Complementary Therapies in Clinical Practice 18 (2012) 204–211

Contents lists available at SciVerse ScienceDirect

Complementary Therapies in Clinical Practice

journal homepage: www.elsevier.com/locate/ctcp

Reflexology has an acute (immediate) haemodynamic effect in healthy volunteers: A double-blind randomised controlled trial

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Keywords:
Reflexology
Randomised controlled trial
Complex interventions
Cardiovascular
Haemodynamic
Complementary therapy

A B S T R A C T

Reflexologists claim that massage to specific points of the feet increases blood supply to internal organs. This study measured changes in cardiovascular parameters in subjects receiving reflexology to areas of their feet thought to correspond to the heart (intervention) compared with other areas which are not (control).

Method: 16 reflexology-naive healthy volunteers received an active and control reflexology treatment in an RCT, double-blind repeated measures study.

Main outcome measures: 'Beat-to-beat' continuous measurement of selected cardiovascular parameters, State Anxiety Inventory.

Results: Cardiac index decreased significantly in the intervention group during left foot treatment (LFT) (baseline mean 2.6; standard deviation (SD) 0.75; 95% CI ± 0.38 vs. LFT mean 2.45; SD 0.68; CI 0.35), effect size ($p = 0.035$, omega squared effect ($w2$) = 0.002; $w = 0.045$).

Conclusion: Reflexology massage applied to the upper part of the left foot may have a modest specific effect on the cardiac index of healthy volunteers.

1. Introduction

Reflexology is one of the most popular complementary and alternative medicine (CAM) therapies used in Norway,[1] Denmark[2] and the UK.[3,4] It is a complex massage intervention, based on the concept that specific areas of the feet (called reflex points) correspond or 'map' to specific internal organs within the body, with each internal organ represented by an individual discreet reflex point.[5–7] The founder of reflexology, Eunice Ingham, made the specific claim that the massage to these points, using touch techniques unique to reflexology, increases blood supply to the corresponding mapped organs.[8] The reflexology haemodynamic treatment-related effect is believed to be quite distinct from non-specific massage components, such as tactile touch, therapeutic exchange and placebo effects, even though these components can evoke systemic haemodynamic responses in their own right.[9–12] The International Institute of Reflexology (IIR), who claim to have 25,000 trained member therapists worldwide[13] and who deliver training courses through 11 global franchised training branches[14] and are currently the largest UK reflexology training provider,[15] offer professional reflexology training exclusively and explicitly based on Ingham's books, distinct theories and treatment techniques.[16]

Reflexology sessions can cost from £15 – £70 per treatment and typically, 6–8 sessions are usually recommended by therapists to in order to gain the optimal therapeutic results.[17,18] Therefore the cost of an eight-week series could easily be in excess of £400 if an average of £50 per session is paid. One review of reflexology even suggests figures of up to £1000 per year for repeated blocks of treatment may not be unusual for a patient with chronic health issues.[19]

Therefore, due to the public-driven financial investment in this therapy, reflexology safety has become a CAM healthcare research priority,[20] particularly as, unlike any other CAM therapy, it makes claims for a specific haemodynamic effect.[21–23] When a therapy makes such a prediction as this, rigorous evidence is needed to determine that the practice is safe and effective for all its users, in particular any relevant patient sub-groups who may be at risk from adverse treatment-related effects.[24] Adverse effects may include

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doi:10.1016/j.ctcp.2012.03.006

both intrinsic safety effects (treatment errors or contraindications) and extrinsic quality effects (poor standardisation or quality control of treatment).[20] However despite its popularity, the evidence base for reflexology efficacy remains small with only four published systematic reviews published to date. These do not appear to support the objective treatment claims of reflexology, as the findings suggest that evidence of any efficacy is largely descriptive or anecdotal, predominately relying on subjective self-reported outcomes which offer little evidence to support any specific active component beyond that of a placebo or physical touch effect.[4,25–27] Furthermore, most studies do not use a blind experimental design and the intervention is typically delivered by the researchers themselves, leading to concerns regarding potential bias.[25]

