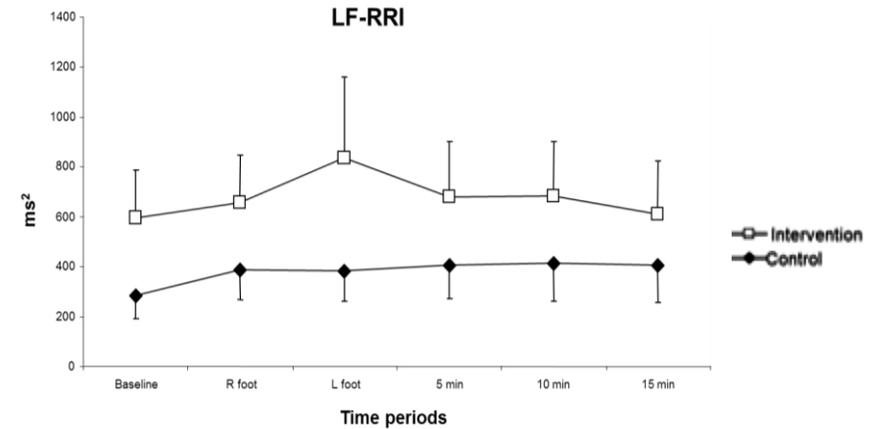


Figure 6.6 – 6.9. ANOVA GLM comparison of SI, SV, TPR and LF-RRI across the six recorded data blocks. The white square points are the intervention group means, the diamond black points are the control group means for each period. The error bars show Standard Error of Mean (SEM)

Fig 6.10

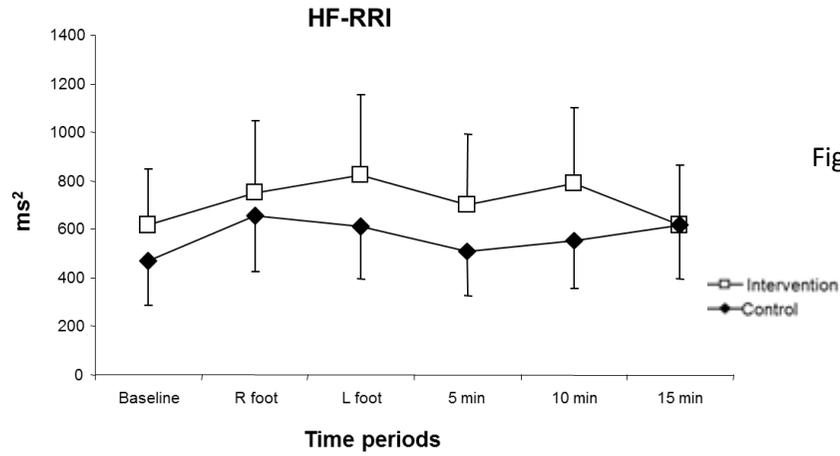


Fig 6.11

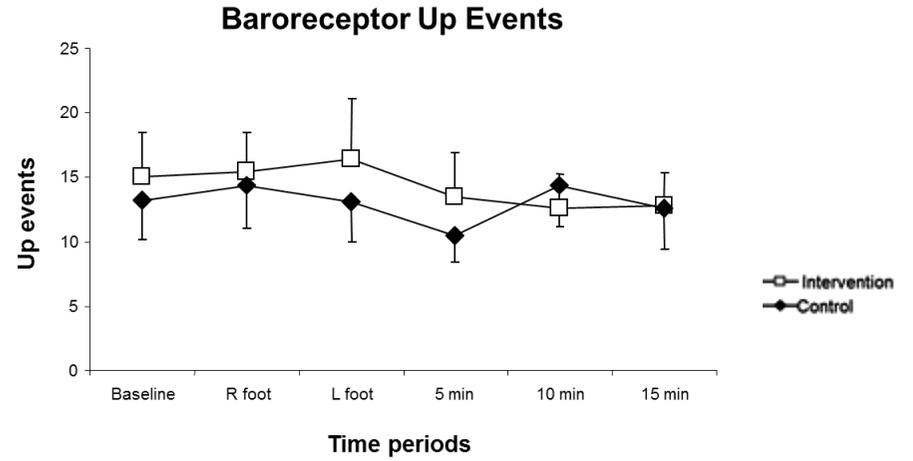


Fig 6.12

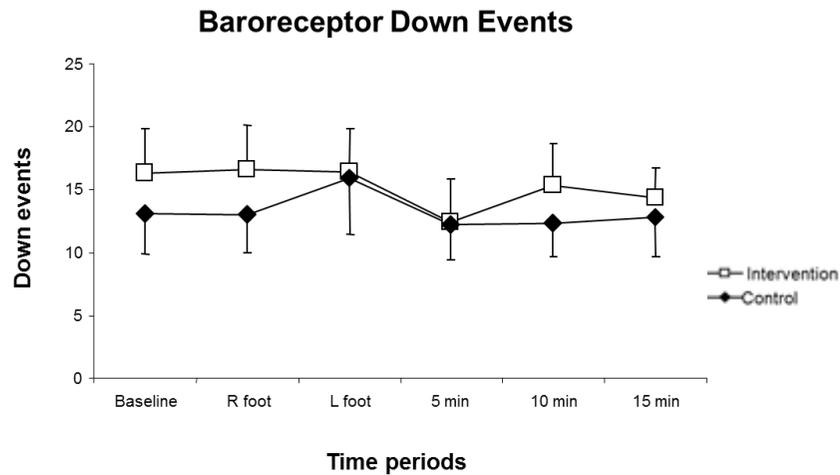


Figure 6.10 - 6.12. ANOVA GLM comparison of HF-RRI, BarUpEv, BarDwEv, across the six recorded data blocks. The white square points are the intervention group means, the diamond black points are the control group means for each period. The error bars show Standard Error of Mean (SEM)

Fig 6.13

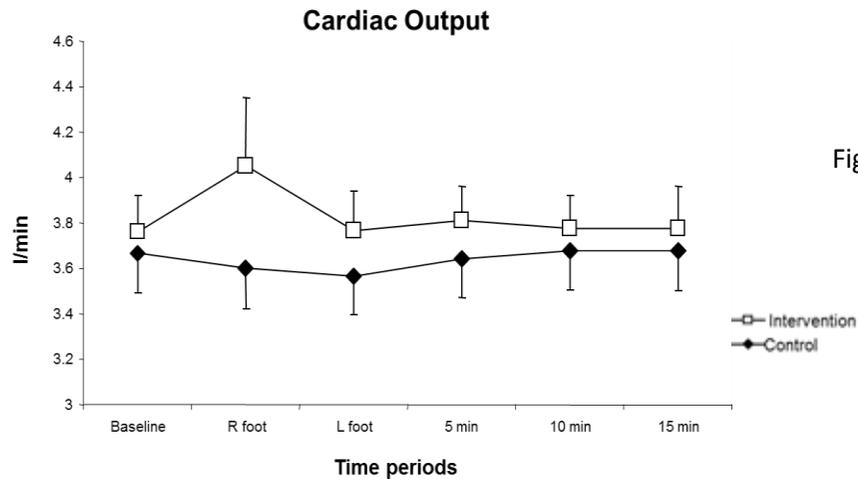


Fig 6.14

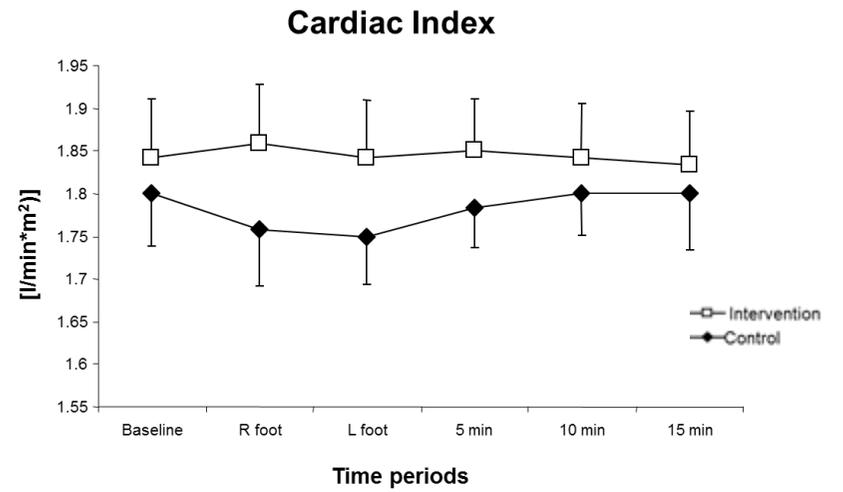


Figure 6.13 – 6.14. ANOVA GLM comparison of Cardiac Output and Cardiac Index across the six recorded data blocks. The white square points are the intervention group means, the diamond black points are the control group means for each period. The error bars show Standard Error of Mean (SEM)

6.3.2. Results of subjective measurements

Transient state anxiety: Transient anxiety was assessed by the SAI tool (figures 6.11. and 6.12). There was no significant reduction in state anxiety post treatment in the intervention group, however the control group revealed a significant post-treatment difference (mean 28.1; SD 9.0; CI +/- 4.6 vs. mean 25.2; SD 6.3; CI +/- 3.2, $p = 0.03$). Possible causes of this difference will be identified in the discussion section. Sub-group analysis found no individual significant outcome differences in STAI pre and post-test scores between the two therapists indicating adequate standardisation of the massage relaxation effect between the two therapists.

Transient pain: Transient pain was assessed using a Visual Analogue Scale (VAS) (figure 6.15). There was no significant difference in the subjective VAS levels of reflexology treatment discomfort between the intervention group (post-test mean 0.2; SD 0.4; CI +/- 0.2) and control (mean 0.3; SD 0.4; CI +/- 0.2; $p = 0.36$). Furthermore, sub-group analysis found no individual significant outcome differences in VAS levels between the two therapists. This indicated that the massage-related discomfort effect was adequately standardised between the two therapists and between the two treatments.

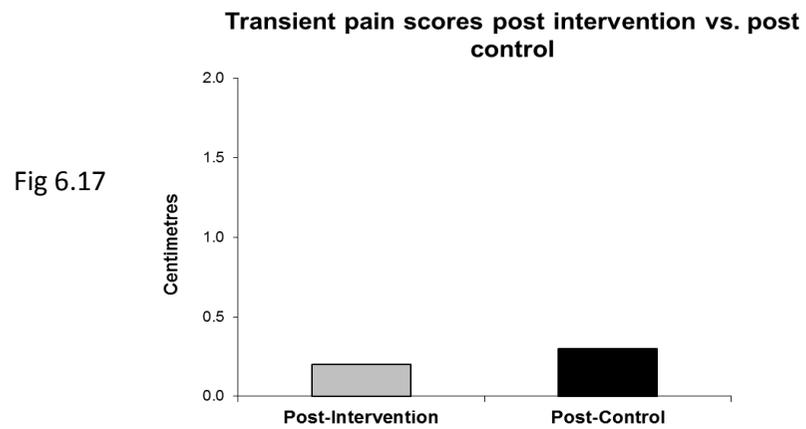
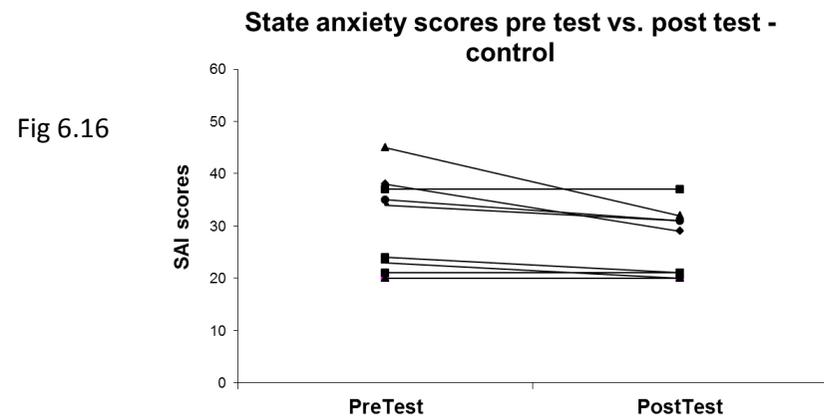
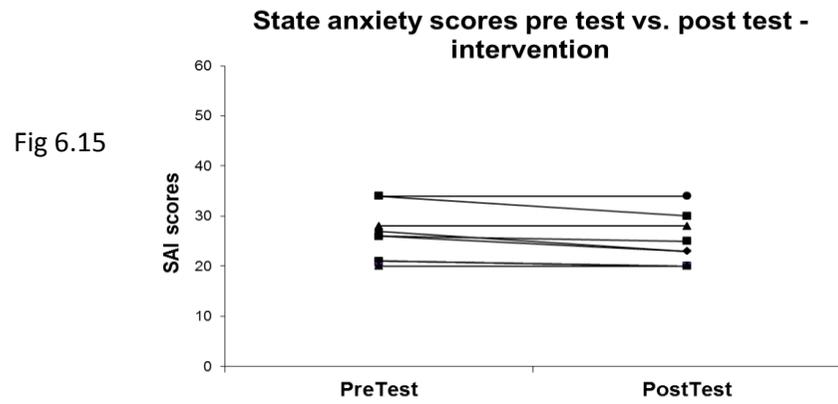


Figure 6.15 – 6.16. Transient anxiety pre and post-test scores as measured by the SAI for the intervention and control group

Figure 6.17. Comparison of transient pain pre and post-test visual analogue scale scores

Table 6.6. Haemodynamic variable results

Cardiovascular measurement		Baseline	Right foot	Left foot	5 mins	10 mins	15 mins
HR (bpm)	Forefoot	67.5 (20.4)	66.3 (20.1)	66.8 (20.2)	67.9 (19.9)	67.6 (19.5)	67.8 (20.5)
	Heel	68.3 (21.3)	67.2 (22.6)	67.0 (22.1)	68.0 (21.6)	67.9 (22.1)	68.1 (21.8)
sBP (mmHg)	Forefoot	122.4 (15.8)	119.3 (17.5)	120.1 (18.8)	125.5 (15.6)	125.3 (17.1)	123.9 (17.1)
	Heel	126.7 (16.2)	124.8 (14.7)	125.3 (15.7)	127.8 (17.3)	129.2 (17.3)	129.2 (15.1)
dBp (mmHg)	Forefoot	76.3 (11.6)	75.6 (12.7)	76.8 (13.1)	79.2 (10.5)	78.8 (11.7)	79.0 (13.0)
	Heel	80.1 (11.9)	79.4 (10.6)	78.6 (10.5)	79.1 (11.2)	81.0 (8.6)	82.6 (8.7)
mBP (mmHg)	Forefoot	93.8 (13.1)	92.4 (14.3)	93.6 (15.1)	96.9 (12.2)	96.5 (13.5)	96.2 (14.5)
	Heel	97.7 (14.1)	96.5 (12.7)	96.4 (13.2)	97.7 (14.1)	99.4 (12.4)	100.3 (11.3)
SV (ml)	Forefoot	58.4 (13.0)	60.3 (13.2)	59.4 (12.7)	59.2 (13.7)	58.8 (13.4)	58.3 (13.1)
	Heel	56.5 (11.7)	56.5 (12.6)	56.3 (12.6)	56.3 (12.6)	57.3 (11.8)	56.8 (12.3)
SI (ml/m²)	Forefoot	28.9 (6.8)	29.6 (6.6)	29.3 (6.6)	29.2 (6.9)	28.9 (6.8)	28.8 (6.7)
	Heel	28.0 (6.6)	28.1 (7.0)	27.8 (6.9)	27.9 (6.7)	28.3 (6.5)	28.2 (6.6)

CO (L/min)	Forefoot	3.8 (0.6)	4.1 (1.0)	3.8 (0.6)	3.8 (0.6)	3.8 (0.5)	3.8 (0.6)
	Heel	3.7 (0.6)	3.6 (0.6)	3.6 (0.6)	3.6 (0.6)	3.7 (0.6)	3.7 (0.6)
CI (L/(min*m²))	Forefoot	1.8 (0.2)	1.9 (0.2)	1.8 (0.2)	1.9 (0.2)	1.4 (0.2)	1.8 (0.2)
	Heel	1.8 (0.2)	1.8 (0.2)	1.8 (0.2)	1.8 (0.2)	1.8 (0.2)	1.8 (0.2)
TPR (dyne*s/cm⁴)	Forefoot	2002.3 (299.5)	1958.3 (336.4)	1982.9 (304.4)	2046.6 (303.0)	2043.1 (326.2)	2052.2 (338.9)
	Heel	2118.7 (298.9)	2138.3 (273.2)	2152.3 (283.6)	2142.8 (343.9)	2161.9 (316.3)	2184.0 (308.4)
LF-RRI (ms²)	Forefoot	596.8 (649.4)*	654.3 (662.6)	836.9 (1118.1)	679.5 (759.0)	683.2 (747.9)	611.4 (731.3)
	Heel	281.8 (309.4)*	384.0 (409.8)	380.1 (422.5)	403.3 (465.4)	413.3 (531.6)	402.7 (503.7)
HF-RRI (ms²)	Forefoot	614.2 (809.41)	751.2 (1011.2)	822.8 (1142.6)	701.4 (1005.3)	789.3 (1082.0)	616.5 (858.1)
	Heel	466.3 (628.6)	654.6 (802.4)	611.8 (753.8)	507.1 (637.3)	550.3 (681.1)	615.6 (774.5)
BarUpEv	Forefoot	15.0 (11.9)	15.4 (10.4)	16.4 (16.2)	13.5 (11.5)	12.6 (9.1)	12.8 (8.6)
	Heel	13.2 (10.6)	14.3 (11.3)	13.1 (11.0)	10.4 (7.1)	14.4 (11.3)	12.6 (11.3)
BarDwEv	Forefoot	16.3 (12.2)	16.6 (12.3)	16.4 (11.8)	12.4 (11.7)	15.3 (11.7)	14.4 (8.1)
	Heel	13.1 (11.3)	13.0 (10.6)	15.9 (15.6)	12.2 (9.8)	12.3 (8.9)	12.8 (10.8)

* Indicates significant difference at baseline / *All data expressed as *mean, **standard deviation (SD)

6.3. Discussion

This is the first double-blind randomised controlled study to examine whether there are any specific haemodynamic benefits, product quality or safety issues associated with reflexology treatment to the area of the feet thought to be associated with the heart in patients with CHF due to LVSD. There were no adverse events and the study was well tolerated by all participants. Reflexology has not been previously rigorously tested for any acute (immediate) specific hemodynamic effect in the CHF patient group despite the claim of reflexologists that massage to specific points of the feet increases blood supply to referred or 'mapped' organs in the body. This has, until now, left the safety question of therapy-specific adverse-effect on CHF patients with LVSD unanswered. The study found no specific treatment-related haemodynamic effect in this patient group when reflexology massage is applied to the upper part of the left foot or indeed any other part of either foot. The findings suggest that there is no significant acute (immediate) haemodynamic effect when reflexology massage is applied to the area thought to correspond to the heart in patients with CHF.

