Appendix F:

Third Party Pain Study Conducted at Toronto East General Hospital, Toronto Canada

During independent third party at the emergency staff of one of Toronto's busiest hospitals significant reductions in pain and discomfort at key areas within the body. The outcome measures were determined using an analog pain scale.

a. Objective: This study was conducted to evaluate the effect of a novel system of shoe inserts that stimulate foot function (Barefoot Science™ Foot Strengthening System [BSFSS]) upon musculoskeletal pain..
b. Design: A prospective cohort study in which volunteers acted as their own controls. Data were recorded for a one-week baseline period and for the following four weeks while using the BSFSS. .
c. Participants: Participants were nurses, administrative and medical staff. Forty-eight individuals initially agreed to participate in the study, 44 submitted pain logs for at least one week and 32 completed an exit questionnaire. The participants were recruited through the Emergency Department (ED) of the Toronto East General Hospital
d. Methods: Data was collected through questionnaire during the use of the insole device during employment shifts at the hospital
e. Outcome measures: Pain logs were used to record self-reported pain and "tiredness" for specific body parts on scales ranging from 0 to 10. Participants also completed entry questionnaires to provide basic demographic information and exit questionnaires that asked them about their experience with the BSFSS..
f. Results: When data were analyzed using repeated measured analysis of variance, there were clinically and statistically significant declines in pain scores for the feet, knees, shoulders, lower back and shoulders, as well as significant declines for "tiredness" for all body parts except the hips (all p values $<.05$). There was also a significant decline in general fatigue ($p<.05$). Between the baseline and the end of the study, 73% of participants had a decline in foot tiredness, 69% in foot pain and 65% in general fatigue. Satisfaction with the product was high, with 87.5% of users reporting they thought it was "great" or "good."
g. Conclusions: The study was able to demonstrate that the BSFSS can significantly reduce many types of musculoskeletal pain and fatigue

Result Summary - A significant number Users reported:

1) Significant decrease in fatigue of the foot.
2) Significant decrease in foot pain.
3) Significant decrease in overall fatigue
4) Significant decrease in knee pain
5) Significant decrease in lower back pain
6) Significant decrease in shoulder pain
7) Decreased pain and discomfort in the knee.
8) Decreased pain and discomfort in the lower back
9) Decreased pain and discomfort in the shoulders

These results are as expected in that the muscle activation, muscle firing and resultant exercise and strengthening produce a more stable foot structure. The presence of stronger more efficient foot muscles allows for increase management of energy within the foot and a reduction in the need for energy dissipation through harmful modes such as soft tissue destruction.

The reductions in fatigue are attributed to the better utilization and management of energy at the level of the foot as well as a resultant of improved muscular skeletal alignment through the body, thus necessitating less chronic muscular contractions at joints superior to the foot and ankle for purposes of stabilization of the relevant joint. The reduction in required muscle contraction reduces energy consumption and related metabolic processes.

The reductions in pain are attributed to better localized energy management and reduction of energy dissipation through soft tissue destruction as well as improved pressure distribution over articulating surfaces resulting from improved musculoskeletal alignment.

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Effect of a Foot-Strengthening System Among Emergency Department Personnel

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Objective: This study was conducted to evaluate the effect of a novel system of shoe inserts that stimulate foot function (Barefoot Science™ Foot Strengthening System [BSFSS]) upon musculoskeletal pain.

Design: A prospective cohort study in which volunteers acted as their own controls. Data were recorded for a one-week baseline period and for the following four weeks while using the BSFSS.

Setting: Volunteers were recruited through the Emergency Department (ED) of the Toronto East General Hospital.

Participants: Participants were nurses, administrative and medical staff. Forty-eight individuals initially agreed to participate in the study, 44 submitted pain logs for at least one week and 32 completed an exit questionnaire.

Intervention: The BSFSS, a shoe insole with a progressive series of Stimulus Inserts, was worn during shifts at the hospital.

Main Outcome Measurements: Pain logs were used to record self-reported pain and "tiredness" for specific body parts on scales ranging from 0 to 10. Participants also completed entry questionnaires to provide basic demographic information and exit questionnaires that asked them about their experience with the BSFSS.