Given the popularity of reflexology, there is a need for healthcare researchers involved in evidence-based medicine to equitably reflect the public-driven investment in this therapy and in particular, to assess the claim that massage to specific points of the feet increases blood supply to referred or 'mapped' organs in the body, in order to determine any benefits or adverse treatment-related effects. Therefore this study aimed to measure the acute (immediate) cardiovascular effects of reflexology treatment applied to specific areas of the feet which are thought to correspond to the heart, and compare this with treatment applied to other areas which are not, to see if there is any evidence to suggest the existence of specific haemodynamic change in the heart organ itself which occurs only when the corresponding heart area on the foot is treated.

2. Methods

2.1. Design

Randomised controlled double-blind repeated measures study.

2.2. Participants and setting

16 healthy volunteers (males $>$ 18 years; post-menopausal women) were recruited if they were reflexology-naïve, on no regular medications and had normal lower limbs (no previous operations including varicose veins, peripheral vascular disease or peripheral neuropathy). Post-menopausal women were recruited in order to eliminate hormonal-related influence on arterial stiffness found in pre-menopausal women.[28,29]

2.3. Intervention

The aim of this study was to measure various cardiovascular parameters whilst the heart reflex point was being treated, and then compare this with cardiovascular data recorded when non-heart related points were being treated. However this research aim presented a significant methodological challenge as there is a surprising lack of consistency of reflex point location in published reflexology foot maps. Many different types of reflexology maps are on sale, produced by a range of map or chart providers. Any reflexologist training provider appears able to create and publish a map according to their own intuitive interpretation of where the various reflex points are located on the planter areas of the feet. Large scale map providers such as the Association of Reflexologists (AoR),[30] the British Reflexology Association (BAR),[31] the International Institute of Reflexology (IIS)[32] and the British School of Reflexology (BSA)[33] sell maps based on the original Ingham (IIS) reflexology chart but all vary to a degree in reflex point placement. Only one previous study has discussed the issue of chart accuracy, but this was a blinded investigation into the diagnostic precision of one chart only and the results did not suggest that reflexology was a reliable method of diagnosis.[34] The inconsistent map issue presents a serious methodological research challenge if the intention is to isolate and measure a specific treatment-related haemodynamic effect related to treatment to the heart reflex point, and at the same time, create a reproducible reflexology intervention.

In the case of the heart reflex point, the AoR and BRA maps place the heart reflex point as an individual point on the ball of the left foot, yet on the IIR map (based on Ingham's original foot map), the heart reflex point is combined with the left lung and breast reflex point within the same region. In contrast, the BSA map also places the heart reflex point in the shoulder girdle zone but extends the point across both the left and right foot. Furthermore, in addition to the reflex point inconsistency problem, previous reflexology research has found it difficult to provide robust controls for adequate comparative purposes. In one recent systematic reflexology review,[4] 11 of the studies appear to use placebo reflexology treatment in the form of general foot massage to act as the study control, yet ten of these studies offer no clear distinction as to how the reflexology intervention is differentiated from general foot massage. This is an important distinction to make, as it is difficult to see how simple foot massage as a control can be differentiated from reflexology foot massage, particularly in terms of avoiding working any of the planter reflex points during the manual manipulation.

In order to meet these two research challenges, this study devised an experimental solution which not only addressed the map problem in terms of heart reflex point inconsistency, but also enabled the development of a standardised robust reflexology control. This was achieved by means of a novel reductionist foot map approach. This reductionist strategy was based on the fact that despite considerable variations, all reflexology charts appear to have one consistent design condition, which is the idea that three transverse zone lines can be transposed across the foot map.[35] In the reflexology construct, 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'.[35,36] Within this transverse map construct, the shoulder girdle area is said to represent the thoracic cavity, and this area corresponds to the ball of the foot. Regardless of map origin, all reflexology maps consistently place the heart reflex point somewhere within the shoulder girdle on one or both feet. 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, which represents the articulation between the mid-foot and forefoot.[35,36] All body parts and structures below the thoracic cavity are consistently mapped below in the abdominal or pelvic zone region and therefore contain no major organ points associated with specific regulation of the heart.