Trying to detect such an effect in CHF patients with LVSD presented a particular challenge. Participants from this patient population often have impaired ventricular contractility, systemic vasoconstriction or damaged heart valves (234). Furthermore, as CHF is symptomatically treated by a number of pharmacological therapies, it is possible that these drugs may have suppressed or diluted a specific haemodynamic treatment-related effect. CHF patients are often on multiple drug therapies. For example, vasodilator drugs are widely used in heart failure. These work through various mechanisms including potassium channel activators, angiotensin converting enzyme inhibitors, angiotensin receptor blockers and nitrates. These drugs inhibit or control components of the blood pressure regulatory system in order to decrease blood vessel tone and lower blood pressure (235). Therefore it is possible to

argue that vasodilator agents could have played a role in masking a specific acute (immediate) haemodynamic effect. Furthermore, despite pharmaceutical management, many patients with CHF have maximal SNS activation which might also mask any subtle haemodynamic changes due to reflexology. However although it was anticipated at the start that certain heart failure pharmacological therapies may potentially dilute or mask a potential specific reflexology haemodynamic effect, strict volunteer medication exclusion criteria were deliberately not applied as it was hoped to be able to generalise the experimental results as widely as possible to include those on standardised drug regimes.

It was not clear why the haemodynamic baseline differences occurred between the two groups. Impedance cardiography methodological guidelines recommend stabilisation periods between times of electrode attachment to beginning of data collection, from 0 minutes (start recording data as soon as clear signals produced), to 10 minutes prior to data collection (180;181). On this basis, it was assumed that allowing 20 minutes from attachment of electrodes and establishment of clear signals, to beginning of data recording, would be sufficient to allow the subjects haemodynamic parameters to stabilise. However as ANOVA GLM analysis was run on each group data separately in order to evaluate differences between patterns of treatment across time under the same condition, the consultant statistician confirmed that the chance baseline difference in LF-RR1 at baseline did not affect the intra-group analysis for specific haemodynamic differences in linear trends across time periods pre, during of post the left or right foot forefoot treatments (195;214).

With regards to Inghams claim that reflexology massage to the heart reflex point specifically and beneficially increases blood supply to the heart (6), the study found no evidence or trend in any of the measured parameters to suggest such an effect in CHF patients with LVSD. For

reflexology treatment to the heart reflex point be beneficial for the heart in this patient group, at least one of several actions must happen in order for the heart muscle itself to receive more blood via the coronary arteries, 1) the heart rate would have to reduce to allow cardiac perfusion to take place (the heart tissue only perfuses in diastole). 2) the heart rate would need to slow without the longer ventricular filling time and increased volume causing adverse contractility effects inherent in this patient group. 3) the cardiovascular system would have to be systemically or locally vasodilated in order to reduce preload contractile force. Therefore, for an increase in cardiac perfusion to take place, there would have to be a reduction in heart rate and cardiac output, indicating that the arterial pressure opposing left ventricular ejection (afterload) had reduced, along with the workload of the heart, in order to allow the cardiac muscle more time to perfuse in a diastole state. However the pathophysiology of LVSD in CHF involves a spiralling of negative effects arising from the inability of the cardiac output to match the metabolic needs of the tissues. Patients with this condition already adversely suffer from a reduction in cardiac output (236). Pharmacological management of heart failure aims to increase cardiac output and reduce cardiac preload and afterload. Therefore a specific effect on cardiac output could be theoretically contra-indicated for this patient group.

There was no significant difference in the subjective VAS levels of reflexology treatment ($p = 0.36$). Furthermore, sub-group analysis found no individual significant outcome differences in VAS levels between the two therapists indicating that the pressure of massage was adequately standardised between the two therapists and between the two treatments. Pre and post treatment transient anxiety state was monitored using SAI psychometric indicators to ensure that both treatments were standardised for relaxation components. The control group demonstrated a significant post-treatment reduction ($p = 0.01$). Although these results suggest that the control treatment may have been more relaxing for subjects, by the play of chance, 7 volunteers were randomised to receive the intervention treatment at first visit. Of

these subjects, 6 scored themselves as being either 99% or 100% fully relaxed state *pre-test*, which is the maximum lowest anxiety SAI levels attainable, making it impossible to reduce the post-test score. Two of the 5 subjects who received the heel treatment at first visit also scored themselves as either maximally relaxed or within 3 points of being maximally relaxed, which indicates a ceiling effect in pre-test scoring. These findings suggest that some CHF patients with LVSD with appeared less willing to disclose levels of anxiety at their first visit. The suppression of negative emotions has been implicated as a contributing factor in cardiovascular disease (237;238). In future reflexology studies involving cardiac patients, treatment relaxation standardisation could be further enhanced by the use of tools such as the Courtauld Emotional Control Scale (239), used to measure the degree to which subjects suppress negative emotions such as anxiety, in order to compare stress reactive characteristics for stratified pre and post-test state anxiety scoring.

6.4. Conclusion

In conclusion, this was the first double-blind randomised controlled study to examine whether there are any specific haemodynamic benefits, product quality or safety issues associated with reflexology treatment to the area of the feet thought to be associated with the heart in in patients with CHF due to LVSD. Reflexology has not been previously rigorously tested for any specific hemodynamic effect during treatment in this patient group. This is despite the reflexology claim that massage to specific points of the feet increases blood supply to referred or 'mapped' organs in the body. The design attempted to address some of the methodological challenges involved in isolating a specific active haemodynamic ingredient from within a complex multi-component reflexology intervention in this patient group. The study findings demonstrate that reflexology applied to the area of the feet thought to be associated with the heart, does not exert any specific effect on the haemodynamic parameters in patients with

chronic heart failure. The study also found no adverse non-specific haemodynamic effects or trends associated with either treatment in this patient group. Therefore although the longer-term accumulative effects of multiple treatments are uncertain, reflexology treatment to the heart reflex point area and other areas of the feet would appear safe for use in patients with CHF due to LVSD. The next chapter report on the same experiment carried out in patients with coronary artery disease.

Chapter 7

Reflexology in patients with coronary artery disease

Jones J, Thomson P, Howie K, Lauder W, Leslie SJ. Reflexology has no acute (immediate) haemodynamic effect in patients with coronary artery disease: a double blind randomised controlled trial (*in preparation*)

Chapter 7

Reflexology in patients with chronic artery disease

7.1. Study aim and research questions

This experiment was the third in the series of three RCT's devised to address research aim 3. In this study, the aim was to examine whether there are any specific haemodynamic benefits, product quality or safety issues associated with reflexology treatment to the area of the feet thought to be associated with the heart in patient with coronary artery disease (CAD), using a double blind randomised controlled trial design.

The following two research questions were devised in order to address this aim.

Q6. Does the reflexology intervention developed for healthy volunteers, using a double blind randomised control trial, result in specific changes in the haemodynamic parameters of cardiac patients with CAD?

Q7. If a specific haemodynamic effect is detected, are there any risks or benefits associated with reflexology treatment to the area of the feet through to be associated with the heart in cardiac patients with CAD?

7.2. Methods

7.2.1. Design

Randomised controlled double blind repeated measures study.

7.2.2. Study participants

Model-validity requirements involved the development of clear selection criteria for the patients with coronary artery disease for this study. The methodology took into account comparable CAD disease categorisations from both the medical and reflexology perspective. This was done in order to meet reflexology model validity requirements, reduce error variance and to ensure homogeneity within both constructs (219). Model validity requires that the participant disease categorisation is congruent with the context of the CAM therapy under investigation. This is done so that the diagnosis and outcomes accurately represent the practice being investigated (128). On this basis, the group selection criteria will now be described, and the disease classification from both the medical and reflexology perspective given. It was important to understand the pathophysiology of patients with CAD in order to anticipate how potential vascular remodelling inherent in this condition could affect the study outcomes.

7.2.2.1 Disease categorisation from the medical perspective

Although recent evidence suggests that variants in neuro-hormonal genes may be involved in the pathophysiology of CAD (231), it is most commonly a modifiable chronic inflammatory disease. In CAD, the blood vessels of the heart (the left anterior descending, circumflex and right coronary artery) become narrowed by cholesterol or fatty deposits called atheroma (240). These deposits are an inflammatory healing response to arterial wall injuries in the sub-endothelial intima of arteries, which arise out of inflammation of the vessel wall. The endothelium is the layer of endothelial cells that provide the interface between circulating blood and the vascular system (241). When functioning normally, endothelial cells regulate

several crucial cardiovascular functions. These include the regulation of vascular tone by endothelial secretions, blood tissue exchange and the initiation of new blood vessel formation (angiogenesis). Endothelial cells also have receptors to many vasoactive agents and secrete vasoactive and anti-platelet agents such as nitric oxide, prostacyclin and endothelin in response to signs of shear stress of blood flow (242). These paracrine vasodilatory agents act on local adjacent endothelial cells in order to allow the vessel wall to compensate for changing blood flow demands, initiating local vasodilation as required (136). When plasma-derived cholesterol becomes trapped between the sub-endothelial intima and the middle smooth fibre layer of the arterial vessel wall, monocyte and leucocyte inflammatory cells accumulate around the oxidised lipids to form macrophages and foam cell plaques (243). Smooth muscle cells form a fibrous cap over the lipid accumulation which then causes the atherosclerotic plaque to extend further into the vessel lumen (236). If the fibrous cap ruptures, platelets accumulate around the exposed material in the plaque and a thrombus is formed. This ongoing inflammatory process and formation of thrombus eventually injures or blocks the artery lumen. It is the underlying pathophysiology of ischemic heart disease. The clinical outcome of the person with CAD is mostly determined by the type and location of the thrombus formed on the atherosclerotic plaque(243). There are several risk factors involved in CAD. Some are modifiable, such as smoking, hypertension, dietary intake, physical activity levels, alcohol consumption and blood apolipoprotein levels. A history of diabetes mellitus type 1 or 2 is also a key risk factor (151).

CAD typically presents with two distinct clinical scenarios. The first is chronic stable angina, where progressive stable atheroma results in chronic stable angina (not usually associated with thrombus and often the most calcified arteries with the highest plaque burden). This form of chronic CAD is generally stable (244). In contrast, when the person with CAD develops unstable plaque (which may not be initially flow limiting but nevertheless very

fragile), these can rupture and expose sub intimal collagen which results in thrombus. The thrombus can then dislodge and occlude or partially occlude one of the coronary vessels, resulting in an acute coronary syndrome. This type of event can take the form of either an ST – elevated myocardial infarction (STEMI), which occurs when a coronary artery is completely occluded by a thrombus as indicated by changes in the ST portion of the PQRST ECG complex, or non-ST elevated myocardial infarction (non-STEMI or non ST elevated ECG characteristics), which occurs when a coronary artery is only partially occluded (245).

7.2.2.2. Disease categorisation from reflexology perspective

In the five reflexology educational texts discussed in chapter two, two made reference to ‘chronic heart disease’ (43;82), one mentioned ‘heart disease’ (44) and one ‘angina’ (233). However no further sub-group disease treatment stratification was given for any specific cardiovascular symptom within the reflexology construct, except for one mention of tachycardia (43). As both tachycardia and angina fit within the coronary artery disease signs and symptoms classification, it was inferred that the reflexology construct appeared to have no further sub-groups within the cardiac disease classification that would render the CAD study recruitment criteria non-homogenous in terms of the reflexology perspective. Therefore the following recruitment criteria were assumed to maintain a degree of homogeneity of patients from both the conventional medical and reflexology perspectives.

7.2.3. Patient population

Any patient attending the Raigmore Hospital cardiology department at any time between 2007 - 2012 for diagnosis and/or treatment of CAD and who fulfilled the criteria listed below, were considered appropriate to approach for recruitment in the study. However for female

volunteers, only post-menopausal women were approached. This was done as although evidence suggests premenopausal women receive a cardiovascular benefit from circulating oestrogen and higher levels of high density lipoprotein (246), the oestrogen and progesterone increase during the luteal phase of the menstrual cycle and these hormones have been found to affect arterial compliance and stiffness (204;205). The influence of these sex hormone changes during the menstrual cycle meant that there would have been a potential for a spurious hormonal-related haemodynamic influence on systolic and/or diastolic BP trends in pre-menopausal women which could have skewed the haemodynamic results. Strict medication exclusion criteria for the CAD patients were deliberately not applied. This was because it was anticipated at the start that despite certain cardiovascular pharmacological therapies in the cardiac patients potentially diluting or masking a potential specific reflexology haemodynamic effect. However, as the aim of the study was to examine whether there are any specific haemodynamic benefits, product quality or safety issues associated with reflexology treatment to the area of the feet thought to be associated with the heart in CAD patients, it was hoped to be able to generalise the results as widely as possible to include those on standardised drug regimes. With this 'real-world' generalisability, the study findings could then provide new scientific data to enable a large proportion of CAD patient purchasers of reflexology and their clinicians to finally assess reflexology safety. On this basis, the following recruitment criteria were applied:

Recruitment criteria for patients with significant coronary artery disease

Inclusion criteria:

12. Able to give informed consent

13. Clinically diagnosed coronary artery disease by coronary angiography with at least one significant flow limiting stenosis (identified from patient notes)
14. Male patients aged >18 years old and post-menopausal women
15. Documented symptomatic angina (identified from patient notes)
16. Normal lower limbs (no previous operations including varicose veins)
17. Abstain from tobacco and caffeine-containing drinks for at least 12 hours prior to the study (to eliminate any confounding effects of caffeine or tobacco stimuli on the central nervous system)
18. Abstain from food for 4 hours before the study (in order to eliminate any effects of digestion on blood pressure rates)
19. Reflexology naive (i.e. have never had training in or received reflexology therapy)

Exclusions criteria:

1. Permanent, persistent or paroxysmal Atrial Fibrillation (The TFM manufacturer instructions state that patients with AF will not produce reliable results)
2. Admission to hospital within the previous 3 months with unstable cardiac disease
3. Pacemaker in situ (contraindicated with the TFM)
4. Participation in pharmacological study within the past three months

7.2.4. Recruitment process

The recruitment process was consistent with the process outlined in Chapter six. All eligible patient volunteers were identified by replying to a letter of invitation sent via their clinician.

The letter of invitation process was as follows. The researcher gave a number of study recruitment letter packs and an outline of the study aims, protocol and inclusion/exclusion criteria to the Raigmore cardiology consultant team. The packs contained 3 documents, 1) a letter of introduction, explaining the reason for contact (Appendix 5), 2) a Patient Information Sheet outlining the trial purpose and design (Appendix 3) and 3) a "Consent to Contact" form (Appendix 4). As the cardiology team confidentially screened the patients for inclusion, to maintain patient confidentiality, it was not known how many were approached or screened for eligibility or the refusal rate. Only basic socio-demographic characteristics and clinical data (degree of flow limiting stenosis and medication data) were passed to the researcher.

7.2.5. The intervention

As described in Chapter 3: Methods, reflexology massage (using touch techniques unique to reflexology) applied solely to the areas on both feet known as the shoulder girdle within the reflexology foot map transverse zones.

7.2.6. The control

As described in Chapter 3: Methods, reflexology massage (using touch techniques unique to reflexology) applied solely to the areas on both feet known as the pelvic and abdominal areas within the reflexology foot map transverse zones.

7.2.7. Reflexology style and techniques

As described in Chapter 3: Methods, both therapists trained at the International Institute of Reflexology (IIS), therefore the intervention and control treatments were formulated using

used standardised Ingham touch techniques and principles. The therapists standardised both intervention and control treatment times (both lasted for 5 minutes each), treatment pressure (light to medium) and depth of touch techniques (light to medium) - (as described in Chapter 3).

7.2.8. Background music

Background music was introduced in this experiment as previously described in Chapter 5, Healthy volunteer pilot study.

7.2.9. Outcomes measurements

See table 7.1.

Table 7.1. Haemodynamic parameters used in the study (as described in Chapter 3)

Haemodynamic parameter	Abbreviation	Method of measurement
Heart rate	HR	Task Force Monitor (TF [®] M) impedance cardiography system
Diastolic blood pressure	dBp	TF [®] M impedance cardiography system
Systolic blood pressure	sBP	TF [®] M impedance cardiography system
Mean arterial blood pressure	mBP	TF [®] M impedance cardiography system
Stroke index	SI	TF [®] M impedance cardiography system
Stroke volume	SV	TF [®] M impedance cardiography system
Cardiac output	CO	TF [®] M impedance cardiography system
Cardiac index	CI	TF [®] M impedance cardiography system
Total peripheral resistance	TPR	TF [®] M impedance cardiography system
Baroreceptor up events	BarUpEv	TF [®] M impedance cardiography system
Baroreceptor down events	BarDwEv	TF [®] M impedance cardiography system
Low-frequency component of HRV	LF-RRI	TF [®] M 2 channel electrocardiogram function (ECG)
High-frequency component of HRV	HF-RRI	TF [®] M 2 channel electrocardiogram function (ECG)

7.2.10. Anxiety and pain assessment

As described in Chapter 3: Methods, pre & post measurement of the subject's self-reported perceived state of anxiety and transient intra-treatment pain were assessed using The State Anxiety Inventory and a visual analogue scale (VAS) (182).

7.2.11. Sample size

As described in Chapter 6, formal statistical advice on the power calculation for the study was sought from Ms Kate Howie, Statistical Consultant, Department of Computing Science and Mathematics, University of Stirling. Data were extrapolated from the pilot study for the power calculation (Minitab version 16.1.1.1, Microsoft, Redmond, Washington, USA). The pilot study data indicated that in order to detect a difference of 0.29 litres per min with 80% confidence and significance level of 0.05, 12 subjects would be required. Ms Howie confirmed the calculation was correct in determining that a sample size of 12 subjects was sufficient for this study also.

7.2.12. Location

As described in Chapter 5, the study took place at the Highland Heartbeat Centre, Raigmore Hospital. The treatments were conducted in a quiet, draught-free room maintained at a constant temperature of 22-24 °C. The lighting was dimmed throughout the session.

7.2.13. Randomisation

As described in Chapter 3: Methods, the equal group random allocation was performed by a third party not involved with the study, using computer generated random numbers. Subjects were randomly allocated to either receive the intervention treatment at the first visit, followed by the control treatment at the second visit, or to receive the treatment schedule in the opposite way round (table 7.2). For the second visit, the subject was automatically assigned to the other treatment in order to act as their own control. The subject remained unaware of group allocation criteria throughout the study. The allocation list was handed directly to the two reflexology therapists in sealed opaque envelopes. The researcher did not have access to the allocation list until data analysis was complete.

Table 7.2 **Treatment schedule random allocation list**

Study Subject	Visit 1	Visit 2
1	Heel	Forefoot
2	Heel	Forefoot
3	Forefoot	Heel
4	Forefoot	Heel
5	Heel	Forefoot
6	Forefoot	Heel
7	Forefoot	Heel
8	Heel	Forefoot
9	Forefoot	Heel
10	Heel	Forefoot
11	Forefoot	Heel
12	Heel	Forefoot

7.2.14. Blinding

As described in Chapter 3: Methods, the study was double-blinded. Neither the reflexology-naive subjects nor researcher knew in which order the intervention or control treatment was delivered. The reflexologists worked behind a screen when delivering the reflexology so the researcher was not aware of the treatment order for each subject (see photograph in Chapter 3).