Results: When data were analyzed using repeated measured analysis of variance, there were clinically and statistically significant declines in pain scores for the feet, knees, shoulders, lower back and shoulders, as well as significant declines for "tiredness" for all body parts except the hips (all p values $<.05$). There was also a significant decline in general fatigue ($p<.05$). Between the baseline and the end of the study, 73% of participants had a decline in foot tiredness, 69% in foot pain and 65% in general fatigue. Satisfaction with the product was high, with 87.5% of users reporting they thought it was "great" or "good."

Conclusions: The study was able to demonstrate that the BSFSS can significantly reduce many types of musculoskeletal pain and fatigue in a working environment involving long periods of weight bearing activity.

Introduction

Nurses and many other hospital personnel spend long hours continuously on their feet and physically active. It is not surprising that nursing has been identified as a high-risk occupation for musculoskeletal disorders. [1] For example, a random sample of nurses' aides in Norway found that in the previous 14 days, 88.8% had experienced musculoskeletal pain, with 51.1% reporting intense pain. [2] An Australian study of rural nursing students found that 80.0% reported a musculoskeletal disorder at some body site, with low back pain being the most common (59.1%), followed by pain in the neck (34.6%), knees (25.0%), shoulders (23.8%) and feet (16.5%). [3] Several reports have focused upon one specific type of musculoskeletal discomfort: back pain. One study that followed female nursing students (n=174) for 7.5 years found the lifetime cumulative prevalence of back pain increased from 31% at entry to nursing school, to 72% at the end of the school and 82% after five years working as a nurse. [4] Another study of Swiss nurses (n=269) found the annual prevalence of lower back pain ranged from 73% to 76%. [5]

As noted by Springett, feet "are subjected to more general wear and tear than many other parts of the body." [6] Population-based surveys conducted in 16 European countries report foot conditions are common among dermatological patients of all ages. Over half (57% to 61%) had at least one foot disease, with 38% to 42% having non-fungal foot problems such as orthopedic conditions or metatarsal corns. [7] Other studies suggest that foot wear can influence the development of foot problems. [8] Foot problems may accompany or contribute to other musculoskeletal problems.

A number of biomechanical studies have been conducted that show that the Barefoot Science™ Foot Strengthening System (BSFSS) is safe and may be beneficial in treating foot and foot-related pain and discomfort. [9] BSFSS is not simply a shoe insert, but a novel system with five to seven progressive stimulus inserts that help to stimulate and strengthen the muscles of the arch.

Although BSFSS has been shown to be beneficial in small, mostly laboratory-based studies and has been used by consumers in North America and Europe, to date there have been no studies documenting how it works and its effectiveness in a "real world" setting and with participants of varying age, weight, and fitness levels. For our study, we recruited staff working in the emergency department (ED) of a busy metropolitan hospital, the Toronto East General Hospital (TEGH).

Methods

Prior to initiation, this study was approved by the Research Ethics Board of the Toronto East General Hospital.

The study was designed so participants would act as their own controls. The only exclusion criterion for the study was hallux rigidus; otherwise, all full-time and part-time nursing, administrative and clinical staff of the TEGH were eligible for the study. Prior to beginning the study, a sample size calculation was conducted for proportions in one sample using SamplePower 1.0 (SPSS, 1997). If chance would suggest that 50% of participants might experience a change in their pain level, the numbers needed to determine if 80% experiencing change is significant would be 30 subjects (95% confidence interval [CI]=0.63, 0.90; alpha=0.05 for a 2-tailed test, power=0.94). Given the demanding work of hospital staff, turnover, and vacations, it was anticipated that drop-outs might be substantive. Based on the findings of Farrar et al, it was also hypothesized that as measured on an 11-point numeric rating scale, a reduction of 30% in pain intensity would be required to represent a clinically important difference. [10]

Posters and word-of-mouth were used to advertise the study among ED personnel. Upon volunteering for the study, participants were asked to sign an informed consent, to complete an entry questionnaire, and their shoe size was recorded. The entry questionnaire queried participants on their general health, whether they had pre-existing foot or muscular problems, and their use of healthcare services, including alternative healthcare practices.