This strict demarcation design allowed us to identify a gross area (the shoulder girdle zone) which could serve as the active 'heart point' intervention (which we labelled the 'forefoot'), as we reasoned that treatment to the shoulder girdle would, at some point, involve the heart reflex point, regardless of its inconsistent exact location. And this reductionist map approach also allowed for 'non-cardiovascular' gross areas (the abdominal and pelvic zones) to be identified (which we labelled as the 'heel'). As this gross area contains no organs specifically associated with regulation of the heart, the area could safely act as the experimental control. The two reflexology therapists recruited for the study used hypoallergenic tape to mark the demarcation line along the border of the shoulder girdle and mid transverse section before every session to ensure that only the designated forefoot (intervention) or heel (controls) areas were treated (Fig. 1).

Fig. 1. Photograph showing the tape applied to the subjects feet, along the shoulder girdle demarcation line.

2.4. 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 (Table 1). The therapists standardised both intervention and control treatment times (both lasted for 4.5 min), treatment pressure (light to medium) and depth of touch techniques as much as possible to ensure adequate comparisons could be made between the two treatment conditions. This reductionist treatment is therefore distinct from typical reflexology treatment lengths.

2.5. Background music

Each subject wore headphones and listening to the same relaxing piece of music throughout both sessions in order 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.

2.6. Outcomes

Heart Rate (HR), diastolic blood pressure (dBP), systolic blood pressure (sBP), mean arterial blood pressure (mBP), stroke index (SI), stroke volume (SV), cardiac output (CO), cardiac index (CI), total peripheral resistance (TPR), Baroreceptor Up Events (BarUpEv), Baroreceptor Down Events (BarDwEv), and both linear and non-linear heart rate variability (RRI) data were continuously measured using the previously validated computer assisted Task Force® Monitor (TF®M).[37,38]

Pre & post measurement of the subject's self-reported perceived state of anxiety was assessed using The State Anxiety (SAI) Inventory.[39] This 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 states. Scores are weighted from 1 to 4, a higher score indicating greater anxiety and a lower score suggesting a more relaxed state. The SAI was used pre and post-test in order to ensure that the subjects did not consistently perceive either the intervention or control treatment as being inherently 'more relaxing' than the other, in order to eliminate the possibility that subjects relaxed more deeply in one condition and therefore spuriously affected the cardiovascular outcome data as a consequence.

A Visual Analogue Scale (VAS) was used post-treatment to measure the peak physical massage pressure pain experienced during the reflexology massage in order to standardise for pressure-related pain across both treatments. The VAS was a 10 cm standard line, labelled "no pain" at one end and "worst pain experienced" at the other. 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.[40,41]

2.7. Sample size

Little is currently known about the magnitude of any specific effects of reflexology or its impact on beat to beat cardiovascular

Table 1
Reflexology treatment protocol. Both the intervention and control treatments were standardised to deliver comparative forms of massage.