7.2.15. Pre-study requirements

As described in Chapter three: Methods, all volunteers were required to abstain from food for at least 4 hours beforehand and from tobacco and caffeine-containing drinks for at least 12 hours prior to attendance.

7.2.16. Protocol

An identical protocol was followed for this study of chronic heart failure patients as outlined in Chapter five: Healthy volunteer pilot study.

7.2.17. Ethics

The study was undertaken with the approval of the Research and Ethics Committee (DREC), University of Stirling (no DREC reference number issued) and the North of Scotland Research Ethics Committee (NOSREC 11/AL/0009) and in accordance with the Declaration of Helsinki. Written informed consent was obtained from each patient before entry into the study.

7.2.18. Statistical analysis

Summary descriptive data were collected as socio demographic characteristics and clinical data (degree of stenosis and medication data). As described in Chapter 3, Analysis of Variance (ANOVA) General Linear Model (GLM) was identified as being the appropriate statistical model to analyse the haemodynamic study data in order to determine whether there was any interaction between condition and time or between the times or conditions using the hypothesis of Subject * Group * Time. Furthermore, as also described in Chapter 3, planned comparison analysis using Tukey significance tests was used to identify where any significant effect occurred (Minitab version 16.1.1.1, Microsoft, Redmond, Washington, USA). As in the analysis of the healthy volunteer data, assumptions of normality and homogeneity of variance were validated and an overall 5% significance level was used. As the post-test VAS scores were normally distributed, it was decided to compare the subjects post intervention and post control data using a paired 't' test statistical model (as described in Chapter three: Methods) (Minitab version 16.1.1.1, Microsoft, Redmond, Washington, USA) (200). As the comparison of pre and post-test STAI scores data were also normally distributed and came from the same participants, the same statistical process was used on these data also (Minitab version 16.1.1.1, Microsoft, Redmond, Washington, USA).

7.3. Results

Five post-menopausal women, (mean age 64 ± 10.2) years and 7 men, (mean age 66.8 ± 4.9 years) with established coronary artery disease were recruited between July and September 2011 (table 7.3). All twelve completed both arms of the study (figure 7.1).

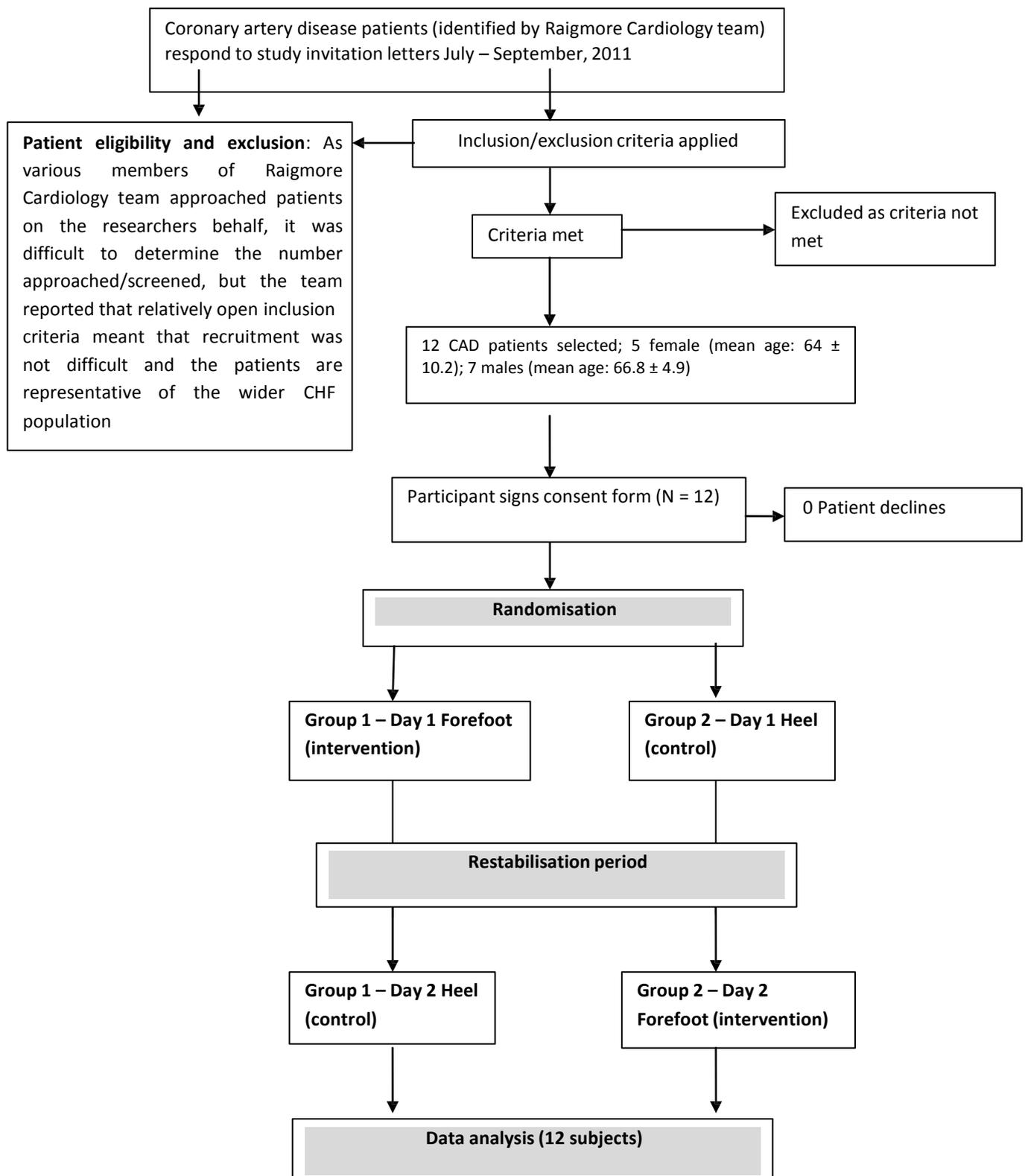


Figure 7.1. Patient Recruitment and Research Study Procedures

Table 7.3 - CAD Patient characteristics and medications

Patient	Sex	Age (years)	BMI	Intervention	Vessel involved	Drugs and dose **	Relevant co-morbidities***
1	F	69	29	PCI: 2 x drug-eluting stents	Cx, OM	ASA75, Ism60, Bis5, Aml5, Sim10, Clo75, GTN	IHD, HBP
2	M	75	27	PCI: Bare metal stent	RCA	ASA75, Bis5, Ator80, Ism60, War	MI, VHD, HBP
3	M	68	29	PCI: Bare metal stent	RCA	ASA75, Clo75, Ator80, Per4, Aten25, GTN	MI, HBP, VHD, AG
4	M	73	26	PCI: Bare metal stent	LAD	ASA75, Sim20, Clo75	PAL, DEP, HBP
5	F	72	25	PCI: Bare metal stent	LAD	ASA75, Per8, Bis5, Aml10, GTN	EH, DEP, AG
6	M	70	26	PCI: Bare metal stent	LAD	ASA75, Per8, Bis10, Sim40	IHD, VHD, LVSD
7	F	58	27	PCI: Drug-eluting stent	RCA	ASA75, Aml5, Lis10, Sim10, War	EH
8	M	67	29	PCI: 2 x bare metal stents	RCA	ASA75, Clo75, Ism60, Sim20	HBP
9	F	49	32	PCI: 2 x bare metal stents	Left Cx, RCA	ASA75, Lev100, Met1000, Nic20, Sim20, FerS200, Aten50, Lis10	IDDM, OB, IHD, HBP, PVD, SX, DEP
10	M	62	35	PCI: 3 x bare metal	RCA, LAD, Cx	ASA75, Clo75, Lis5, Sim40, Aten25,	IHD, HBP, AG

				stents		GTN	
11	F	72	27	CABG	LAD	ASA75, Lev100, Ram1.5, Bis1.5, Insulin	NIDDM, HC, HTH, MI
12	M	62	26	PCI: Bare metal stent	RCA	ASA75, Ros5, Lis2.5, Ben 2.5, Nic20, GTN	EH, AG, IHD, SB

*Left anterior descending, LAD; Right coronary artery, RCA; Circumflex, Cx; Obtuse marginal, OM

* **Doses in mg except for digoxin (ug) and Warfarin (as determined by daily blood tests): Aml, amlodipine; ASA Aspirin; Aten, atenolol; Ator, atorvastatin; Ben, Bendrofluazide; Bis, bisoprolol; BMI, body mass index; Clo, clopidogrel; Dig, digoxin, FerS, ferrous sulphate; Glyceryl trinitrate, GTN; Frus, furosemide; Ism, isosorbide mononitrate; Lev, levothyroxine; Lis, lisinopril; Met, metformin; Nic, nicorandil; Per, perindopril; Ram, Ramipril, ; Ros, Rosuvastatin; Sim, simvastatin; Spir, spironolactone; War, warfarin

* **Angina, AG; coronary artery bypass graft, CABG; depression, DEP; Essential hypertension, EH; Hypertension, HBP; Hypercholesterolemia, HC; Hypothyroidism, HTH; Ischaemic heart disease, IHD; Left ventricular systolic dysfunction, LVSD; Obesity, OB; Palpitations, PAL; Peripheral vascular disease, PVD; Myocardial Infarction, MI; Sinus bradycardia, SB; Syndrome X, SX; Type 11 Diabetes Mellitus, NIDDM; Type 1 Diabetes Mellitus, IDDM; Valvular heart disease, VHD;

7.3.1. Results of haemodynamic measurements

There was no statistically significant difference or overall trend noted in and of the haemodynamic parameters (table 6.5) in either the Forefoot or Heel treatments (all $p > 0.05$). Furthermore, sub-group analysis found no individual significant outcome differences between the two therapists suggesting that the therapists' treatment deliver was adequately standardised. The Forefoot HR baseline was significantly different from the Heel group baseline ($p = 0.02$), as was sBP ($p = 0.01$), CI ($p = 0.01$) and TPR ($p = 0.05$) (table 7.4).

Table 7.4. **Baseline variable differences between the intervention and control groups**

Outcome	Intervention	Control	p value
HR	56.2 (9.5)	58.5 (9.32)	0.023 * *
dBP	80.4 (9.0)	75.5 (10.3)	0.151
sBP	127.3 (9.6)	120.9 (10.4)	0.009 * *
mBP	98.0 (8.1)	93.3 (9.8)	0.127
SV	59.8 (10.1)	60.3 (11.6)	0.997
SI	31.9 (6.5)	32.4 (7.7)	0.878
CO	3.3 (0.6)	3.5 (0.8)	0.060
CI	1.8 (0.4)	1.9 (0.5)	0.009 * *
TRP	2368.5 (415.6)	2218.3 (500.2)	0.042 * *
BarUpEv	13.1 (17.1)	17.8 (26.5)	0.855
BarDwEv	16.9 (18.8)	17.7 (23.9)	1.000
LF-RRI	438.4 (859.6)	524.1 (955.7)	1.000
HF-RRI	1264.6 (3663.0)	1410.8 (3394.9)	1.000
*All data expressed as mean, standard deviation (SD)			
* * indicates significance at the $p < 0.05$ level			

Fig 7.2

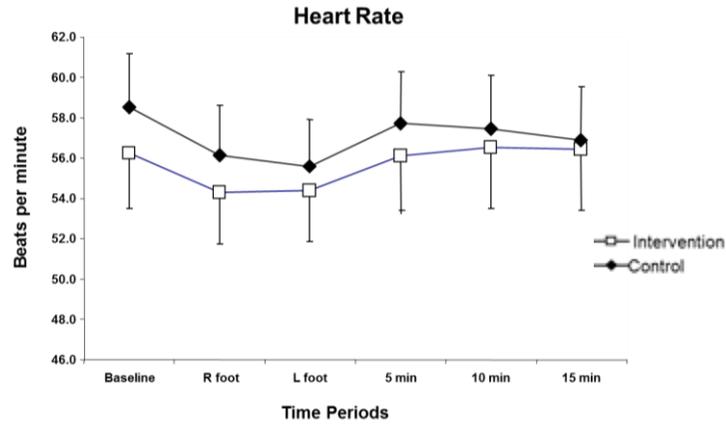


Fig 7.3

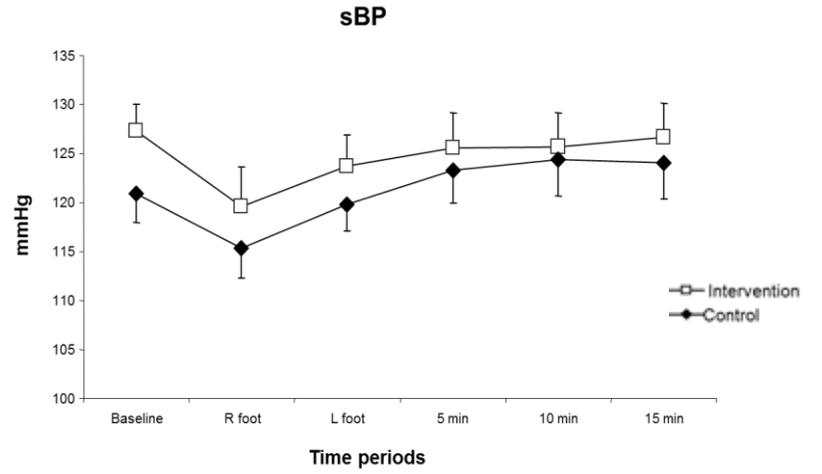


Fig 7.4

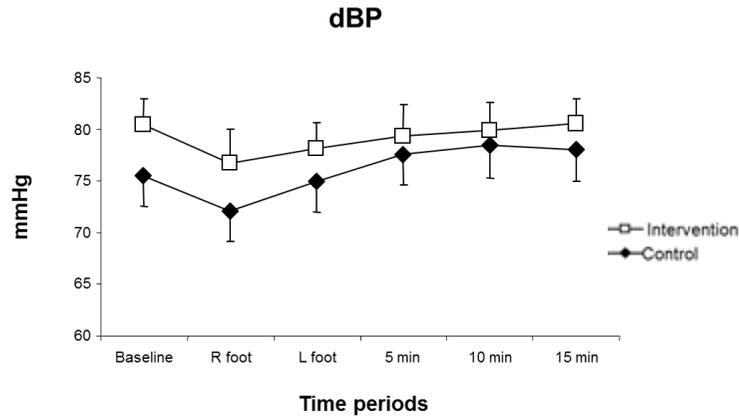


Fig 7.5

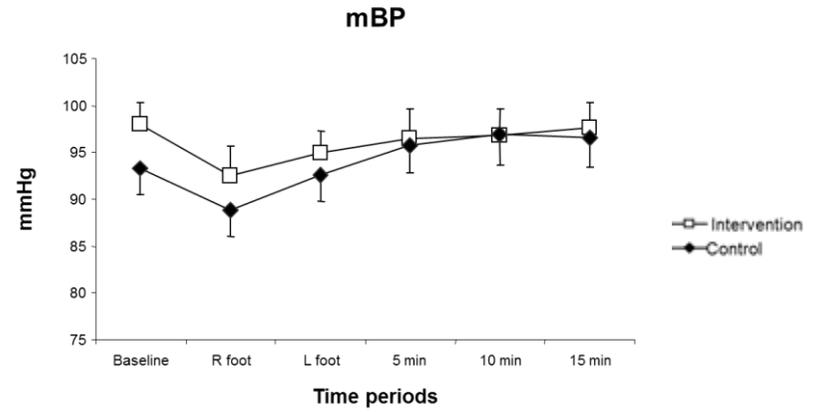


Figure 7.2 – 7.5. ANOVA GLM comparison of HR, sBP, dBP and mBP across the six recorded data blocks. The white square points are the intervention group means, the diamond black points are the control group means for each period. The error bars show Standard Error of Mean (SEM)

Fig 7.6

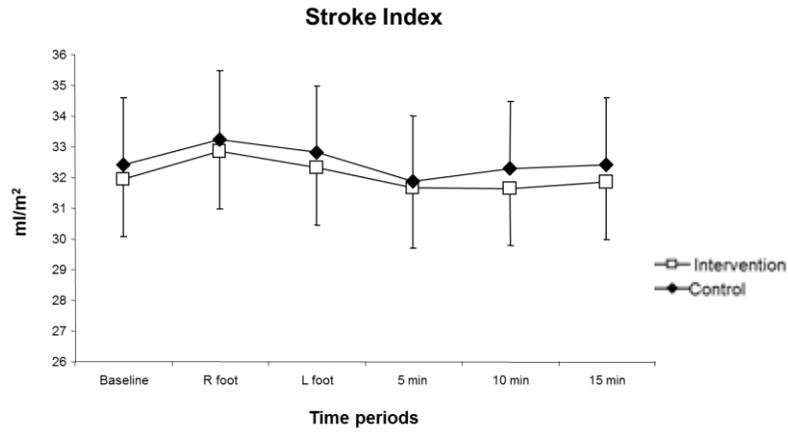


Fig 7.7

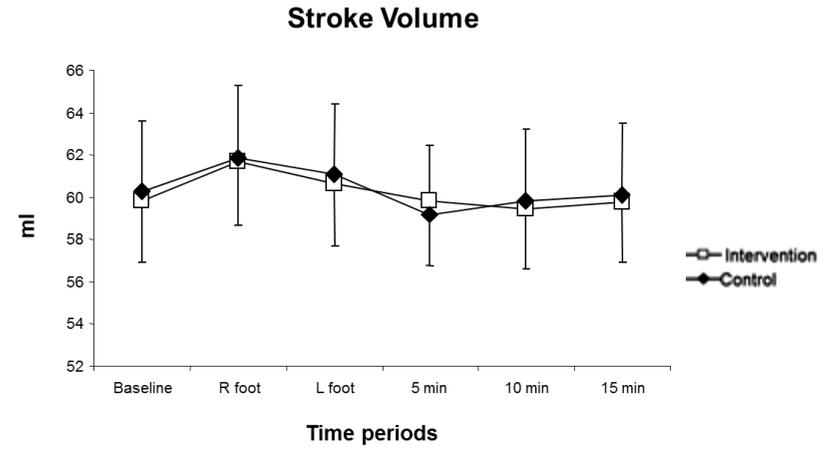


Fig 7.8

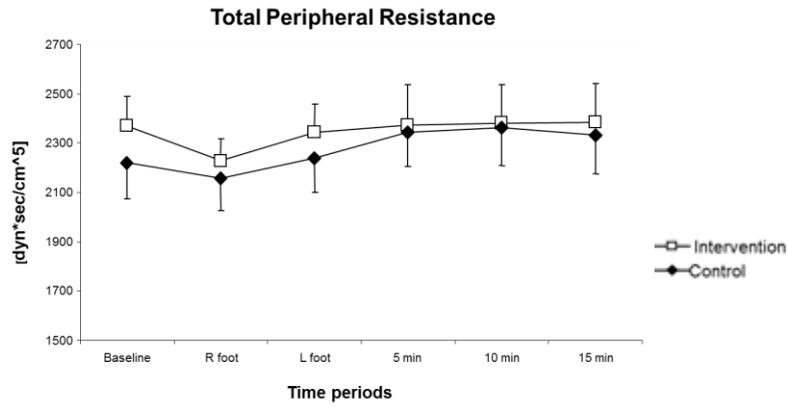


Fig 7.9

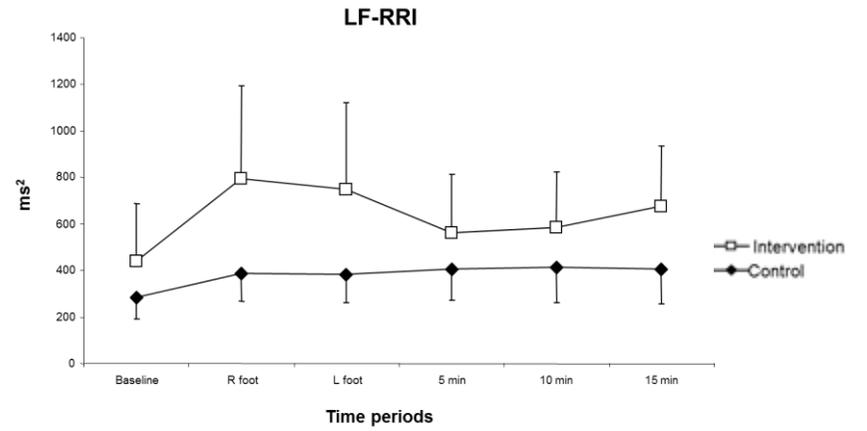


Figure 7.6 – 7.9. ANOVA GLM comparison of SI, SV, TPR and LF-RRI across the six recorded data blocks. The white square points are the intervention group means, the diamond black points are the control group means for each period. The error bars show Standard Error of Mean (SEM)