Pain and discomfort were recorded on 0-10 scales on a daily Pain Log (see Figure 1). The scales were model after 11-point descriptive or categorical pain intensity scales commonly utilized in pain research. The Pain Log (see Figure 1) captured a number of facets of foot and muscular pain and discomfort, including:

1 level of pain for the different parts of the body, ranging from 0 (“no pain”) to 10 (“excruciating pain”);
2 number of hours recorded level of pain was experienced;
3 how “tired” the parts of the body felt by the end of their shift, on a scale ranging from 0 (“not tired at all”) to 10 (“extremely tired”); and
4 general level of fatigue during the shift, on a scale ranging from 0 (“no fatigue”) to 10 (“extremely fatigued”).

There was also space on the form for participants to record any illness, unusual activity during their shift, injuries, their BSFSS insert level, and how long they wore their BSFSS. Data was gathered for the left and right foot, ankle, lower leg, knee, hips and shoulder and for the upper back and lower back. For analysis, reports for the left and right sides of the body were combined, as was the report for the shoulders and upper back.

Subjects were not paid for participating in the study. However, in recognition of the fact that ED staff are extremely busy and deal with a lot of paper work, incentives were offered for those who submitted their Pain Logs, such as weekly coffee vouchers, a chance to win a weekly draw for modest gift certificates

(valued at approximately $25 Canadian), and a chance to win a “grand prize” of a weekend in Montreal. It was stressed to participants in the consent form that reports on the Pain Logs would not affect the rewarding of prizes and that all information supplied should be accurate and honest.

For the first week of the study, participants were asked to wear their usual footwear but to complete a Pain Log at the end of each shift worked at the TEGH. These logs constituted the baseline for each participant. At the end of the first week, BSFSSs were distributed and for the following four weeks, participants were asked to wear the BSFSS at work and to complete a Pain Log at the end of each shift. There was no special orientation process to the BSFSS product, so the experience of participants would parallel that of any consumer who purchased it from a store, on the Internet or in response to direct response television marketing. Participants were only asked to wear their BSFSS while at work at the TEGH; as some participants might choose to wear them elsewhere, there was space on the Pain Logs to record this information.

A brief exit questionnaire was conducted when the participant completed or withdrew from the study. This questionnaire asked the participants to describe their experience and to make any comments they would like.

A data entry clerk hired by the hospital put the information into Excel spreadsheets. An independent data analyst then transformed the Excel spreadsheets into SPSS data files for statistical analysis. Categorical data were tested using Chi squares, and continuous data such as mean pain scores were analyzed using paired t-tests and repeated measured analysis of variance (ANOVA). In cases where the Huynh-Feldt epsilon for the repeated measures ANOVA was $\geq$0.750, the Hyunh-Feldt corrected p value is reported. Analysis was conducted using SPSS 14.0 (SPSS Inc, 2005) and Systat 11.0 (SYSTAT Software, Inc. 2004).

Results

Entry Questionnaire

In total, 47 individuals completed the entry questionnaire. Of those 47, 28 (59.6%) were nurses, 3 (6.4%) were doctors, and 16 (34.0%) fell into the “other” category (administrators, orderlies, etc.). The majority of participants (38 or 80.9%) were female and 60% (n=28) were between 30 to 49 years of age. A little over 40% give a height and weight suggesting they are in the normal weight range, with 25% appearing to be overweight, and 32% obese (BMI 30 or more).

In terms of personal health habits, 72% said their diet was generally healthy, although only 15% were able to say it was very healthy. Fourteen (30%) said they exercise about twice a week, 18 (38%) three to five times a week and 5 (11%) five or more times a week; less than one-quarter (21%) reported they

never exercised. Only 5 participants (11%) smoke daily; over half (55%) never smoked and almost one-third (32%) had quit smoking. Forty-seven percent reported moderate stress and 43% high stress, with a small proportion (3 or 6.4%) reporting very high stress. Only 2 of the participants (4.3%) report low stress.