Forefoot (Intervention) right foot	Heel (Control) left & right foot
1. Greet the feet. 2. Right foot, dorsal and plantar massage/relaxation 3. Big toe **thumb walk** up 5 zones medial to lateral 5 × 1 4. **Thumb crawl** neck medial to lateral 5 × 3 5. **Finger roll** the brain reflex × 3 6. Pituitary **hold** 7. Shoulder reflex finger roll and walking × 3 8. Lung reflex thumb crawl 4 × 3 9. Thyroid roll and **finger walk** × 3 10. Trachea/Chest 2 rows × 3 11. Plantar/dorsal massage 12. Plantar/dorsal **kneading** 13. **Toe feathering**	1. Greet the feet by cupping under heels 2. **Cat tail pulls** 3. Finger walk up chronic sciatic/reproductive reflexes × 3. Slide back down 4. Finger walk pelvic/hip area, uterus, ovaries etc. medial aspect 4 rows × 3 5. Medial pelvic/hip area walking from underside 4 strips × 3 6. Thumb walk plantar heel medial to lateral 4 × 3 7. Lateral pelvic/hip area walking from underside 4 rows × 3 8. Thumb walk plantar heel lateral to medial 4 × 3 9. Knuckle massage upwards around the ankle bones × 3 10. Heel kneading 11. Hold and release
Forefoot (Intervention) Left foot.	
Left foot	
Left foot: (identical to the Right Foot Treatment with the addition of) - 1. Lateral to medial thumb walk the chest area 3 rows × 3 2. *Heart* reflex – press and hold 3. Plantar/dorsal massage 4. Plantar/dorsal kneading Toe feathering.	

KEY.
Thumb walk: Bend the thumb at the first joint and place 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 (1).
Thumb crawl: 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 craw along the area of contact (1).
F**inger roll**: Roll the end of the index finger using the thumb and the middle finger to hold the index finger and apply pressure (2).
Hold: Place the tips of the thumbs into the area and apply pressure (2).
Finger walk: Bend the finger at the first joint and rest 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 (1).
Kneading: 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 (2).
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 (1).
Cat tail pull: 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 (2).

measures therefore the study was carried out using a pragmatic sample size of 16 healthy volunteers.

2.8. Location

Highland Heartbeat Centre, Raigmore Hospital, Inverness, Scotland.

2.9. 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 Group 1 or Group 2. Group 1 received the intervention treatment at the first visit, followed by the control treatment at the second visit, with group 2 the opposite way round (Fig. 2). 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.

2.10. Blinding

The study was double-blinded. Neither the reflexology-naive subjects nor researcher knew in which order the intervention or