Fig 7.10

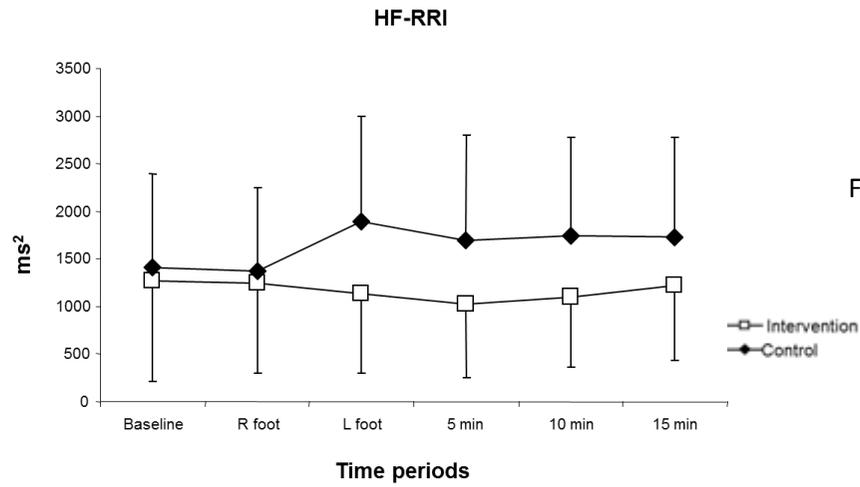


Fig 7.11

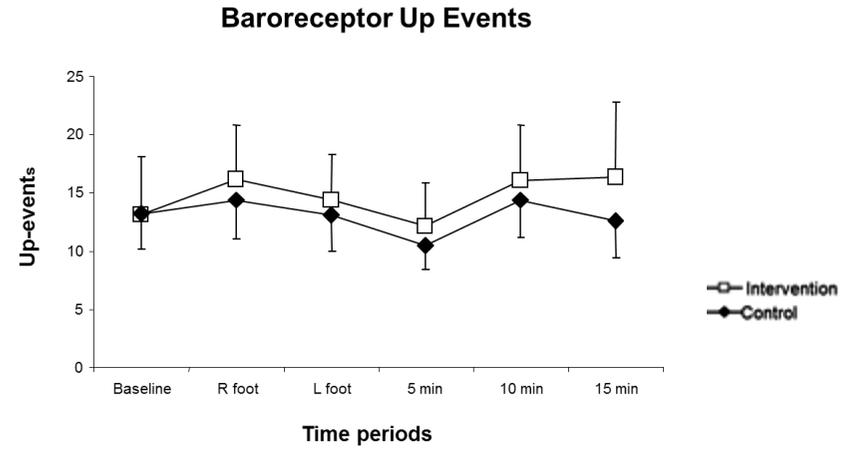


Fig 7.12

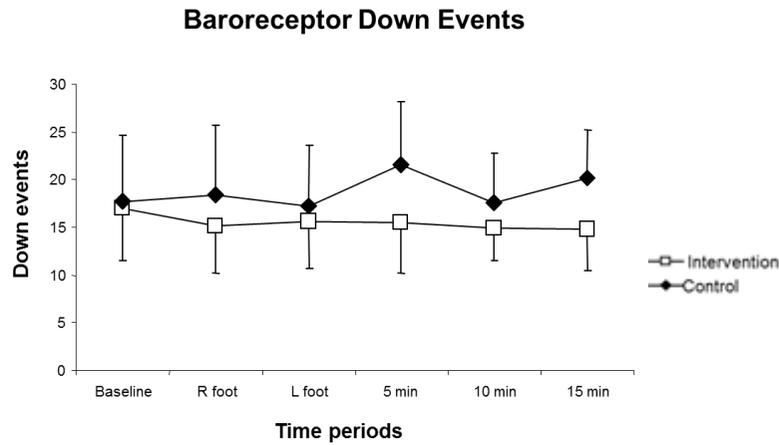


Figure 7.10 – 7.12. ANOVA GLM comparison of HF-RRI, BarUpEv, BarDwEv, across the six recorded data blocks. The white square points are the intervention group means, the diamond black points are the control group means for each period. The error bars show Standard Error of Mean (SEM)

Fig 7.13

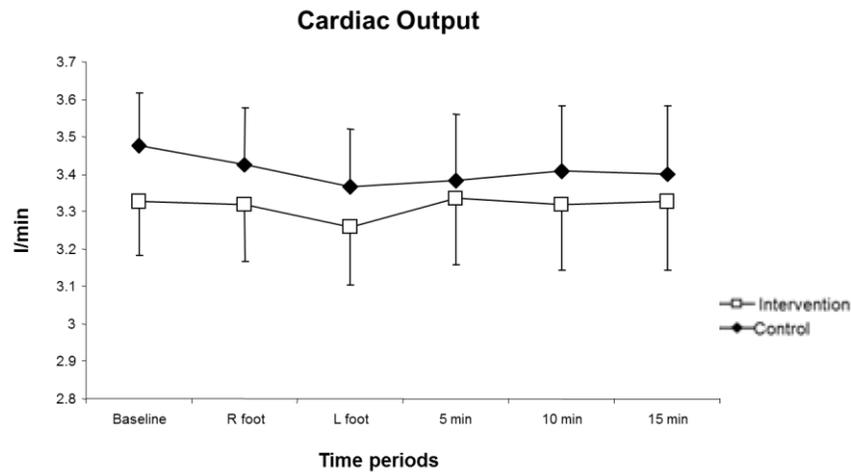


Fig 7.14

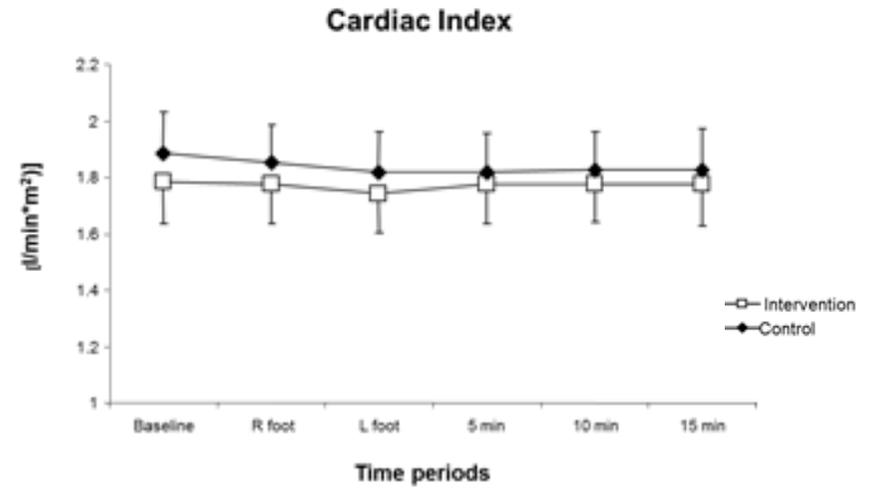


Figure 7.13 – 7.14. ANOVA GLM comparison of Cardiac Output and Cardiac Index across the six recorded data blocks. The white square points are the intervention group means, the diamond black points are the control group means for each period. The error bars show Standard Error of Mean (SEM)

7.3.2. Results of subjective measurements

Transient state anxiety: Transient state of anxiety was assessed by the SAI tool (figures 7.11 and 7.12). Perceived state of anxiety was reduced post treatment in both the intervention group (pre-test mean 30.6; SD 8.6; CI +/- 4.4 vs. post-test mean 22.2; SD 2.3; CI +/-1.2, $p = 0.007$) and control group (mean 31.3; SD 11.3; CI +/- 5.7 vs. mean 24.3; SD 3.4; CI +/- 1.7, $p = 0.021$) with no significant post-treatment difference between the two groups. Sub group analysis revealed no significant difference between the two therapists indicating adequate standardisation of relaxation effects of massage between the two therapists.

Transient pain: Transient pain was assessed using a Visual Analogue Scale (VAS) (figure 7.13). There was no significant difference in the subjective VAS levels of reflexology treatment discomfort between the intervention group (post-test mean 0.3; SD 0.3; CI +/- 0.2) and control (mean 0.2; SD 0.3; CI +/- 0.2; $p = 0.24$). Furthermore, sub-group analysis found no individual significant outcome differences in VAS levels between the two therapists indicating that the massage related pain/discomfort effect was adequately standardised between the two therapists and between the two treatments.

Fig 7.15

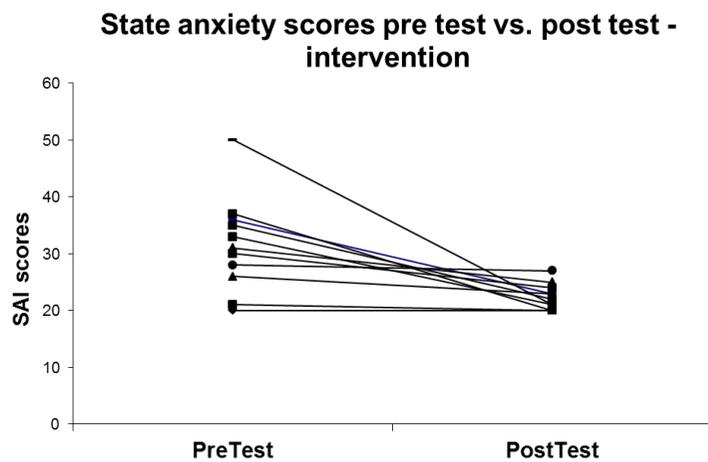


Fig 7.16

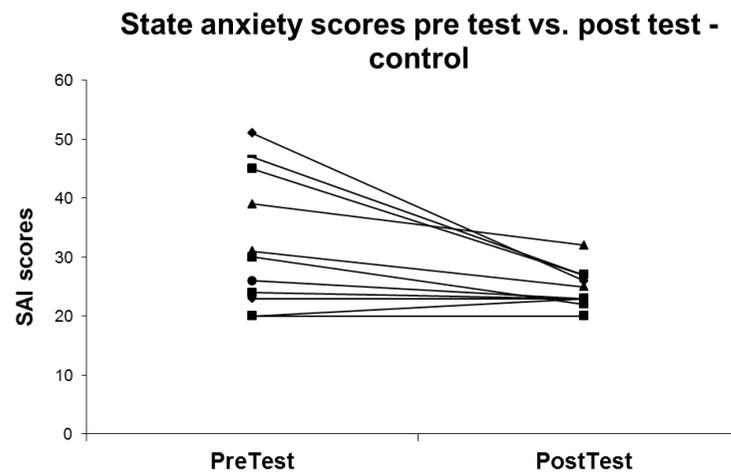


Fig 7.17

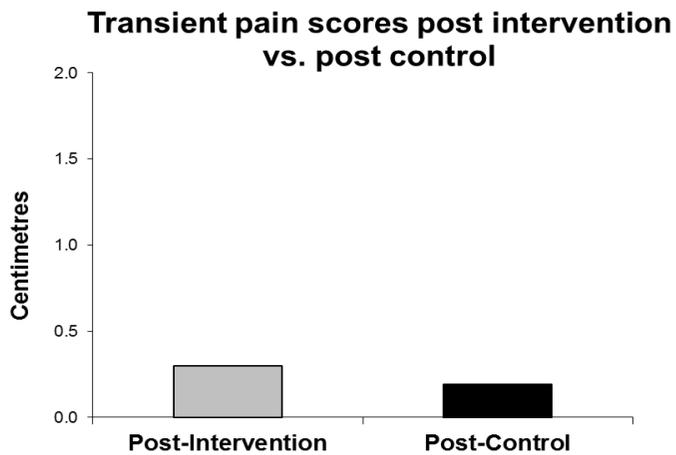


Figure 7.15-7.16. Spielberger State Trait Inventory comparisons of pre and post-test scores for Forefoot (intervention) group

Figure 7.17. Spielberger State Trait Inventory comparisons of pre and post-test scores for Heel (control) group

Table 7.5. Haemodynamic variable results

Table 2. CAD Cardiac Patient Results						
Cardiovascular measurement	Baseline	Right foot	Left foot	5 mins	10 mins	15 mins
HR Forefoot	56.2 (9.5)* *	54.3 (8.9)	54.4 (8.7)	56.1 (10.0)	56.5 (10.5)	56.4 (10.5)
HR Heel	58.49 (9.32)* *	56.15 (8.5)	55.58 (8.0)	57.70 (8.9)	57.46 (9.1)	56.90 (9.2)
sBP Forefoot	127.3 (9.6)	119.6 (13.9)	123.7 (10.8)	125.5 (12.7)	125.7 (11.8)	126.6 (11.9)
sBP Heel	120.9 (10.4)	115.4 (10.8)	119.8 (9.5)	123.3 (11.7)	124.3 (12.8)	124.0 (12.6)
dBp Forefoot	80.4 (9.0)	76.7 (11.3)	78.1 (8.9)	79.3 (10.7)	79.8 (9.5)	80.5 (8.4)
dBp Heel	75.5 (10.3)	72.0 (10.0)	74.9 (10.2)	77.6 (10.3)	78.5 (11.1)	78.0 (11.0)
mBP Forefoot	98.0 (8.1)	92.5 (10.8)	94.9 (8.3)	96.5 (11.1)	96.8 (9.9)	97.6 (9.3)
mBP Heel	93.3 (9.8)	88.9 (9.8)	92.5 (9.7)	95.8 (10.2)	96.9 (11.4)	96.6 (11.3)
SV Forefoot	59.8 (10.1)	61.7 (10.4)	60.7 (10.3)	59.8 (10.6)	59.4 (9.9)	59.8 (9.8)
SV Heel	60.3 (11.6)	61.8 (12.0)	61.1 (11.5)	59.2 (11.4)	59.8 (11.8)	60.1 (11.7)
SI Forefoot	31.9 (6.5)	32.9 (6.6)	32.3 (6.5)	31.7 (6.9)	31.6 (6.4)	31.8 (6.4)

SI Heel	32.4 (7.7)	33.2 (7.8)	32.8 (7.5)	31.9 (7.4)	32.3 (7.6)	32.4 (7.6)
CO Forefoot	3.3 (0.6) * *	3.3 (0.6)	3.3 (0.6)	3.3 (0.7)	3.3 (0.7)	3.3 (0.7)
CO Heel	3.5 (0.8) * *	3.4 (0.7)	3.4 (0.7)	3.4 (0.7)	3.4 (0.7)	3.4 (0.8)
CI Forefoot	1.8 (0.4)	1.8 (0.4)	1.7 (0.4)	1.8 (0.5)	1.8 (0.4)	1.8 (0.4)
CI Heel	1.9 (0.5)	1.9 (0.5)	1.8 (0.5)	1.8 (0.5)	1.8 (0.5)	1.8 (0.5)
TPR Forefoot	2368.5 (415.6) * *	2227.7 (303.6)	2342.8 (398.8)	2373.7 (557.9)	2380.7 (541.3)	2383.1 (539.4)
TPR Heel	2218.3 (500.2) * *	2154.8 (451.5)	2236.4 (474.3)	2343.9 (481.9)	2360.0 (523.3)	2329.8 (537.6)
LF-RRI Forefoot	438.4 (859.6)	792.4 (1390.9)	746.5 (1293.1)	562.5 (866.9)	583.0 (832.5)	674.8 (905.6)
LF-RRI Heel	524.1 (955.7)	585.7 (937.3)	827.7 (1466.5)	863.7 (1321.2)	765.8 (1285.8)	750.4 (1282.9)
HF-RRI Forefoot	1264.6 (3663.0)	1241.6 (3285.8)	1133.8 (2907.5)	1017.4 (2658.6)	1092.5 (2549.6)	1219.4 (2729.1)
HF-RRI Heel	1410.8 (3394.9)	1366.8 (3053.0)	1885.8 (3826.9)	1693.1 (3825.7)	1735.0 (3603.0)	1727.5 (3603.0)
BarUpEvForefoot	13.1 (17.1)	16.1 (16.2)	14.4 (13.2)	12.1 (12.8)	16.0 (16.3)	16.4 (22.1)
BarUpEvent Heel	17.8 (26.5)	17.3 (15.6)	20.4 (17.7)	17.1 (19.9)	17.2 (20.7)	14.1 (15.2)
BarDwEv Forefoot	16.9 (18.8)	15.1 (17.0)	15.6 (17.1)	15.5 (18.4)	14.9 (11.8)	14.8 (14.9)

BarDwEvHeel	17.7 (23.9)	18.4 (25.1)	17.2 (22.0)	21.5 ()	17.6 (17.9)	20.1 (18.0)
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*All data expressed as mean, standard deviation (SD)

* * Indicates significant difference at baseline

7.4. Discussion

This is the first double-blind randomised controlled study to examine whether there are any specific haemodynamic benefits, product quality or safety issues associated with reflexology treatment to the area of the feet thought to be associated with the heart in patients with CAD. There were no adverse events and the study was well tolerated by all participants. Reflexology has not been previously rigorously tested for any acute (immediate) specific hemodynamic effect in the CAD patient group despite the claim of reflexologists that massage to specific points of the feet increases blood supply to referred or 'mapped' organs in the body. This has, until now, left the safety question of therapy-specific adverse-effect on CAD patients unanswered. The study found no specific treatment-related haemodynamic effect in this patient group when reflexology massage is applied to the upper part of the left foot or indeed any other part of either foot. The findings suggested that there is no significant acute (immediate) haemodynamic effect when reflexology massage is applied to the area thought to be associated with the heart, in CAD patients.