When asked what health practitioners they consult, the most common response by participants was a family doctor. High proportions of participants reported no consultation with a naturopath (100%), herbalist (94%), chiropractor (79%) or massage therapist (68%). None report ultrasound or laser treatment on their feet and only 2 (4.3%) had had foot massages. Five report using orthotics (11%) and 7 (15%) having body massages.

The most common problems cited by participants were lower back pain (47%), upper back or shoulder pain (30%), knee pain (28%), plantar fasciitis (28%), calluses (23%) and hip pain (23%). Overall, 24 of the 48 participants (50%) reported some sort of pre-existing foot problem, including heel spurs, Achilles tendon, ingrown toenails, corns, calluses, hammertoe, Morton's, bunions, bunionette or plantar fasciitis.

Pain Logs

In total, 596 pain logs were submitted during the course of the study: 149 for week 1, 130 for week 2, 113 for week 3, 104 for week 4 and 100 for week 5. At least one week of pain logs were submitted by 44 individuals. Of the 44 individuals who volunteered for the study, 13 (29.5%) dropped out before completion. The majority of these losses (7/12) occurred after the first week, after the BSFSS were distributed but before participants were to start wearing them. One of these losses was due to a maternity leave. Four participants stopped after week 2 of the study (after one week of wearing BSFSS) and one after week 3.

Of the remaining 31 cases, 3 had to be excluded from analysis because there were no baseline data (logs had not been submitted for week 1). Four individuals missed at least one of weeks 2 through 4, and one missed both week 3 and 5. Some of these gaps were caused by vacations or scheduling of contract staff. In total, pain logs for all 5 weeks of the study were submitted by 23 individuals.

Mean foot, knee, hips, shoulder and back pain scores for week 1 tended to be significantly lower for those who did not complete the study compared to those who did (see Table 1). Among those who completed the study, there was no statistically significant difference in the mean numbers of hours worked per shift (means were 8.546 for week 1, 9.072 for week 2, 9.335 for week 3, 9.286 for week 4 and 9.231 for week 5, $p=.253$).

Previous reports of foot problems did not influence whether or not a person completed the study. Among those who reported a pre-existing foot problem, 79.2% (19 of 24) completed the study, compared to 70.8% (17 of 24) of those without (p=.740). Mean pain scores for those who reported foot problems tended to be higher in week 1 than those without, but independent t-tests showed the differences were not statistically significant (data not shown, all p's>.05).

Table 2 shows the week 1 and 5 means for those participants (n=26) who submitted Pain Logs for those weeks. Paired t-tests showed significant reductions in reported pain in the feet (p=.002), knees (p=.001), lower back (p=.012), upper back and shoulder (p=.016) and overall fatigue (p=.006). A paired t-test power calculation comparing mean foot pain for weeks 1 and 5 found the probability of correctly rejecting the null hypothesis was .863 when there were 23 comparisons, increasing to .904 for 26 comparisons. The percent reduction in pain was 30.7% for feet, 41.2% for knees, 48.8% for the lower back and 34.2% for the upper back and shoulders.

There were 23 participants for whom there were data for all 5 weeks of the study. Repeated measures ANOVA showed significant declines in foot, knee, lower back and shoulder pain (all p <.001) and in combined upper back and shoulder pain (p=.006; see Table 3). Table 3 also shows the pain reduction between week 1 and 5.

Table 4 shows the mean scores for body part "tiredness", percent reduction and statistical significance of the change. Tiredness scores were higher than pain scores and, with the exception of the hips, also decreased significantly within subjects over time. Figures 1 and 2 show pain and tiredness scores, respectively, for those body parts for which there was significant change over time.

In addition, overall fatigue reported by the participants (n=26) decreased over time, from a mean of 5.259 at week 1 to 4.909 (week 2), 4.412 (week 3), 4.47 (week 4) and 4.287 (week 5; p=.012, with the scores declining 19.8% between week 1 and 5. Whether the person reported a pre-existing foot condition on the entry questionnaire had no significant effect on any of the comparisons (data not shown; all p's >.05).