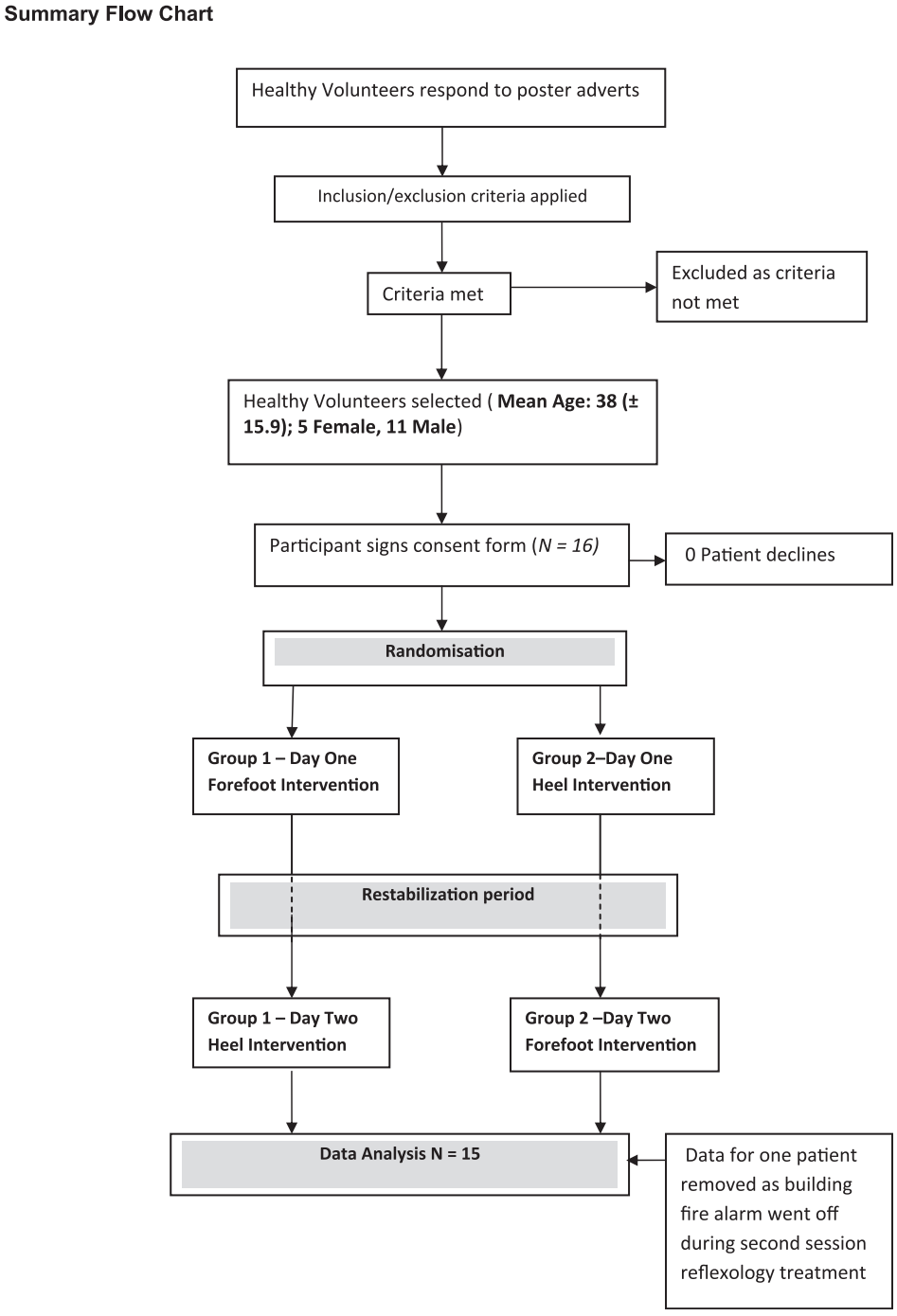

Fig. 2. Patient recruitment and research study procedures.

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.

2.11. Protocol

All volunteers were required to abstain from any form of medication for at least 48 h prior to study participation, food for at least 4 h beforehand and from tobacco and caffeine-containing drinks for at least 12 h prior to attendance. The volunteers were observed over six time periods under two conditions, with a restabilization period of at least 48 h between first and second treatment. The treatments were conducted in a quiet, draught-free room maintained at a constant temperature of 22–24 °C. All participants wore headphones and the same piece of relaxing instrumental music was played throughout each session.

2.12. Ethics

The study was undertaken with the approval of the Research and Ethics Committee, University of Stirling, the North of Scotland Research Ethics Committee (10/S0801/49) and in accordance with the Declaration of Helsinki. Written informed consent was obtained from each patient before entry into the study.

2.13. Statistical methods

Data was continuously recorded by the TF®M software which automatically divides the recorded data into distinct 5 min statistical blocks, each assigned to a stationary measuring phase defined by a start and end. Recording started with a baseline block, right foot treatment block, left foot treatment followed by three post-treatment blocks (Fig. 3). For each block, the number of detected events, minimum and maximum values, the mean and standard deviation (SD) were calculated.

As there was one group of subjects, observed over six time blocks under two conditions in a repeated measures model, Analysis of Variance (ANOVA) General Linear Model was chosen as the appropriate analysis method (Minitab version 16.1.1.1, Microsoft, Redmond, Washington, USA). The intention 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. Assumptions of normality and homogeneity of variance were validated and an overall 5% significance level was used.

Following on, planned comparison analysis was run using Tukey significance tests to identify the specific block of data where the significant effect had been detected. Finally, the data was transformed using omega squared effect process to reveal the actual effect size. Paired '*t*' tests were used to compare pre & post state anxiety and post-treatment VAS pain results across both intra and inter group (Microsoft Excel Version 10, Microsoft, Redmond, Washington, USA). Data are expressed as mean, SD or area under the curve (AUC) unless otherwise specified.