Trying to detect such an effect in patients with CAD presented a particular challenge when attempting to experimentally isolate a specific haemodynamic influence. CAD patients are more likely to have distinct vascular characteristics associated with arterial disease which are symptomatically treated by a number of pharmacological therapies. These factors may have potentially suppressed or diluted a specific reflexology treatment haemodynamic effect. For example, endothelial paracrine secretions regulating central vascular tone could be one potential mechanism that reflexologists could appeal to as explanation of how localised changes in organ perfusion rates occur. In healthy endothelial cells, localised arterial vasodilation occurs as a result of secretion of paracrine agents, which act on the adjacent endothelial cells in the arterial wall of the coronary arteries (136). However in CAD, the

influence of genetic polymorphisms of the renin-angiotensin-aldosterone system (231) and the fixed vascular defects such as atheroma and increases in angiotensin II and plasma sodium (Na⁺) cause a remodelling of the arterial wall over time (232). Function defects such as increasing levels of circulating angiotensin II, vasopressin and shearing forces, act on the vascular endothelium and lead to endothelin being released from endothelial cells. Vasopressin is an anti-diuretic. It also binds to V₁ receptors in the smooth muscle of the vascular walls to cause vasoconstriction (229). Endothelin is also a powerful vasoconstrictor (230). Although Endothelin is normally kept in balance by other mechanisms, increased circulating levels have been associated with chronic hypertension (220). Angiotensin II is another vasoconstrictor agent and is linked to increased endothelial cell size and numbers. This increase adversely changes the ratio of wall thickness to internal radius (247), which leads to a narrowing or blockage (stenosis) of affected arteries. Therefore, if endothelial paracrine secretions regulating central aortic vascular tone are one of the potential mechanisms that could be invoked by reflexologists to explain of how the cardiac output reduction effect occurred, the mechanism of action could be masked or diluted within this group due to the maladaptive vascular remodelling already present.

Furthermore, there may be another potential maladaptive vascular remodelling factor present which could explain why no specific haemodynamic effect was observed in this patient group. As CAD progresses, significant damage occurs in both the peripheral and central conduit arterial walls. The central conduit arteries, being more elastic in nature, progressively stiffen as a result of atherosclerotic vascular disease and lose their ability to remain compliant with the changing blood pressure flows (248). As the central arterial vessels stiffen, the pulse pressure wave caused by the output ejection of blood travels down the aorta. The wave then travels on into the network of arterial bifurcations and vascular beds. Two problems occur in connection with the amplification of the ejection pulse wave pressure. First, during systole

when the left ventricle contracts, the output ejection of blood causes a pulse pressure wave to travel down the aorta and into the network of arterial bifurcations and vascular beds. This pressure wave is represented by the outgoing waveform of systole ejection. As the pulse wave travels along the arterial system it generates a reflected wave back as the resistance to flow is felt, predominately from the lower part of the body. The speed of this returning wave depends on the stiffness of the arterial walls. Stiffer arteries reflecting the wave back more quickly (249;250). When this happens, a returning wave form can arrive back at the heart before systole ejection is even complete. This returned wave form increases pressure around the aortic root which in turn places additional pressure on the still systolic left ventricle. Therefore the left ventricle ends up having to attempt to eject blood against an increased afterload (249;251). The raised arterial pressure also triggers the baroreceptor reflex neurophysiological control mechanisms and cardiac sympathetic nerve activity is suppressed. The reduction in ANS sympathetic innervation then slows the heart rate and reduces stroke volume in an attempt to return the arterial pressure to normal levels (209). The compensatory changes in response to CAD vascular characteristics, including a drop in cardiac output, can become chronic as the disease develops (209). Therefore any specific treatment effect related to treatment of the heart reflex point that relies on cardiac output reduction as a potential mechanism may have been masked or diluted within this group, due to already chronically reduced output related to failing arterial compliance.

In addition to maladaptive vascular remodelling, CAD drug management therapies could have suppressed or diluted a specific haemodynamic effect. For example, CAD is typically treated with angiotensin-converting inhibitor therapy, which is a class of vasodilator drugs whose therapeutic effect is to block the activity of the vasoconstrictor, angiotensin II. This improves blood flow and heart workload (252). Angiotensin II receptor antagonists are also used. These work in a similar way to ACE inhibitors by limiting angiotensin II bio-availability (240). Calcium

channel blocker therapy prevents the movement of calcium into the muscles of the blood vessels. This causes the muscle layer in the vessel wall to relax, reducing heart workload due to less peripheral vascular resistance (240). Diuretics reduce circulation blood volume and increase osmotic/oncotic pull of fluid from oedematous extremities. As a result, the heart action improves due to the reduction in blood volume pressure (252). Beta blocker therapy interrupts the transmission of the stimulating action of norepinephrine hormone. This action slows the heart rate, which reduces the force of the heartbeat and lowers blood pressure because the rate and force of the heart output is reduced. Beta blockers also exert a vasoconstriction effect on the blood vessels surrounding the brain and extremities (240). The overall aim of these drugs therapies is to systemically relax and widen the muscular vessel walls of the cardiovascular system, thereby relieving circulating pressure by expanding the cardiovascular fluid volume space. All the study participants were taking various combinations of these haemodynamic-modifying drug therapies. Therefore even if the reflexology intervention affected any of the measured haemodynamic components using means such as the hypothesised paracrine endothelium-derived vasodilator secretion, the effect(s) may have been too subtle to be revealed against the pharmacologically-induced systemic modifying effects acting on the same haemodynamic components. Nevertheless, it was anticipated at the start that CAD pharmacological therapies may potentially dilute or mask a potential specific reflexology haemodynamic effect. However the strict volunteer medication exclusion criteria were deliberately not applied as it was hoped to be able to generalise the experimental results as widely as possible to include those on standardised drug regimes.

It was not clear why the haemodynamic baseline differences occurred between the two groups. Impedance cardiography methodological guidelines recommend stabilisation periods between times of electrode attachment to beginning of data collection, from 0 minutes (start recording data as soon as clear signals produced), to 10 minutes prior to data collection

(180;181). On this basis, it was assumed that allowing 20 minutes from attachment of electrodes and establishment of clear signals, to beginning of data recording, would be sufficient to allow the subjects haemodynamic parameters to stabilise. However as ANOVA GLM analysis was run on each group data separately in order to evaluate differences between patterns of treatment *across time* under the *same* condition, the consultant statistician advised that the chance baseline differences between the four conditions at baseline did not affect the intra-group analysis for specific haemodynamic differences in linear trends across time periods under the left or right foot forefoot intervention condition, which was the main aim of the experiment (195;214). Pre and post treatment transient anxiety state was monitored using SAI psychometric indicators to ensure that both treatments were standardised for relaxation components. The results suggest that neither treatment was significantly more relaxing (anxiety reducing) than the other. Transient pain was assessed using a Visual Analogue Scale (VAS) (figure 7.13). There was no significant difference in the subjective VAS levels of reflexology treatment discomfort between the intervention group. Furthermore, sub-group analysis found no individual significant outcome differences in VAS levels between the two therapists indicating that the pressure of massage was adequately standardised between the two therapists and between the two treatments.

7.5. Conclusion

In conclusion, this was the first double-blind randomised controlled study to examine whether there are any specific haemodynamic benefits, product quality or safety issues associated with reflexology treatment to the area of the feet thought to be associated with the heart in patients with CAD. Reflexology has not been previously rigorously tested for any specific hemodynamic effect during treatment in this patient group. This is despite the reflexology claim that massage to specific points of the feet increases blood supply to referred or

'mapped' organs in the body. The design attempted to address some of the methodological challenges involved in isolating a specific active haemodynamic ingredient from within a complex multi-component reflexology intervention in this patient group. The study findings demonstrate that reflexology does not exert any specific effect on the haemodynamic parameters of patients with CAD. The study also found no adverse non-specific haemodynamic effects or trends associated reflexology in this patient group. Therefore although the longer-term accumulative effects of multiple treatments are uncertain, reflexology treatment to the heart reflex point area and other areas of the feet would appear safe for use in patients with CAD. The next chapter brings together the results of the three RCT's in order to contrast and compare the findings.

Chapter 8

Discussion

Chapter 8

8.1. Introduction

This thesis set out to address three research aims. First, to develop a reflexology treatment protocol for use in the three experimental studies; consisting of healthy volunteers, patients with chronic heart failure and patients with coronary artery disease patients. Second, to conduct an internet based survey of AoR reflexologists to identify whether they are treating cardiac patients and to determine which area of the feet is being used as the heart reflex point in current reflexology practice, to help inform the development of the reflexology treatment protocol. Third, to use the reflexology treatment protocol to examine whether there are any specific haemodynamic benefits, product quality or safety issues associated with reflexology treatment to the area of the feet thought to be associated with the heart in healthy volunteers and cardiac patients, using double blind randomised controlled trials. To this end, several appropriate research questions were devised to answer these aims. These were as follows:

Q1. Can an experimental method be devised which controls for non-specific effects associated with reflexology treatment of the heart reflex point in order to isolate any specific haemodynamic effect?

Q2. What are the perceptions of UK reflexologists regarding the safety and efficacy of treating cardiac patients?

Q3. Is there a consistency in the location of the heart reflex point as identified by reflexologists?

Q4. Does reflexology applied to discreet areas of the feet thought to correspond to the heart result in specific changes in the haemodynamic parameters of healthy volunteers?

Q5. If a specific haemodynamic effect is detected, are there any risks or benefits associated with reflexology treatment to the area of the feet through to be associated with the heart in healthy volunteers?

Q6. Does the reflexology intervention developed for healthy volunteers, using a double blind randomised control trial, result in specific changes in the haemodynamic parameters of cardiac patients?

Q7. If a specific haemodynamic effect is detected, are there any risks or benefits associated with reflexology treatment to the area of the feet through to be associated with the heart in cardiac patients?

The rest of this chapter will describe how the thesis successfully addressed the research aims by answering the all the research questions. First, it will be shown that the novel reductionist protocol method outlined in Chapter 3: Methods and experimental findings from the three RCT's in Chapters 4 to 7, have successfully answered research questions 1, 4, 5, 6 and 7. Also, that the survey findings in Chapter 4 have successfully answered the remaining research questions 2 and 3. As a follow-on discussion from this, the haemodynamic results from the three RCT's will be compared and contrasted in order to investigate why both patient studies failed to replicate the specific haemodynamic effect found in healthy volunteers. From this discussion, recommendations for improving future reflexology research will be identified. This discussion will then progress to a comparison of the experimental findings to existing literature and examination of potential mechanisms which could explain the specific effect found in healthy volunteers. Then, the reflexologist survey findings will be discussed in relation to reflexology product quality concerns. From the survey discussion, recommendations for improving future reflexology education will be identified. The chapter will then conclude by summarising the thesis limitations and outlining the implications of the thesis findings for future practice.

8.2. Thesis findings

To begin the thesis experimental enquiry, research question 1 asked if a method could be devised which controls for non-specific effects associated with reflexology treatment of the heart reflex point in order to isolate any specific haemodynamic effect. Chapter 3: Methods, described a novel reflexology treatment protocol which was developed on the basis of the findings of the literature search in Chapter 2. The protocol purpose was to investigate the specific haemodynamic effect associated with the heart reflex point area. As discussed in the model validity discussion in Chapter 3, the protocol appeared to satisfy reflexology validity requirements, yet still be robust enough to meet the experimental demands of isolating a specific haemodynamic effect from within a complex multi-component reflexology intervention. The protocol representation of reflexology was further strengthened by the survey answers generated in response to research questions 2 and 3. Question 2 asked what the perceptions of UK reflexologists are regarding the safety and efficacy of treating cardiac patients. As the thesis survey identified two dominant views regarding approaches for treatment of the heart reflex area in the survey, the reflexology used in the thesis was able to compromise between these approaches and therefore reflect current reflexology practices. In addition, as question 3 asked if there is consistency in the location of the heart reflex point amongst reflexologists, the survey findings confirmed the marked inconsistencies in clinical practice. This meant that the foot map reductionist approach was indeed necessary in order to establish an 'active' heart area of the feet for the experimental protocol. Therefore, although there may have been some potential experimental limitations using the experimental protocol (which will be discussed shortly), the novel reductionist protocol appeared to have both model validity and be methodologically fit for purpose. This is evidenced by the fact that when the method was applied to the healthy volunteer pilot study, a specific haemodynamic effect was detected. On this basis, the thesis devised a novel protocol, informed by the views

of practising reflexologists, which successfully controlled for non-specific effects associated with reflexology treatment of the heart reflex point in order to isolate a specific haemodynamic effect. Therefore the thesis answered research questions 1, 2, and 3. Furthermore, by identifying the two distinct therapeutic approaches and conceptualising them into two categories, (*'therapy specific benefit'* and *'therapy specific risk'*), the thesis has also made a theoretical contribution to future reflexology literature analysis.

Using this protocol, research question 4 asked if reflexology applied to discreet areas of the feet thought to correspond to the heart results in specific changes in the haemodynamic parameters of healthy volunteers. Although the purpose of the healthy volunteer study was principally to test the reflexology protocol and to look for potential safety issues prior to using the protocol in patient studies, the data demonstrated that there was a small but significant change in cardiac index when reflexology massage was applied to the upper part of the left foot in healthy volunteers. In contrast, there was no difference in cardiac index observed during treatment to the upper part of the right foot or in the lower half of either foot. On this basis, the study findings suggest that a specific haemodynamic change occurred intra-treatment. This change appeared quite distinct from non-specific massage components, such as physical touch, therapeutic exchange and placebo effects. Therefore this thesis successfully demonstrated that reflexology applied to discreet areas of the feet thought to correspond to the heart did result in specific changes in the haemodynamic parameters of healthy volunteers. Therefore the pilot study experiment answered research question 4.

Research question 6 asked if the reflexology intervention developed for healthy volunteers results in specific changes in the haemodynamic parameters when applied to cardiac patients. As discussed in Chapters 6 and 7, this thesis found no evidence of a specific haemodynamic

impact in either CHF patients with LVSD or patients with CAD. Which means this thesis successfully demonstrated that reflexology applied to discreet areas of the feet thought to correspond to the heart did not result in specific haemodynamic changes in CHF patients with LVSD or patients with CAD. Therefore the thesis patient experiments answered research question 6.

Research question 5 asked if a specific haemodynamic effect is detected, are there any risks or benefits associated with reflexology treatment to the area of the feet thought to be associated with the heart in healthy volunteers. As identified in Chapter 5, a significant drop in cardiac index occurred in the healthy volunteers during the forefoot intervention. The precise mechanism which caused the drop remains uncertain. The reduction seems to be associated with an increase in total peripheral resistance and a drop in heart rate. Furthermore, the location where the effect was measured (the upper part of the left foot) appeared to be consistent with the majority of the most popular published reflexology foot maps, which put the heart reflex point somewhere within this same region. However as discussed in chapter five, with regards to Inghams claim that reflexology massage to the heart reflex point specifically and beneficially increases blood supply to the heart (6), the study results are inconclusive. For reflexology treatment to the heart reflex point to cause an increase in coronary perfusion rates, at least one of several physiological actions must happen in order for the heart muscle itself to receive more blood via the coronary arteries, 1) the heart rate would have to reduce to allow cardiac perfusion to take place (the heart tissue only re-perfuses in diastole). 2) the heart rate would need to slow without the longer ventricular filling time and increased volume causing adverse contractility effects 3) the cardiovascular system would have to be systemically or locally vasodilated in order to reduce preload contractile force. Which means, for an increase in cardiac perfusion to take place, there would have to be a reduction in heart rate and cardiac output, indicating that the arterial pressure opposing left

ventricular ejection (afterload) had reduced, along with the workload of the heart, in order to allow the cardiac muscle more time to perfuse in a diastole state. The healthy volunteer study findings suggest that there was a trend towards a reduction in heart rate during the left foot treatment (LFT) intervention which did not occur in the right foot treatment (RFT) intervention or control groups. And as perfusion occurs primarily during diastole and there was an uncompensated, transient fall in cardiac index and trend indicating a transient reduction in heart rate, it is possible that the coronary arteries had an increased arterial perfusion time. Furthermore, this specific haemodynamic change corresponded with reflexology massage being applied to the area thought to contain the heart reflex point. Therefore the thesis successfully demonstrated that the specific haemodynamic effect associated with reflexology treatment to the heart point area appeared to be beneficial. This is because the specific effect produced the right haemodynamic changes which would allow increased coronary perfusion to take place. The specific haemodynamic reduction in cardiac index had no adverse effect in the healthy volunteers and posed no risk to any of the participants as the actual reduction in cardiac index (and therefore cardiac output) was very small. No other risks were identified. In addition, the healthy volunteers in both the intervention and control groups were found to have had a significant post-test reduction in transient state anxiety. This indicates that reflexology offers a non-specific beneficial transient anxiety reducing effect in this group. Therefore this thesis answered research question 5.

Research question 7 asked if a specific haemodynamic effect is detected, are there any risks or benefits associated with reflexology treatment to the area of the feet thought to be associated with the heart in cardiac patients. As chapters six and seven identified, there appeared to be no specific haemodynamic effect found in either patient group. There was no non-specific haemodynamic effect or trend measured in either the intervention or control treatment either. These findings indicate that there are no specific benefits or risks associated with

reflexology treatment to the area associated with the heart (or any other areas on the feet) in either patient group. This means that although the longer-term accumulative effects of multiple treatments are uncertain, the thesis found that reflexology in the short (immediate) term appears to have no risk for CAD and CHF patients. In terms of identifying any benefits, Chapter six reported a non-specific post-treatment reduction in state anxiety in the control CHF patient group (suggestions were given in the Chapter discussion as to why this effect did not occur in the intervention group). Chapter 7 reported on a reduction in state anxiety post treatment found in both the intervention and control groups in the CAD patient study. Which means that any potential benefit associated with reflexology treatment in these two patient groups appears to be limited to its non-specific effect on transient state anxiety. Therefore as specific risks or benefits associated with reflexology treatment to the area of the feet thought to be associated with the heart were found in CAD or CHF patients, the thesis answered research question 7.