Exit Questionnaire

Thirty-two exit questionnaires were completed, of whom 31 respondents (96.8%) completed the study (the one who did not complete the study went on maternity leave after the end of the first week). Table 5 shows the reports of the 31 respondents who completed the study on the effect of wearing BSFSS on their pain or discomfort levels. Over half of participants believed BSFSS was effective in reducing their foot pain, close to half believed it had reduced ankle and knee pain, and about one-third reported reductions in lower leg and hip pain. Only

small numbers reported increases in pain, with such reports being most common for the feet.

When asked their overall opinion of BSFSS, 7 of the 32 participants (21.9%) agreed it was “great” and 21 (65.5%) that it was “good”, for a total positive response of 28 out of 31 (90.3%). Two respondents said they “weren’t impressed” and only one respondent rated the product as “awful.” Fifteen (46.9%) indicated they wore the product only at work and on their way to work but 16 (51.6%) wore it more frequently, with 5 (15.6%) reporting they wore them “all the time or almost all the time.”

Discussion

Utilizing the device in this study is a novel method to attempt modification of loading and stimulation of the foot during everyday activity. The importance of the foot and foot loading in overall limb and body function (i.e., its contribution to kinetic chain dysfunction) is generally not appreciated with shoe wear. Shoe wear and shoe wear modification are one aspect of work and loading pattern of the body that could have a significant impact on the rest of the lower extremity and central core. [11] In previous studies, static modifications in orthoses and shoe type have shown inconclusive benefits in preventing the incidence of overuse injuries and stress fractures. [12,13]

In this study, the in-shoe orthosis used not only modified loading, but also stimulated the intrinsic muscles of the foot as a dynamic effect during walking and loading. BSFSS is a patented insole device that has a midfoot section with an asymmetric structure that generates a gentle recoil pressure on the foot’s plantar surface at a location directly beneath the midfoot that corresponds to the optimal arch apex (height) during weight bearing. The system incorporates a series of resilient and progressively firmer and higher inserts that act as proprioceptive catalysts to stimulate the tibialis anterior, anterior extensors and peroneals. Over time, the muscles are conditioned to maintain the optimal arch apex necessary to effectively manage loads through the arch system. According to the manufacturer, a number of biomechanical studies have produced both quantitative and qualitative data of the product’s effectiveness. [14]

With this rationale in mind, this study was conducted among busy health professionals in a major metropolitan hospital. The participants represent a cross-section of working adults; half were overweight, reported high stress levels, or had pre-existing back or foot problems. Although this was a relatively health-conscious population (up to 75% reported exercising in their leisure time), little attention was paid specifically to the foot and shoe wear as a means of preventing overuse problems and fatigue (only 11% used shoe orthotics). If benefit could be shown in this population, it would likely be significant.

On an 11-point scale, participants started out reporting relatively modest levels of pain. Given the environment in which they work (i.e., daily exposure to patients who may be in extreme pain) and the busy nature of their work, it is not surprising that staff rated their pain as relatively low. When asked about how "tired" parts of the body felt, scores tended to be higher.

It was interesting, but not totally unexpected, that those who dropped out of the study in the first three weeks tended to report lower pain levels at baseline. This suggests that those with the least pain may not have appreciated the difference the BSFSS could make. Drop-outs were largest after week 1, before participants had started wearing BSFSS, and declined thereafter (numbers of drop-outs were 12 before they started wearing BSFSS, 4 after 1 week of wearing BSFSS and 2 after 2 weeks of wearing BSFSS). If drop-outs were caused by problems with the product, one would expect the numbers to increase with time. This pattern suggests that the longer people wore BSFSS, the less likely they were to leave the study. Several drop-outs reflect reasons unrelated to the product, such as vacations, reluctance to complete the necessary paper work (the daily pain logs), loss of interest in the study, or an opportunistic means of obtaining free products.