3. Results

11 healthy men (>18 years old) and 5 post-menopausal women, mean age 38 (±15.9), mean BMI 27.9 (±4.3) were recruited between July and August 2010 and completed the study and all received both the intervention and control treatments. The data from one patient was discarded from final analysis as the fire alarm went off during the second session reflexology treatment.

3.1. Outcomes

The effects of reflexology treatment were modest with no statistically significant difference noted in HR, dBP, sBP, mBP, SI, SV, TPR, BarUpEv, BarDwEv and RRI (Table 2), however analysis of the data using ANOVA General Linear Model indicated that reflexology appeared to affect cardiac index to a significant level ($p = 0.035$). Planned comparison analysis using Tukey simultaneous tests identified that cardiac index decreased significantly in the intervention group during the left foot treatment (LFT) block by 0.15 l/min*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 process to reveal the actual effects size ($w^2 = 0.002$; t-contrast 1.18; $w = 0.045$). Cardiac output also appeared affected in the intervention group and whilst not significant as an interaction overall ($p = 0.051$), showed a statistically significant difference($p = 0.007$) between the baseline block when compared with the same LFT block (baseline mean 4.83; SD 1.07; CI ± 0.54 vs. LFT mean 4.57; SD 1.06; CI ± 0.54).

Perceived state of anxiety was reduced post-treatment 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. Subjective VAS levels of treatment discomfort were

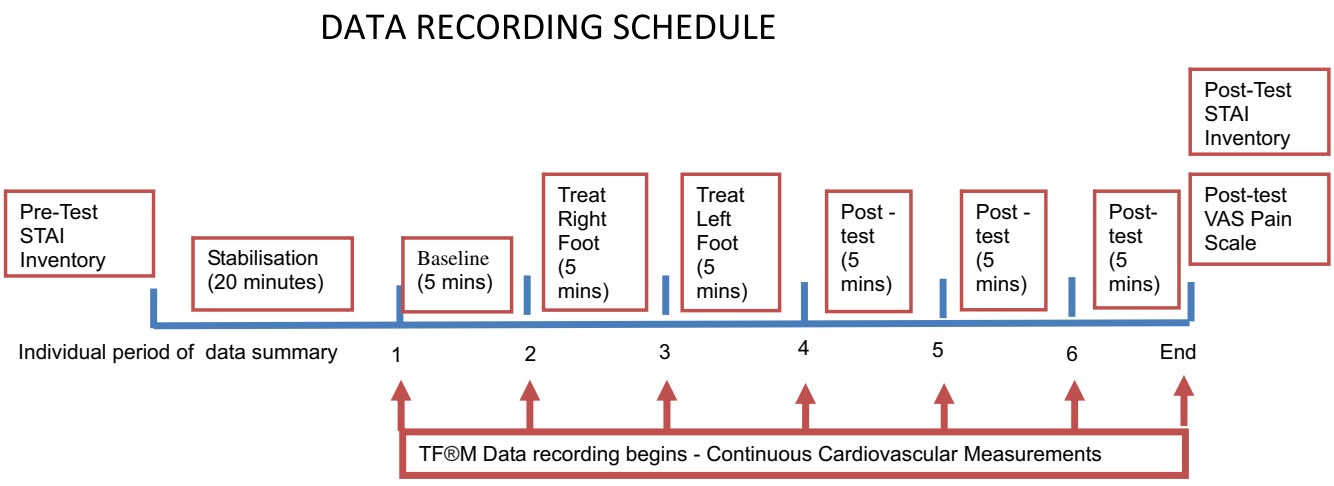

Fig. 3. Data recording schedule.