8.3. Experimental findings and recommendations for future reflexology research

Although the experimental aims of the thesis had been successfully met, an important question remains unanswered from the three RCT's. Why did both patient studies failed to replicate the specific haemodynamic effect found in healthy volunteer study? One possible answer is that whatever unknown mechanism was involved in the reduction of cardiac index in healthy volunteers, this mechanism could have been diluted or masked in cardiac patients. The possibility of compromised heart output and medication effects suppressing or diluting a specific reflexology haemodynamic effect in CHF patients was discussed at length in Chapter 6. The potential suppressing effect of vascular remodelling and drug therapies in patients with

coronary artery disease was also discussed at length in Chapter 7. However in addition to these potential influences, the failure to detect a specific effect or emerging haemodynamic trends in either patient group could also have occurred for several other, less obvious reasons.

First, it is possible that the effect observed in the healthy volunteers was due to a non-specific effect, which is simply to do with the order of treatment. For every participant, the treatment started on the right foot, regardless of whether it was the intervention or control treatment. The hypothesis in the experiments was that there was something different between the forefoot and heel area. However the findings from the healthy volunteer study could be attributed to the heel area simply being a less neuroreceptor sensitive area in response to massage, rather than a specific effect related to the heart reflex point. For example, the plantar region of the foot has more sensory nerve ending (corpuscle) representation in the general top half (forefoot) area than the heel. Therefore the forefoot region is a more densely innervated area (253;254). This is one of the reasons why the forefoot area appears to be more ticklish or sensitive in general than the heel area (253). Based on this explanation, it is possible that in many of the healthy volunteer subjects, a non-specific 'sensitivity' response started when the therapists began to do something pleasant to the forefoot area on the right foot. As the brief intervention treatment progressed, the participants emerging physiological responses were reflected in measurements taken during the left forefoot treatment.

If the effect on cardiac index can be explained by the non-specific effect of order of treatment and increased sensitivity of the forefoot plantar area, this may explain why the effect occurred in the second half of the intervention treatment in healthy volunteers. As outlined in Chapter 3, cardiac index measurements are derived from cardiac output / body surface area. Cardiac output is calculated from stroke volume * heart rate. There appeared to be a trend in the

intervention group for a reduction in heart rate during the left foot intervention (forefoot) treatment. It is unclear from the data whether the heart rate began to drop before cardiac index, or vice versa. Nevertheless, regardless of which came first, if the subjects progressively 'enjoyed' or were sensitive to the on-going intervention, the massage-related drop in heart rate and borderline significant reduction in cardiac output could have been enough to cause the observed change in cardiac index. Although it is not entirely clear how increased 'sensitivity' in the forefoot plantar area could be linked with a non-specific reduction in cardiac index, massage has been shown to have all sorts of non-specific autonomic and mechanical effects on the human body. These include a reduction in respiration rate (84), heart rate (255) and blood pressure (256), all of which can be linked to a corresponding reduction in cardiac output. Therefore the significant reduction of cardiac index during the left foot treatment could be simply down to a non-specific massage response to a more sensitive area of the foot, combined with the regularity of treatment order.

Interestingly, the idea that non-specific foot sensitivity can explain the HV study haemodynamic response aligns with one of the proposed mechanisms of action that some reflexologists appeal to in order to explain the specific effects of reflexology. Reflexology theorists assume that reflexology massage techniques trigger local action potentials in the various sensory nerve receptors (254). They believe that selective degrees of reflexology pressure act on different receptor sensory nerve endings (corpules) according to pressure intensity. In this theory, reflexologists classify different grades of reflexology physical stimulus (e.g. "slight touch", "mild pressure", "deeper pressure") as being exclusively associated with unique receptor responses from selected sensory corpules (254). However although the classification of what the skin receptors respond to is correct (257), reflexologists fail to explain the significance of applying pressure to the different levels of sensory receptors or how

reflexology massage effects on these receptors are any different from those induced by simple foot massage.

There is also speculation in reflexology about the beneficial effects of touch in reducing the level of excitability in motorneurone cells (254). In massage, motorneurone cell excitability, which directly or indirectly controls the contraction or relaxation of muscles, has been found to be inhibited. However the inhibitory effect in massage is localised to the muscle being treated (258). Therefore this effect should be common to both reflexology and massage responses, as both involve varying degrees of physical stimulus on the skin. Which means although reflexologists appeal to this mechanism of action to explain some of the effects associated with reflexology treatment (254), they fail to explain how reflexology stimulus is distinguished from simple massage or even relaxation, all of which can also inhibit the motorneurone cell response excitability (253).

There was no significant difference in recorded heart rate variability parasympathetic dominance during the right or left foot forefoot (LFT) treatment. Therefore if the 'sensitivity' and treatment order explanation accounts for the haemodynamic change during the LFT, the cardiac index response does not appear to be mediated through parasympathetic activity capable of being monitored by the Task Force® Monitor equipment. Furthermore, this potential explanation does not explain the trend in increased peripheral resistance in this same data block in the healthy volunteer study. Nor does it explain why this non-specific 'sensitivity' response was not evident in either cardiac patient group experiments. However one possible factor that may support the sensitivity explanation is the ages of the participants. The mean age of the 11 men in the healthy volunteer study was only 21.1 years, ± 17.3 and the 5 post-menopausal women, 53.4 years, ± 7.3 . By comparison, in the CHF patient study, the mean age

of the 9 men was 71 ± 7.6 years and the 3 post-menopausal women, 64 ± 6.1 years. Furthermore, the mean age of the 7 men in the CAD study was 66.8 ± 4.9 years and the 5 women, 64 ± 10.2 years. Therefore, the average age of males in both cardiac patient studies was between 45 – 50 years older than the healthy volunteer participants. And the majority of subjects in all three studies were men. Neuropathic and peripheral vascular changes are far more common in older patients with chronic medical conditions (259). Therefore, if the suggestion of plantar sensitivity and treatment order affecting outcomes is correct, the age-related likelihood of reduced level of neuroreceptor sensitivity on the planter region of the feet in older chronic cardiac disease patients could explain why this non-specific massage-sensitive effect was not replicated in the generally older patient groups.

As discussed in Chapter 3 Methods, the study design included a pre & post-test measurement of transient anxiety using the State Anxiety Inventory (SAI) at each session. This inventory was used in an attempt to infer the 'relaxation' component of the intervention and control treatments by measuring pre and post anxiety levels. Although the SAI is a self-report scale that has been extensively validated to be a sensitive psychometric indicator of changes in transitory anxiety or tension states (182;183), this tool did not allow any evaluation of whether the subjects found the intervention (forefoot) treatment more 'sensitive' or 'enjoyable'. Therefore it is possible that this domain of subjective 'sensitivity' was not captured by the use of the SAI. Furthermore, although a visual analogue pain scale was used in an attempt to standardise the level of massage-pressure related pain, the subjects responses to scoring peak discomfort were dependent upon memory of the pain and sensitivity of the foot area experienced after the treatment has finished (260). No significant difference was found in the visual analogue scores between the forefoot and heel groups in any of the experimental studies. This was interpreted as suggesting that the pressure depth and intensity had been adequately standardised. However it is possible that there may have been inaccuracies in

recalling the degree of massage-related pain sensitivity, either through inaccuracy of recall at the end of the session (261), or through not wanting to “offend” the therapist by implying that the treatment was painful. It could be argued that treatment to the heel wasn’t generally more painful as such, but for the healthy volunteer subjects, perhaps the heel was simply less ‘sensitive’ area than the forefoot area. Therefore it is possible that this domain of subjective ‘sensitivity’ was not captured by the use of a VAS either. In future reflexology studies, methodological rigour could be further enhanced by the additional use of questionnaire tools such as the Touch Aversion Questionnaire (262) to capture the perceptual touch ‘sensitivity’ experiences associated with the neuroreceptor sensitivity in the two different areas of the feet. Also, rigour could be improved by the randomisation of foot treatment order. This should not compromise reflexology model validity as the review of selected texts from the ‘core curriculum’ reflexology literature in Chapter 3 found that as with the inconsistent maps, detailed reflexology treatment sequences and massage techniques appeared to vary, dependant on author referenced. Therefore in future, reflexology researchers could adopt the reductionist foot-map approach and randomise foot treatment order.

Another reason which may explain the failure to detect a specific haemodynamic effect in the cardiac patients groups may be related to the therapists awareness of the study aims. It is possible that the therapists knowledge that the heart reflex point was the area of interest made a difference in the HV study. Research has demonstrated that even when experimenters are blinded in a double-blind RCT, their knowledge of potential treatment options can be sufficient to make a substantial difference on the experience of the experimental subjects without even realising it. This is done by unconsciously conveying the therapeutic aim of what the subject might be randomised to receive (263). In effect, the therapists could have somehow conveyed to the participants that the forefoot treatment would be more ‘powerful’ or ‘important’ in terms of the experimental aims. Particularly as the HV study was the

therapists first experience of participating in experimental research. Therefore it is acknowledged that the results of the three experimental studies would have been further enhanced if the reflexologists themselves had been blinded to treatment type. In the experimental design developed for use in this thesis, this extra layer of blinding was not possible. The Ingham method trained therapists were aware that the heart reflex point was the experimental focus of interest. And quite clearly, both have a vested interest in reflexology which extends deeply into their personal belief systems. Although they generously co-operated with the restrictions placed upon their normal practice, both believed that the heart reflex point was located within the region of the ball of the left foot. Which means it is possible that the experimental importance of this area could have been unconsciously communicated to the HV participants.

This knowledge could have potentially introduced a degree of bias in several other ways too. For example, the therapists might have subconsciously attempted to work the area they believed to be the heart reflex point area in a different way in order to 'prove' its effect, particularly in the pilot study. However this possibility was anticipated in the study design. It was hoped that the enforcement of a strict time-limit on both treatments would ensure that the therapists did not 'linger' on any particular area as they were required to complete a treatment routine within the short time allotted. Furthermore, it was assumed that if the therapists had 'lingered' on the heart reflex point during the intervention treatment, or treated it with a different level of pressure or intensity, the patient-reported relaxation or pain might scores might have systematically varied. As it was, there was a fairly uniform significant reduction in pre vs. post SAI and post VAS scores in both the healthy volunteers and CAD patient groups. (As Chapter 7 discussed, there was no significant pre vs. post SAI difference was found in the CHF control group but this was thought to be potentially due to the suppression of negative emotions and maximum pre-test SAI scores rather than a difference in

treatment content (237;238). In future reflexology research, therapist bias could be addressed by blinding the therapist as well as the data collector and study participants. This could be achieved by not informing the therapists which reflex point area was under investigation. This would mean that they would be required to deliver the two treatments based on the reductionist map approach, without knowing which treatment was the active intervention.

Another reason that no effect was detected in the cardiac patient experiments could be to do with the study size. Although statistically significant, the difference in absolute clinical values in the healthy volunteers was very small. Therefore it is possible that regardless of the power calculation derived from the healthy volunteer data, the degree of heart failure, coronary vascular remodelling and drug management present in the two patient groups may have meant that there was insufficient power in the cardiac patient studies to detect a subtle difference. The fact that there were no apparent trends revealed in any of the examined outcomes in either patient study to suggest that even a subtle effect was beginning to emerge further indicates that this may be a possibility.

Finally, the failure to detect a specific haemodynamic effect in cardiac patients may indicate that the effect recorded in the healthy volunteer study was simply down to chance variation. In other words, by play of chance, in that particular recorded data block, the majority of the subjects happened to have a fall in cardiac index which appeared to suggest a meaningful, ordered variation. Although this is a possible explanation, 8 healthy volunteer subjects in the intervention group had a reduction in cardiac index intra-treatment to the left Forefoot area, and the remaining 7 had no change from the previous period. Whereas in the control group, 5 had an increase in cardiac index and 10 stayed the same as the previous period. On this basis, the degree of variation does appear to suggest that it is more likely that systematic variation occurred.

Although several potential confounding factors have been discussed, it is proposed that researcher objectivity was maintained in the experiments. Therefore any threat to the internal validity of the study from researcher bias was minimised as much as possible. The researcher was blinded throughout to treatment type and throughout the data analysis, until analysis was completed. In addition, the researcher had no way of knowing which set of data referred to the intervention or control condition until unmasked at the end. Also, the researcher is not a reflexologist and has no vested interest in reflexology other than as an object of experimental interest. Furthermore, the risk of bias was further reduced by the use of true unpredictable randomisation of participants to the two treatment schedules. This was done by a third party not involved in the study.

8.4. Comparison of thesis findings to existing literature

As the healthy volunteer study appeared to find a specific reflexology haemodynamic effect, it is interesting to revisit the studies included in the Chapter 2 literature review. The purpose of this is to see if any of their findings provide a biological context in which to place the thesis findings. In other words, whether any these studies hint at, or suggest, a potential biologically plausible mechanism that may explain how a specific haemodynamic effect in healthy volunteers could be mediated. For instance, as discussed in Chapter 2, Sudemeier et al (92) used a double blind RCT design to measure reflexology induced changes in the resistive index in renal vessels in healthy volunteers. The authors reported a highly significant decrease in resistive index ($p = < 0.001$) intra and increase ($p = 0.001$) in the renal vessels. This occurred when mechanical reflexology stimulation was applied to the reflex point thought to be associated with the right kidney. An unrelated reflex point was used as the treatment control.

There was a significant difference between the pre vs. intra measurements in both groups ($p = 0.002$) and intra vs. post-treatment ($p = 0.031$) (absolute values not stated).

Although the intervention and control group had a significant post-test drop in sBP ($p=0.014$) vs. ($p=0.048$), the lack of significance between pre vs. intra test sBP levels in either group indicate that the change in resistive index was not due to intra-treatment systemic vasodilation. However there were methodological problems with this study. Apart from the poor definition of the reflexology intervention itself, there are problems with the colour Doppler Sonography methods used for haemodynamic interpretations. First, the arcuate arteries of the kidneys are not ideal for measurement of resistive index using this technique. Their bended course meant that they could give erroneous resistive index measurements with any minor shift of the transducer. More accurate Doppler readings are obtained when the vessels being examined run straight towards or run parallel with the transducer (160). Also, in a strict interpretation, resistive index is not a measure of absolute flow volume, but of a relationship between peak systolic velocity – end diastolic velocity / peak systolic velocity. Actual volume is a product of flow velocity and vessel diameter combined (264). Although resistive index is a sign of less resistance, which could signify an increase in blood flow in the vessel, the opposite can also be true. More perfusion can lead to a higher resistive index if the blood vessel diameter does not enlarge proportional to the increased blood flow volume in the vessel (265). Also, as the measurement only strictly refers to velocities, no conclusion can be drawn concerning flow volume or perfusion rates. Furthermore, although resistive index appeared initially promising as a method of quantifying alterations in renal blood flow, subsequent validation studies did not support its clinical use (266). Therefore the assumptions that the researchers make about increased perfusion rates based on resistive index changes are not strictly justified.

The same methodological criticisms apply to the Mur et al study (89). In this study, the researchers used the same technology and same experimental design to test the specific haemodynamic effect of the intestine reflex point in healthy volunteers. Resistive index of the superior mesenteric artery was recorded. An unrelated reflex point was used as the treatment control. The intervention group had an intra-treatment significant reduction in resistive index in the artery ($p = 0.021$) (absolute values not stated), compared to the control group. The reduction occurred in 14 out of 16 subjects intra-intervention. From this, the authors hypothesised that blood flow had increased into the superior mesenteric artery during the mechanical reflexology stimulation to the intestinal reflex point. Although it is undeniably interesting that both studies measured a significant change in resistive index intra-intervention treatment, their hypothesis that blood flow increased as a result of single reflex point stimulation is unsupported. However their findings do indicate that one derived haemodynamic measurement changed in relation to specific point treatment. The specific haemodynamic effect appeared to occur in the relationship between peak systolic velocity – end diastolic velocity / peak systolic velocity. On this basis, although methodologically flawed, both studies support the findings of this thesis, as both researchers found evidence of a specific haemodynamic effect associated with the relevant reflex point area. The effect found in both studies appears to suggest a local vascular response to reflex point stimulation in healthy volunteers. However although both support the existence of a specific haemodynamic component in reflexology, neither study suggests any potential biologically plausible mechanisms that may explain the changes in local vascular response through which a specific haemodynamic effect could be mediated.

Two other studies included in the Chapter 2 review attempted to measure specific intra-treatment effects associated with a full reflexology intervention. These studies used heart rate

variability parameters as the experimental outcomes. Zhen et al (96) and Joseph et al (97) found significant differences during the reflexology intervention in 'Entropy' (mean 1.79802, SD \pm 30.63818; p = 0.03) and (0.54, SD \pm 0.05; p = 0.03) and 'Correlational Dimension' (5.819767, SD \pm 0.268013; p = 0.006) and (4.29, SD \pm 0.24; p = 0.05) when compared to the control state. Both papers claim that as correlational dimension has been previously shown to decrease in patients under anaesthesia, their results suggest that the intervention subjects became more 'conscious' during the reflexology treatment. However CD and Entropy parameters are not typical of heart rate variability experimental components. In HRV analysis, the meaning associated with these measurements is still speculative. Furthermore, both research teams used non-linear chaos theory as the statistical analysis model to derive their results. The Heart Rate Variability Standards of Measurement, Physiological Interpretation and Clinical Use guidelines state that nonlinear methods of analysis such as these are lacking (169). This means the full scope of this statistical model has not been properly assessed in heart rate variability analysis. Therefore the results of these two studies offer little to support the thesis findings or to explain the potential mechanism of action, despite their claim of significant intra-treatment effects. None of the other studies reviewed in Chapter 2 made any attempt to identify intra-treatment specific haemodynamic effects or intra-treatment haemodynamic trends. Also, most lacked a suitable form of experimental control. As previously discussed, the type, duration and 'dose' of reflexology varied considerably, as did the foot maps, making direct comparison almost impossible. Furthermore, all except one used pre and post treatment measurements; therefore only one set of intra-treatment data is available from this selection. Therefore although these studies report on pre and post-treatment haemodynamic outcomes, it is difficult to make any inferences from their results that can be used to identify a biologically plausible mechanism that may explain how a specific reflex-point associated reflexology haemodynamic effect could be mediated.