Table 2
This table shows the mean and standard deviation data for each recording period. The cardiovascular measurements were recorded in 5 min statistical blocks. For each block, the mean and standard deviation (SD) were calculated.

Cardiovascular measurement	0–5 min baseline	5–10 min treatment right foot	10–15 min treatment left foot	15–20 min post-treatment	20–25 min post-treatment	25–30 min post-treatment
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)
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)
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)
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)
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)
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)
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)
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)
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)
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)
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[a]	22.4 (16.6)	23.2 (18.1)	22.3 (18.1)	22.9 (19.9)	21.4 (18.2)	23.0 (19.7)
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)
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)

[a] All data expressed as mean, standard deviation (SD).

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).

3.2. Harms

There were no adverse events and the study was well tolerated by all volunteer participants.

4. Discussion

This is the first double-blind randomised controlled study to investigate the acute (immediate) cardiovascular effects of reflexology treatment applied to specific areas of the feet which are thought to correspond to the heart. This study has shown that there is a small change in cardiac index when reflexology massage is applied to the upper part of the left foot. In contrast, there was no difference in cardiac index when the lower half of either foot or the upper half of the right foot was massaged using the same reflexology techniques.

The precise mechanism which caused a drop in cardiac index in the intervention group remains uncertain. In extreme cases of increased afterload (e.g. cross clamping of the aorta) there is a reflex reduction in heart rate and cardiac output[42] but it seems unlikely that similar mechanism are involved in this patient group. In this study, the reduction in cardiac index seems to be associated with a trend towards an increase in total peripheral resistance and a drop in heart rate (Fig. 4). 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. Indeed, there was no change in sympathetic or parasympathetic tone indicated by heart rate variability and baroreceptor variability suggesting an absence of autonomic stimulation. Measure 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 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 and it is tantalising to hypothesis that the haemodynamic changes were a direct result of stimulation of the heart point in the feet.

Our findings are consistent with two other short-term studies which also suggest a specific haemodynamic effect in reflexology. Sudemeier et al reported statistically significant changes in resistive index of the renal arcuate artery when the kidney foot point was massaged.[43] Mur et al found significant changes in the mesenteric artery resistive index when the intestinal point was massaged.[44] No such change in resistive index occurred when control or unrelated points were touched in either study. However colour Doppler sonography technology has yet to be widely validated as a reliable measurement method of detecting perfusion flow rates. Furthermore, neither paper defined the organ-associated foot reflexology map location used which makes it difficult to reproduce their methods. One recent study suggested

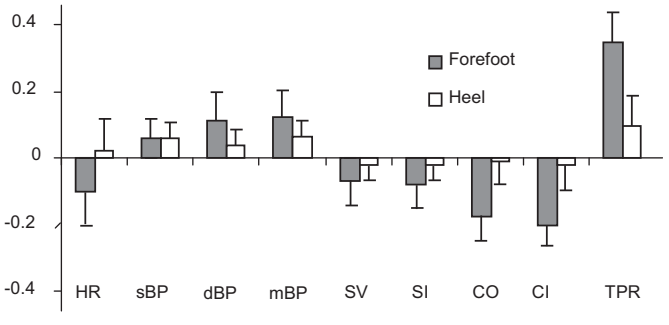

Fig. 4. Area under the curve graph. Area under the curve histogram for main haemodynamic parameters, heart rate (HR), systolic blood pressure (sBP), diastolic blood pressure (dBP), mean blood pressure (mBP), stroke volume (SV), stroke index (SI), cardiac output (CO), cardiac index (CI), total peripheral resistance (TPR); comparing forefoot reflexology (grey bars) (control) and heel reflexology (white bars) (intervention).

a somatotopic relationship between distinct reflex point treatment and corresponding cortical activity using fMRI techniques, 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, which 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.[45,46]

This current 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.[47,48]

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.[49,50] The House of Lords Select Committee report[3] and the King's Fund report[51] 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.[26,52] 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.