For example, McVicar et al (95) measured pre and post sBP, dBP and heart rate in healthy volunteers receiving reflexology. The intervention was a full reflexology treatment, single session, style and map source unknown. A significant sBP reduction post-intervention (mean - 6.3, SEM 1.6 mmHG; $p < 0.001$) and HR (-7.9 bpm SEM 1.3; $p < 0.0001$) was found. However this study used relaxation as the control, so their design does not attempt to isolate any specific haemodynamic component to the therapy. On this basis, the reduction in sBP could be nothing more than a non-specific massage effect. Wilkinson et al (94) measured pre and post BP, heart rate, respiratory rate and oxygen saturation levels in patients with COPD receiving reflexology. The reflexology intervention was a series of four treatments over four weeks, style and map source unknown. They reported a significant reduction in HR post-intervention ($p = 0.01$) (absolute values not stated) after one session. But again, this was compared to relaxation as a control and the drop in HR could be a non-specific massage relaxation response. Frankel (88) measured pre and post baroreceptor reflex sensitivity, BP and sinus arrhythmia in healthy volunteers receiving reflexology, foot massage or relaxation (control). The intervention was a full reflexology single treatment using Ingham-derived reflexology techniques. A reduction trend in baroreceptor reflex sensitivity (BRS) indices was found intra reflexology and foot massage treatments vs. control (nothing) (mean difference 0.016, $p = 0.087$ vs. 0.019, $p = 0.057$ vs. 0.066, $p = 0.52$). But again, the poor differentiation between reflexology and foot massage and the significant BRS reduction being common to both treatments implies that the change is due to a non-specific massage effect. The same design limitations also apply to Gunnarsdottir (93), who measured pre and post sBP, dBP heart rate and respiration rate in five patients awaiting CABG. The intervention was a series of five reflexology sessions delivered over five days, using Ingham-derived reflexology techniques. The only finding was a significant post-test reduction in sBP for the control (relaxation) group (mean 4.6, SD 7.2, $p = 0.05$). Also Mackareth et al compared reflexology with muscle relaxation training (MRT) in patients with multiple sclerosis. The intervention was six full reflexology

treatments, delivered over six weeks, using Ingham-derived reflexology techniques. The only haemodynamic finding in this study was a significant reduction in sBP in the MRT group post intervention ($p = 0.002$). Therefore the only changes evident in both these studies appear to be non-specific relaxation effects. Hodgson and Anderson measured pre and post intervention sBP, dBP and heart rate in patients with dementia. The intervention in this study was four full reflexology treatments delivered over four weeks, reflexology style and foot map source not known. The researchers found no significant difference in any of the haemodynamic parameters in either the intervention or control group.

The similarity of haemodynamic findings between the reflexology studies and foot massage studies suggest that the haemodynamic effects found were as a result of the non-specific massage component in reflexology. Therefore from a biological perspective, these studies do not hint at, or suggest, any plausible mechanism that may explain how a specific haemodynamic effect in healthy volunteers could be mediated. Ordinary foot massage alone in cardiac patients has been shown to produce similar pre and post haemodynamic effects, although in these studies, they are not presumed to be specific effects. For example, a five-minute foot massage in critical care cardiac patients has been shown to produce significant transient reductions in heart rate (pre-test mean 97.34, SD 20.40, vs. intra-test 94.68, SD 21.61 vs. post-test 96.30, SD 21.04; $p < 0.003$), respiration rate per min (23.04, SD 6.22 vs. 21.25, SD 5.72 vs. 20.97, SD 3.71; $p < 0.001$) and pre versus intra-test mean arterial blood pressure (85.53, SD 12.26 vs. 83.57, SD 12.26; $p = <0.05$) (84). A 20 minute massage using aromatherapy essential oils in post-surgical cardiac patients found a significant difference in respiration rates before and immediately after the massage, when compared to the control relaxation group (resp. rate per min (-1.72, SD 3.34 vs. 0.36, SD 4.36; $p < 0.05$) (267). And cardiac patients who received a series of massages both pre and post a CABG surgical intervention were found to have a significant decrease in respiratory rate on day 2 post-

surgery (-1.7, $p = 0.03$) and on day 4 (-1.2, $p = 0.05$) compared to the relaxation control group (9). However in a second study in post CABG cardiac patients, a similar 20 minute foot massage produced no significant effects on sBP, dBP, heart rate or respiration (8). What is interesting is that in contrast to these foot massage studies, there were no post-test non-specific massage-related changes found in the cardiac patient studies in this thesis. This is most likely due to the fact that the reductionist treatment period was short in comparison to a typical reflexology/foot massage treatment length. However as a specific haemodynamic effect appeared to occur in the healthy volunteers, it is interesting to examine hypothesised mechanisms of action for the haemodynamic effect from the reflexology perspective. The chapter has already critically discussed one reflexology theory, which is the selective triggering of local action potentials in the various sensory nerve receptors and the inhibition of excitability in motoneurone cells (254). Three other theories are now briefly discussed.

8.4.1. Hypothesised mechanisms of action from the reflexology perspective

8.4.1.1. Crystal toxins

The analysis of reflexology educational literature in Chapter 1 identified that Ingham's mechanism of action relied on her theory that organs have some kind of 'nerve canal'. She believed these canals formed two-way haemodynamically active feedback loops with reflex points found on the soles of the feet. She assumed that if a nerve canal or organ became 'sluggish', obstruction would then impair the nerve canal flow and blood flow to the organ would become impaired as a result (63). Blood flow obstruction was thought to manifest either as a form of perceived 'grittiness' (a sense of 'crystals' under the planter skin of the sole of the foot), or physical tenderness. For Ingham, the perception of grittiness in a reflex point

was a sign of accumulating 'crystals', which indicated that the corresponding organ blood supply was becoming blocked. She believed that reflexology reflex point massage broke down the crystals and as a result, organ perfusion increased.

Ingham offered no explanation as to the origins of these toxic crystals. Nor did she give the name of a single, identifiable chemical toxin which could be measured or extracted for testing, except for the occasional mention of 'calcium' deposits giving rise to 'acid' crystals (63). Ingham's idea of 'toxins' is problematic because any metabolic waste products from the tissues are washed out into the cardiovascular system for eventual filtration and excretion by the kidneys (158). There is no evidence that metabolic waste products crystallise and 'settle' in the nerve endings of the feet. So Ingham's idea of toxins arguably has no scientific meaning, even though she stated that the efficacy of reflexology was built on the opinions of practising physicians (268).

8.4.1.2. Dermatomes

Other more contemporary reflexologists appeal to Sir Henry Heads theory of dermatomes (or "*Heads zones of hyperalgesia*") as evidence that discreet two-way feedback loops exist between the peripheral skin and internal organs (269). Head was a 19th century neurologist who experimental work focused on the somatosensory system and sensory nerves (270). Reflexologists interpret Heads work as providing evidence that a neurological relationship exists between the skin and internal organs. The reflexology claims for specific organ influence relies on one sentence from Heads (1926) publication "*Aphasia and Kindred Disorders of Speech*". On page 481 of this book, Head writes, "*The bladder can be excited to action by stimulating the sole of the foot, and movement of the toes can be evoked by filling the bladder*

with fluid". Some reflexologists infer from this single proposition that all organs can be individually affected by stimulation of distinct areas of skin on the feet.

It is an anatomically correct assumption that the sensory nerve endings in the skin run all the way to terminals within the central nervous system in a pattern of zones or 'dermatomes' as described by Head. And the ganglia roots next to the spinal cord are connected in an orderly way to various regions of the skin which can be drawn out or 'mapped' to regions of the body (271). However in Heads neurological model, the feet and legs have been demonstrated to be mapped to one of the five fused sacral bones labelled as S1. Whereas the heart is innervated by sympathetic fibres which leave the spinal cord at segments T1 – T5 (272). Therefore in Heads neurological model, the dermatome which maps to S1 is not a part of the central nervous system that has any direct influence on the heart. All of which means there is no evidence to support the claim of activation of organ activity from the foot, based on the single mention of bladder stimulation in Heads original work.

8.4.1.3. Energy

Some reflexologists claim that the specific mechanism of action is based on the Traditional Chinese Medicine (TCM) meridian model (36). In TCM, 'Energy' or 'Chi' is said to flow through the body in precise and orderly patterns called meridians. There are thought to be 14 meridians in all, 12 of which are associated with specific organs of the body (273). Each meridian runs vertically through the body, bringing Chi down or up to specific organs as required. Meridians are non-biological in nature and have no known biologically plausible correspondences. Reflexologists who believe in the existence of meridians assume that Chi can be manipulated or activated via external 'access' reflex points on the feet. However this is as far as the two constructs overlap, as there is little correspondence between the foot

endpoints of the Chinese organ-related meridians and the majority of published reflexology foot maps.

The Chinese health exercise systems Tai Chi and Chi Kung, which are based on ideas of meridian energy, have already been evaluated in patients with symptomatic heart failure and patients with essential hypertension. Tai Chi is based on a low intensity series of slow, gradual movements which aim to balance internal Chi and maintain suppleness and mobility. Chi Kung uses distinct movements and breathing techniques specifically to cultivate Chi (273). Like reflexology, they are both complex, multi-component interventions which present similar research challenges in terms of isolating any specific component (121). Tai Chi was found to improve symptoms scores in patients with symptomatic heart failure (comparison of deltas, -2.4 control vs. -14.9; $p = 0.01$) when compared to standard treatment. But a meta-analysis of studies involving self-practised Chi Kung for less than one year in patients with essential hypertension found no significant benefit over drug therapy management, conventional exercise or muscle relaxation technique (274). After reviewing these hypothesised mechanisms of action, it is clear that existing theories currently put forward by reflexologists have no adequate scientific or biological foundation that can explain how reflex points on the feet correspond to specific internal organs within the body. Therefore speculations by reflexologists regarding potential mechanisms of action in the hypothesised two-way haemodynamic correspondence appear to lie beyond the domain of science at this point in time.

8.5. Survey findings and recommendations for future reflexology education

The thesis survey of AoR registered reflexologists demonstrated a lack of clarity and consistency in therapists' views regarding reflexology indication in cardiac patients. In addition, the findings suggested marked differences in reflexologists treatment approaches in this patient group. Therefore the survey findings indicated a lack of skills and competency standardisation in the profession, which is a product quality concern. A variation in reflexology educational standards was implied by the difference in responses to survey questions 6 and 7. Question 6 asked "If your client had stable diagnosed heart problems, would you be happy to treat?" Q7 asked "If your client reported having stable angina or heart failure, would you be concerned about doing reflexology on them?" 97% answered "Yes" to Q6, whereas only 67% answer "no" to Q7. Although the difference could suggest a possible weakness in internal consistency between these two questions, (where the use of more specific biomedical disease term produced an incorrect false negative response from some therapists) (202) it could also imply that reflexology education is lacking in basic disease category recognition. Stable angina and heart failure are two of the most common syndromes in chronic heart disease and therefore it is difficult to see how reflexologists logically differentiate between the umbrella term "heart problems" and common heart disease terms such as heart failure or angina. However this could be explained by potential differences in the quality of reflexology training providers. Reflexology courses are offered by a variety of providers. These range from modular courses within BSc (Hons) degrees in complementary medicine (275) which include biomedical anatomy and physiology classes and research education, through to privately-run beautician therapy schools (276). Therefore the quality of basic anatomy and physiology teaching in the reflexology educational curriculum may vary considerably between training providers. In which case, some therapists may lack sufficient anatomy and physiology education to be able to differentiate between even basic disease terms. As the AoR helped to provide linguistic validity by co-scripting all 9 survey questions, it was hoped that the language and terminology would be familiar to as many therapists as possible. However future research

could aim to further stratify survey responses in this population by collecting data on where respondents received their reflexology training.

The review of reflexology educational literature in Chapter 1 also found two contradictory beliefs regarding the indication of treatment to the heart reflex point in cardiac patients. The thesis analysis summarised these beliefs into '*therapy specific benefit*' or '*therapy specific risk*' categories. The experimental findings of this thesis suggest that neither educational viewpoint is valid. Because although Ingham-style reflexologists believe that reflexology massage exerts a specific effect on the heart reflex point in cardiac patients, no specific or non-specific haemodynamic risks or benefits associated with this or any other point treatment were detected in either patient study. Therefore this thesis suggests that a new, more evidence-based category of treatment advice is warranted in contemporary reflexology educational literature which reflects the evidence suggested by this and other reflexology research.

The survey findings also found marked inconsistencies in heart reflex point placement amongst the respondents. As Chapter 4 discussed, many variations of reflexology foot maps are publicly available, produced on a smaller scale by individual reflexology training providers and on a larger scale, by professional reflexology member organisations such as the International Federation of Reflexologists, the Association of Reflexologists, the British Reflexology Association and the British School of Reflexology. The cost of purchasing a copyrighted foot map from each provider varies considerably. It was suggested by the AoR that this may be a contributing factor to the diverse array available. For example, the International Institute of Reflexology (IIR), the only school licensed to teach Inghams original reflexology method, sells the Ingham map for £15/US\$20/16€ (211). Inghams map combines the heart reflex area with the left lung and breast reflex area (4) and on the Chapter 4 survey foot template, the heart

reflex would appear be positioned in the area of boxes D13-15/E13-15 on the left foot. The AoR foot map, available on-line to both members and non-members, costs £1/US\$1.5/1.2€ (212). On the foot template, the AoR heart reflex point seems to be positioned across D14/E14, which also falls in the middle of the Ingham heart reflex area, again, on the left foot. The British Reflexology Association use a map based on the work of reflexologist Doreen Bayley, a student of Inghams. The BRA/Bayley chart is available for members and non-members for £12.50/US\$19/15€ (213) and the heart reflex area appears to be positioned across the left foot area, this time across boxes D12-D14. The British School of Reflexology offers a foot map based on the work of reflexologist Ann Gillander, available on-line for £7.25/US\$11.7/9€ (277) and in this chart, the heart reflex area appears mapped to D11-13/E11-13 on the left foot template and also across boxes D8/E8 on the right foot. As far as reflexology product quality is concerned, if reflexology wishes to commercially distinguish itself from simple foot massage as a distinct therapy, then it is clear from the thesis survey results that commercial map standardisation needs to be investigated further. If not, the claim of specific two-way correspondences in an ever-changing map is untenable.

There are both financial and ethical reasons for complementary therapies who make specific treatment claims, to have a body of evidence to substantiate that such a claim can be shown to be a specific effect above and beyond placebo (17). Also, if possible, to provide robust explanations of how specific key interventions at the heart of their therapies work (130). This is seen as important in order to justify both clinical worth and cost effectiveness (25). In the case of reflexology, this thesis suggested that unless evidence to support the claim of a specific haemodynamic effect in cardiac patients could be identified, reflexology was theoretically indistinguishable from simple foot massage for this patient group. Given the cost of commercial reflexology sessions, this distinction has financial implications for cardiac patients (24). The thesis findings may hopefully stimulate healthy debate amongst reflexology

educators and training providers, not only in terms of ensuring that educational literature claims are valid and where possible, evidence-based, but also in relation to the obvious product quality issue this thesis has identified in published reflexology foot maps.

8.6. Limitations

The Task Force® Monitor measures the majority of haemodynamic parameters, including cardiac output and index, by impedance cardiography. This is acknowledged to be less robust than more invasive measures of cardiac output, however use of invasive methods would not have been practicable or ethical in a healthy volunteer or cardiac patient population. The data from the healthy volunteer and CAD and CHF patient samples came from predominantly male white participants. However the sample was quite typical of other haemodynamic outcome studies in cardiac patients and healthy volunteers. The results may be generalised to male and post-menopausal female patients with CHF due to LVSD and male and post-menopausal female patients with CAD, but not to pre-menopausal women in any of these groups or to other groups of patients with cardiac disease. It is acknowledged that as multiple statistical testing at the 5% level was done, any significant results could be purely significant by chance, however this does not detract from the robustness of the design. Statistical help was sought at all stages of the protocol design, data analysis and post analysis publication stage. Furthermore, Tukey's Test was used to reduce the probability of making a Type 1 error. As discussed earlier in this chapter, despite using the same protocol, the three experimental studies did not find consistent results. However a major strength of this study is that it included continuous haemodynamic observations in the experiments. Furthermore, it was useful in that it helped to develop a suitable experimental protocol which can help other reflexology researchers. This protocol is unique in methodological approaches for reflexology

research and addressed the methodological limitations of previous reflexology research in several ways. First, by using adequate controls for non-specific components such as the effect of lying supine for the duration of the experiment, the patients treatment expectations, the effects of therapist interaction, and the experimental environmental. This meant that all these non-specific components would be equal in both treatments. Second, by comparing two forms of reflexology as the experimental intervention and control, the design also controlled for the relaxing effects of simple foot massage across both sessions. This method allowed for a specific effect to reveal itself in the intervention group only. Third, the study design also uniquely attempted to control for subject perceptions of treatment relaxation effects and touch pressure, using pre and post-test measurement of transient state anxiety and a post-test VAS pain scale. Therefore, as the thesis used the best possible design to support the thesis aims, it is assumed the inconsistency in results may be potentially due to factors that are outwith the protocol design scope. The study of healthy volunteers had a relatively small sample size to give a solid conclusion. However recruiting 16 healthy volunteers with enough diversity to enable generalisation of any results to a wider population at large had to be balanced with the possibility of the reflexology treatment effect being potentially quite subtle. Therefore, for the small sample size involved and the wide participant inclusion criteria, statistically visible results were anticipated to be small. Which meant the sample size was a pragmatic balance between the variation or statistical 'noise' of potential physiological differences in the healthy volunteers balanced against the smaller effects or 'noise' of the intervention. Nevertheless a retrospective power calculation demonstrated that in order to detect the recorded cardiac index difference of 0.15 l/min*m2 (Alpha = 0.05; assumed SD of paired differences = 0.14 with 0.8 power) a sample size of 9 would have been sufficient. The sample sizes of the CHF patient and CAD patient studies were relatively small. However both were adequately powered to replicate the healthy volunteer study findings by showing a significant 0.29L/min change in cardiac output. The pre-study requirements asked all

participants to abstain from food for 4 hours beforehand and from tobacco and caffeine-containing drinks for at least 12 hours prior to attendance. The volunteers conformity to the requested pre-study criteria regarding food, drink and smoking was not scientifically checked. Although it is possible to detect evidence of nicotine in human urine (278), traces can stay in the body for up to d-4 days, even with occasional smokers (279;280). On this basis, the volunteers own self-reporting of abstinence was accepted. With regards to the thesis survey questions, there was no “gold standard” for validation comparison (202). However the validity of the questionnaire content was assessed by reflexology experts during its construction. Also, it is acknowledged that the survey response rate was low. Furthermore, only members from one professional association were surveyed and practices may vary between associations which may have limited the generalisability of findings. And as survey-monkey.com online security settings prohibited multiple attempts from the same IP address, this may have prevented multiple reflexologists sharing one computer in a clinic setting from responding. Nevertheless, this survey attempted to avoid sampling bias by inviting all members of the AoR to participate. Furthermore, even though the actual number of respondents was low, the aim of the survey was to detect the existence of a true difference between two broad beliefs in therapists’ views towards cardiac patient clients and to identify the extent of reflex point variation in clinical practice. As the analysis of quantitative data findings suggested marked variation even with a smallish sample size – a larger sample size would potentially not have reversed these results and may have made the variation even greater as the existing sample may have underestimated the variation between the two beliefs.

8.7. Implications for future practice

This thesis adds new knowledge by identifying a specific haemodynamic effect associated with reflexology treatment to the area thought to correspond to the heart in healthy volunteers.

This specific effect appears haemodynamically beneficial in healthy volunteers. Furthermore, the study developed a novel protocol using double blind randomised controlled trial design which can be used to inform future reflexology research. The thesis findings in healthy volunteers supports the claims of Ingham-method trained reflexologists in the healthy volunteer population. Further research is warranted to investigate this effect and to identify the biological mechanisms that may be involved. The thesis also adds new knowledge by identifying that there are no specific or non-specific risks associated with reflexology in patients with CAD or CHF due to LVSD. The thesis findings of a non-specific effect in post-treatment transient anxiety reduction in the two patient studies offers new evidence to indicate that reflexology may offer cardiac patients a means of reducing transient anxiety levels. This effect may therefore provide short term emotional stress relief. On this basis, the non-specific reflexology relaxation effect could be therapeutically useful in more acute coronary care settings. Further investigation into this potential application is warranted.