We felt that the aim of investigating the claim of a specific haemodynamic component was an important one, as the notion of a two-way active connection between discreet areas of the feet and corresponding organs or body parts is the one constant condition that reflexologists evoke, regardless of differing ideas of touch techniques,[53–55] theories of causality[56] or indeed, foot map used. Without this hypothesised active two-way connection, it could be argued that reflexology is completely indistinguishable from simple foot massage. Therefore it is this claim for a specific effect,[21] manifesting as an increase in circulation to the corresponding organ,[6] which we set out to investigate, being one of the few empirically testable specific components that reflexology can offer.

While no firm conclusion can be drawn about the reflexology 'organ perfusion' claim at this stage, coronary perfusion occurs in diastole[57] and a reduction in heart rate is associated with increased coronary artery blood flow. What the effect of these subtle haemodynamic changes might be in patients with coronary disease or heart failure is unknown. However if there is underlying heart failure present, a drop in cardiac index could lead to a reduction in cardiac muscle perfusion, therefore be clinically contra-indicated in some instances. Further randomised controlled trials using appropriate patient groups are needed to investigate this.

4.1. Study limitations

This study had a relatively small sample size, nevertheless a retrospective power calculation demonstrated that in order to detect the recorded cardiac index difference of 0.15 l/min*m^2 (Alpha = 0.05; assumed SD of paired differences = 0.19 with 0.8 power) a sample size of 15 would have been sufficient. However the sample size in this study was still too small to give a solid conclusion. The Task Force® Monitor measures cardiac index and output by impedance cardiography, while this is acknowledged to be less robust that more invasive measures of cardiac output, these would not have been practicable or ethical in a healthy volunteer population. Furthermore, as reflexology is a complex intervention with many components, there may be other non-specific variables involved in reflexology that have not been experimentally accounted for in this study design.

5. Conclusion

Reflexology has not been previously rigorously tested for any specific haemodynamic effect during treatment despite the reflexology claim that massage to specific points of the feet increases blood supply to referred or 'mapped' organs in the body. This current study measured the acute (immediate) cardiovascular effects of reflexology and attempted to address some of the methodological challenges involved in isolating a specific active haemodynamic ingredient from within a complex multi-component reflexology intervention. The study findings suggest that reflexology to the upper half of the left foot may have a modest effect on the cardiovascular parameters of healthy volunteers. Further research is needed to investigate whether this effect is repeated in patients with various gradations of cardiac disease in order to determine 1) if a beneficial effect is likely and 2) for safety purposes. This and further research will have the potential to provide unique data to enable both reflexology purchasers and clinicians to evaluate the clinical and cost-effectiveness of reflexology.

Acknowledgements

The authors wish to thank Tracey Smith, Reflexology Support Manager, Association of Reflexologists, for devising the intervention and control reflexology treatments and the two reflexologists who delivered the treatments, Gillian MacKay and Sheila Mackenzie. We also wish to thank the staff of Raigmore Hospital Cardiorespiratory Department and the healthy volunteers. Without their support, the study would not have been possible.

Conflict of interest statement

All authors declare that they have received no support from any organisation for the submitted work; no financial relationships with any organisations that might have an interest in the submitted work in the previous three years and no other relationships or activities that could appear to have influenced the submitted work.

Contributors

JJ and SJL conceived the study hypothesis, JJ met all the subjects and conducted the study, JJ, KH and SJL conducted the statistical analyses, JJ wrote the first draft of the manuscript, SJL, PT, KH and WL critically reviewed the analyses and contributed to the final draft. All authors are guarantors.

Funding

This study was partly funded by a research grant from NHS Research & Development Endowment Fund. No one representing

the funding source read or commented on any version of the manuscript.

Sponsorship

This study was sponsored by the University of Stirling; the sponsor had no role in any part of the survey design, data collection, analysis or interpretation of data, in the writing of the manuscript and in the decision to submit the manuscript for publication.

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