The product quality concerns identified in the survey, namely the inconsistent reflexology treatment approaches, the unsubstantiated treatment claims made by reflexologists for cardiac patients and the marked inconsistencies reported in heart reflex point placement will hopefully stimulate healthy debate amongst reflexology educators and training providers. Not only in terms of ensuring that educational literature claims are valid and where possible, evidence-based, but also in relation to the obvious product quality issue this thesis has identified in published reflexology foot maps. If reflexology is to become more integrated with conventional healthcare, it needs to develop a stronger evidence base for its claims or amend the claims accordingly. If cardiac patients are to make informed choices about whether to use reflexology, they are entitled to know that there may not be a specific clinical benefit in terms of improved symptoms, but that there may be a non-specific benefit in terms of transient anxiety reduction. A stronger evidence base will allow cardiac patients to weigh up the pro and cons of reflexology treatment, so even if they know there is no haemodynamic benefit,

they know that it is safe and cost-effective in other ways. The new knowledge generated by this study means that if cardiac patients ask their clinicians about the potential haemodynamic risks in using reflexology, or enquire about potential non-specific benefits, there is new information available to enable clinicians to answer patient questions from a science and evidenced-based perspective. However although risk and benefit assessment is a paramount concern for clinicians when evaluating any healthcare intervention, cardiac patients have a fundamental freedom and right to make the therapeutic choice to use any form of CAM (including reflexology) alongside conventional surgical, pharmacological management and rehabilitation service. This freedom of patient choice is fundamental, even if evidence of efficacy is lacking. It is clear that many people, including cardiac patients, choose to use and pay for reflexology, which implies that there may be something of value in the practice for them, beyond that of a simple relaxation effect. A deeper understanding of what cardiac patients value in reflexology treatment may not only benefit the cardiac population, but also illuminate what might be missing for the patient in conventional cardiac care delivery. Therefore, wherever possible, healthcare researchers should reflect the obvious public and patient-driven interest in reflexology and other forms of CAM by engaging further in rigorous enquiry into the risks and benefits of CAM therapies if insufficient evidence currently exists.

Furthermore, as this enquiry unfolded, additional ethical issues emerged that only became apparent as the study progressed. These issues included the impact of potentially negative findings on the belief frameworks of both the reflexology therapists and on the patients' belief systems. These ethical considerations may have to take into account by future reflexology researchers who continue to investigate the core claims of reflexology efficacy.

8.8. Conclusion

The aim of this thesis was to examine whether there are any specific haemodynamic benefits,

product quality or safety issues associated with reflexology treatment to the area of the feet thought to be associated with the heart in healthy volunteers and cardiac patients, using double blind randomised controlled trials. In addition, as a precursor to the RCTs, to conduct an internet based survey of AoR reflexologists to identify whether they are treating cardiac patients and to determine which area of the feet is being used as the heart reflex point in current reflexology practice, to help inform the development of a reflexology treatment protocol. And finally, to develop a reflexology treatment protocol for use in the three experimental studies; consisting of healthy volunteers, patients with chronic heart failure and coronary artery disease patients.

The thesis identified a specific acute (immediate) haemodynamic effect associated with treatment to the reflex point area most commonly thought to correspond to the heart, in healthy volunteers. Although this chapter identified several potential and unanticipated non-specific effects that could have accounted for the reduction in cardiac index in this group and the potential suppression of the effect in the patient groups, the findings suggest that more research is warranted. The chapter offered several suggestions how future reflexology research in these populations could improve on the novel reflexology reductionist protocol developed for this thesis for this purpose. Therefore the findings in this thesis may hopefully guide future research which aims to investigate the apparent specific haemodynamic effect further. In relation to CAD or CHF patient use, the thesis found that no specific or non-specific haemodynamic effect which suggested that there was any risk associated with reflexology treatment in either patient group. Therefore the evidence from the three thesis experiments suggests that reflexology treatment to the heart reflex point does not appear to exert any specific haemodynamic benefit, product quality or safety issue in CAD or CHF patients. In which case, although the longer-term accumulative effects of multiple treatments are uncertain, reflexology in the short (immediate) term appears safe, even in patients with

significant chronic heart failure and coronary artery disease.

Glossary of terms

Heart rate: Heart rate is the number of heart beats over a specific period of time. Although normally fairly constant, pulse rate does differ with age, with the average healthy adult pulse rate estimated to be between 60 – 100 beats per minute (bpm) (272).

Brachial blood pressure: Blood pressure is the force of pressure exerted by the circulating blood flow against the walls of the arterial vessels which contain it. The systolic measurement refers to the peak pressure of the blood in the arteries following cardiac muscle contraction (281). The diastolic measurement is a direct indication of the lowest pressure within the arteries which occurs when the heart is refilling with blood between muscle contractions (157).

Doppler method: This diagnostic process uses a transmitter crystal placed over the heart to send pulses of ultrasound direct down to the ascending aorta. The ultrasound reflects off the moving red blood cells and from the data recording of every instant of ejection, the mean blood velocity is used to infer aortic flow and left ventricular stroke volume (282).

Electrocardiogram (ECG): The electrical activity of the heart is recorded by electrodes which are attached to defined places on the skin. This method measures both the rate and regularity of heartbeats. Once the electrodes are in place and the ECG machine set to record, beat-to-beat data collection is automatic and requires no further operator intervention other than to terminate the recording phase.

Impedance cardiography: Impedance cardiography uses electrodes on the skin to pass a small current through the thorax from chest and neck leads, to measure changing electrical resistance (impedance) in the thorax cavity, determined by the change in aortic blood volume over each cardiac cycle (figure 3.6).

Autonomic nervous system (ANS): The ANS is a part of the peripheral nervous system and is divided into two parts, the sympathetic drive and the parasympathetic drive (also known as vagal activity). Sympathetic fibres from the spinal cord extend along the great vessels to the heart to innervate the ventricular muscles, atria and pacemaker conductive cells and the sympathetic drive modulates the inotropy of the heart and vasoconstriction/vasodilation of the vessels as required. The parasympathetic fibres mainly innervate the pacemaker cells and the left atrioventricular node, although some fibres reach the ventricles and this vagal activity regulates the heart rate (283). The ANS plays a key role in regulating systemic blood flow by maintaining a stable mean arterial blood pressure in any situation. The ANS achieves this through control of the heart rate, stroke volume (the volume of blood pumped from one ventricle of the heart with each heartbeat) and radial size of the peripheral terminal arteries and arterioles (272).

Heart rate variability (HRV): The parasympathetic and sympathetic components of HRV can be measured using several different methods. The simple linear Time Domain method is where the variation in each successive normal ECG derived QRS complex is used to determine the 'normal to normal' (NN) interval (the interval between adjacent QRS complexes). However the more complex Frequency Domain method reveals that the beat-to-beat frequency varies continuously. The changing intervals between beats, represented as frequency wave data, contain rich information about the level of sympathetic and parasympathetic cardiovascular influence.

Pulse wave analysis: A derived measurement of peripheral pulse pressure combined with the maximum and minimum systolic and diastolic pressures allows calculation of the central aortic pressure waveform. This measurement is highly indicative of degree of arterial stiffness (284;285).

Continuous blood pressure using vascular unloading technique: Continuous blood pressure is monitored using finger cuffs. The cuff is compressed in order to apply sufficient pressure on the finger arterial wall to push the wall back to the point where it would balance with the pulsatile arterial pressure of the cardiac cycle, when intra-arterial pressure distension is most relieved. The finger cuff counter-pressure has to modify pressure continuously and instantaneously on the arterial wall in order to maintain this unloaded state on a beat-to-beat basis (286). In this altered compression technique, it is assumed that the arterial wall tension is zero when the compression pressure is zero, which is why the technique is called vascular unloading. As this state occurs only when external and internal pressures are equal, then blood pressure can be determined using this technique (287). As this measurement on the finger is not representative of systolic blood pressure in the larger arteries, the continuous BP data is automatically corrected to the oscillatory BP data recorded by the TFM on the brachial artery.

Baroreceptor reflex sensitivity: Baroreceptors are sensory fibre endings found in the carotid sinus origin of the carotid artery and on the transverse arch of the aorta. These receptors are stretch receptors which respond to the magnitude of pressure and the rate of change in the carotid artery and aortic arch (288). Abnormalities in baroreceptor reflex sensitivity are seen as having important prognostic implications, particularly post myocardial infarction (289).

Stroke volume: Stroke volume (measured in [ml]) is the amount of blood which the left ventricle ejects into the aorta with each heartbeat. Stroke volume is influenced by the energy of contraction versus the amount of aortic pressure needed to be overcome in order to eject the blood in the left ventricle into the aorta.

Cardiac output: Cardiac output is the amount of blood the left ventricle ejects into the systemic circulation in one minute, measured in litres per minute (l/min). The adult resting

heart pumps out 4 – 7 litres of blood every minute, the cardiac output being continually adjusted in order to meet the changing demands of the body.

Total peripheral resistance: Total peripheral resistance is the resistance (where dyn defined as the force required to accelerate a mass of one gram at a rate of one centimetre per second squared) – of the small and large vessels against which the left ventricle is pumping the blood,

Thumb walk: Reflexology massage technique. This involves bending the thumb at the first joint and placing the outside corner of the thumb on the foot planter surface. Then use the outside tip to rock the thumb and in doing so, move it forward a fraction, this enables the thumb to ‘walk forward’ using a caterpillar type-movement along the plantar skin (290)

Thumb crawl: Reflexology massage technique. Similar to thumb walk, consisting of repetitive small movement using the outside tip of the bent thumb and reducing pressure on the unbend motion, causing the thumb to crawl along the area of contact (290)

Finger roll: Reflexology massage technique. Involves rolling the end of the index finger using the thumb and the middle finger to hold the index finger and apply pressure (143)

Hold: Reflexology massage technique. Involves placing the tips of the thumbs into the area and applying pressure (143)

Finger walk: Reflexology massage technique. Involves bending the finger at the first joint and resting the edge of the finger on the planter skin. The walking motion is a slight rocking from the fingertip to the lower edge of the fingernail (290).

Kneading: Reflexology massage technique. This is a technique like kneading break, used mainly on the heel, applied by making a fist with the working hand then kneading the area to be treated (143)

Toe feathering: This is a very light, stroking or rhythmic motion using the thumb walking technique or on the toes, using the fingers to lightly caress and to move very lightly and rapidly through the area to be feathered (290)

Cat tail pull: Reflexology massage technique. Here the support hand cups the foot at the back of the ankle and the working hand moves up and down the tendon at the back of the leg, pinching it gently between the thumb and index finger (143)

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Appendix 1

STATE TRAIT INVENTORY

N.B. the State-Trait Inventory Tool is only supplied in PDF form and as such, is not reproducible for inclusion in this document in a Word document format. The questions and instructions are taken directly from the questionnaire tool but do not reflect the PDF layout or formatting.

SELF-EVALUATION QUESTIONNAIRE STAI Form Y-1

Please provide the following information:

Patient ID No: _____ Date _____

Age _____ Gender (Circle) M F

DIRECTIONS:

A number of statements which people have used to describe themselves are given below. Read each statement and then blacken the appropriate circle to the right of the statement to indicate how you feel right now, that is, at this moment. There are no right or wrong answers. Do not spend too much time on any one statement but give the answer which seems to describe your present feelings best.

1 = NOT AT ALL; 2 = SOMEWHAT; 3 = MODERATELY SO; 4 = VERY MUCH SO

1. I feel calm..... 1 2 3 4
2. I feel secure 1 2 3 4
3. I am tense 1 2 3 4
4. I feel strained..... 1 2 3 4
5. I feel at ease..... 1 2 3 4
6. I feel upset..... 1 2 3 4
7. I am presently worrying over possible misfortunes..... 1 2 3 4
8. I feel satisfied 1 2 3 4
9. I feel frightened..... 1 2 3 4
10. I feel comfortable..... 1 2 3 4
11. I feel self-confident 1 2 3 4
12. I feel nervous 1 2 3 4
13. I am jittery..... 1 2 3 4

14. I feel indecisive..... 1 2 3 4
15. I am relaxed..... 1 2 3 4
16. I feel content 1 2 3 4
17. I am worried 1 2 3 4
18. I feel confused 1 2 3 4
19. I feel steady 1 2 3 4
20. I feel pleasant 1 2 3 4

Appendix 3



A Study Investigating the Effects of Reflexology

PARTICIPANT INFORMATION SHEET

You are being invited to take part in a research study. Before you decide to take part it is important for you to understand why the research is being done and what it will involve. Please take time to read the following information carefully and discuss it with others if you wish. Please ask us if there is anything that is not clear or if you would like more information. Take time to decide whether you wish to take part.

What is the purpose of the study?

Reflexology is a complementary therapy. It is the practice of applying pressure to specific points on the feet which are thought to influence the health of corresponding parts of the body. This study is being undertaken as part of a PhD research project being carried out by Stirling University designed to try to find out whether reflexology helps healthy people. Two types of reflexology therapy will be examined in the study in order to evaluate the effects of both kinds of treatment.

Who is eligible to participate in this study?

We are inviting any healthy volunteer between the ages of 18 to 65 years.

Is participation voluntary?

Yes, your participation in this study is entirely voluntary. You may choose to participate or not. You may withdraw from the study at any time without giving a reason.

What will taking part in the study involve?

You will be invited to take part in 2 reflexology treatments during which a therapist will use their hands to apply gentle pressure to your feet. Most people find it to be a very relaxing experience. The reflexology study sessions will last around 60 minutes which will include around 20 minutes of actual treatment. If you volunteer to take part, you will be asked to attend for two sessions on two separate days. These reflexology sessions will be free of charge and will take place at the Highland Heartbeat Centre and your transport costs will be reimbursed.

Will my taking part in this study be kept confidential?

All information collected about you during the course of the research will be kept strictly confidential. The results of this study will be used to help inform future practice relating to the use of reflexology. The results will be used as part of a doctoral thesis and/or published in a scientific journal however your name will never be used in any presentation or publication of the study results.

What will I have to do?

Please take as much time as you need to make a decision whether to participate in this study. If you are interested in hearing more about the research, please complete the attached form and post in the envelope provided. You will then be contacted by Jenny Jones, the researcher (PhD student) from Stirling University. She will arrange an appointment to explain the study in more detail and answer any questions you may have. If you then decide you want to take part, you will be asked to sign a consent

form and to attend for two reflexology sessions on two separate days. During each session, in addition to the reflexology treatment, you will also be asked to complete a short questionnaire at the beginning and then again at the end of the session. This questionnaire will ask you about any anxiety you may be feeling at the time. The questionnaire should take around 5-10 minutes for you to complete.

What are the risks involved?

At this time, there are not thought to be any direct risks involved in receiving a reflexology treatment. Indeed, many people use reflexology as an adjunct to medical treatment because of its potential therapeutic benefits. Having to complete a short questionnaire about anxiety may upset some people. This is considered an indirect risk and should this happen, participants will be provided with the phone number of a confidential helpline and a person they can speak to.

What if new information becomes available?

You will be notified of any new information learned during the course of this study if you would like to be informed. If you are interested in learning more about when and how to get the results of this study, you may contact the lead researcher at the number below.

Further information

If you require further information about this study, please contact:

Lead Researcher:

Supervisor:

Jenny Jones
Post Graduate Office
Department of Nursing & Midwifery
Stirling University, Centre for Health Science
Old Perth Road, Inverness, IV2 3JH

Telephone: 01463 255000
Email: jenny.jones@stir.ac.uk
Stephen.leslie@nhs.net

or

Principal Academic

Professor Stephen Leslie
Cardiology Department
Raigmore Hospital
Old Perth Road
Inverness, IV2 3JH

01463 704000
Email:

You can also contact:

Professor William Lauder
Department of Nursing & Midwifery
University of Stirling
FK9 4LA

Tel:01786 466345
Email: william.lauder@stir.ac.uk

Appendix 4



Participant Identification Number for this Study:

A Study Investigating the Acute Cardiovascular Effects of Reflexology

CONSENT FORM

Principal Investigator: Jenny Jones

Principal Academic Supervisor: Professor Stephen Leslie

Please initial box

- 1. I confirm that I have read and understand the information sheet dated (version) for the above student PhD research study. I have had the opportunity to consider the information, ask questions and have had these answered satisfactorily.

- 2. I understand that my participation is voluntary and that I am free to withdraw at any time, without giving any reason, without my medical care or legal rights being affected.

- 3. I understand that this form will be kept separately from any other information that I provide and will be stored in a locked room for the researcher's use only and will not be shared with anyone else.

- 4. I understand that any information I provide will be treated in the strictest confidence.

- 5. I understand that no personally identifiable information will be collected and my data will be identified only by a randomly generated number.

7. I agree to take part in the above study.

Name of Participant Date Signature

Name of Person taking consent Date Signature
(if different from researcher)

Researcher Signature Date

Complete 2 copies: 1 copy for participant; 1 copy for researcher file

Appendix 5



[Patients name and address here]

[Consultants name here]

Cardiology Department

Raigmore Hospital

Old Perth Road

Inverness, IV2 3UJ

Tel: 01463 705459

Fax: 01463 888252

Date

Dear *[name]*

Reflexology Study at the Raigmore Hospital

We are undertaking a research project to find out if reflexology massage is beneficial for people with heart disease. This letter has been sent to you as you recently attended the cardiac department.

Reflexology is a form of complementary therapy. It is the practice of applying pressure to specific points on the feet which are thought to influence the health of corresponding parts of the body.

The researchers are looking at the effects of reflexology to identify if any changes take place during a treatment session. Two types of reflexology therapy will be examined in the study in order to evaluate the effects of both kinds of treatment.

The study is looking for volunteers who have been diagnosed with heart disease and who have never had a reflexology treatment before.

Participation will require two visits to the Cardiac Department at Raigmore Hospital. During the reflexology sessions, volunteers will have blood pressure and heart rate variations measured and afterwards, be asked to complete a short questionnaire. A patient information sheet related to the study is enclosed for you to read.

Should you be interested in taking part in this study, please call the lead researcher Jenny Jones on 01463 255638 for further information or complete the 'Consent to Contact' form and return it back to the researcher in the stamped addressed envelope provided.

Replying does not mean that you have to take part. Your normal care will not change at all if you do not reply or do not decide to take part.

Thank you for reading this letter.

Yours sincerely

[Consultant name]

Consultant Cardiologist

Appendix 6

Reflexology Study Visual Analogue Scale

Patient ID _____ Date: _____ Visit No: _____

What was the level of the worst pain you experienced during the Reflexology treatment itself?

Place a vertical mark on the line below to indicate how much pain you experienced.

No Pain | _____ | Worst Pain Experienced

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