At the end of the study, after four weeks of wearing the product, there were clinically (i.e., 30% or greater) and statistically significant reductions in foot, knee, lower back, and shoulder pain, and a statistically significant decline in combined upper back and shoulder pain that was close to 30% (27.6%). Perceived "tiredness" also declined 30% or more for the feet, knees, lower legs, knees, lower back, shoulders, and combined upper back and shoulders (all $p<.05$) and close to 30% for the upper back (26.3%, $p=.034$). Perhaps because of these changes, levels of general fatigue while at work declined 20% ($p=.012$).

The literature suggests that musculoskeletal discomfort and overuse disorders are common place among healthcare professionals such as nurses. This study suggests that the BSFSS does significantly relieve musculoskeletal discomfort, including back pain, and fatigue. It is possible that such improvements in limb and body function during activity could enhance the well-being of healthcare professionals and workplace productivity.

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PAIN/DISCOMFORT LOG – COMPLETE ONE PER DAY WORKED AT TEGH

ER NURSES STUDY NAME: _____ DATE: _____ No. HRS WORKED: _____ Insert BfSc Level#: __

Wore Barefoot Science™ for: ___ whole shift ___ part of shift ___ did not wear Did you also wear them at home? ___ yes

PART A: Pain or discomfort in specific parts of the body		**Pain Scale (circle number that represents your highest level of pain during the past shift)**	**Number of hours at this level of pain**	**On a scale of 0 to 10, with 0 meaning "not tired at all" and 10 meaning "extremely tired", how "tired" would you describe this part of your body by the end of your shift?**	**Any other sensations in this area (e.g., tingling, numbness)? If so, please write in.**
FEET	( ) Left foot	0 1 2 3 4 5 6 7 8 9 10	____ hrs.	LF: _____	
	( ) Right foot	0 1 2 3 4 5 6 7 8 9 10	_____ hrs.	RF: _____	
ANKLES	( ) Left ankle	0 1 2 3 4 5 6 7 8 9 10	____ hrs.	LA: _____	
	( ) Right ankle	0 1 2 3 4 5 6 7 8 9 10	_____ hrs.	RA: _____	
LOWER LEG (up to knee)	( ) Left leg	0 1 2 3 4 5 6 7 8 9 10	____ hrs.	LL: _____	
	( ) Right leg	0 1 2 3 4 5 6 7 8 9 10	_____ hrs.	RL: _____	
KNEES	( ) Left knee	0 1 2 3 4 5 6 7 8 9 10	____ hrs.	LK: _____	
	( ) Right knee	0 1 2 3 4 5 6 7 8 9 10	_____ hrs.	RK: _____	
HIPS	( ) Left hip	0 1 2 3 4 5 6 7 8 9 10	____ hrs.	LH: _____	
	( ) Right hip	0 1 2 3 4 5 6 7 8 9 10	_____ hrs.	RH: _____	
LOWER BACK		0 1 2 3 4 5 6 7 8 9 10	____ hrs.	_____	
UPPER BACK		0 1 2 3 4 5 6 7 8 9 10	____ hrs.	_____	
SHOULDERS	( ) Left shoulder	0 1 2 3 4 5 6 7 8 9 10	____ hrs.	LS: _____	
	( ) Right shoulder	0 1 2 3 4 5 6 7 8 9 10	_____ hrs.	RS: _____	

PART B: GENERAL FATIGUE -- circle the number that best represents your overall level of fatigue during this shift

0 1 2 3 4 5 6 7 8 9 10

No Fatigue — Mild Fatigue — Moderate Fatigue — Very Fatigued — Extremely Fatigued

PART C: ACTIVITY DURING SHIFT -- check all that apply

( ) unusually difficult lifting/patient transfers
( ) prolonged standing
( ) prolonged sitting
( ) a lot of brisk walking/running
( ) I was very active during the 24 hours prior to my shift
( ) other: _____

PART D: ILLNESSES

Do you have cold or flu symptoms that might explain any body or muscle aches you are experiencing? ( ) Yes ( ) No

PART E: INJURIES

Have you been injured within the past 24-hours? ( ) Yes ( ) No

Figure 1: Pain Scores for Participants who Completed the Study

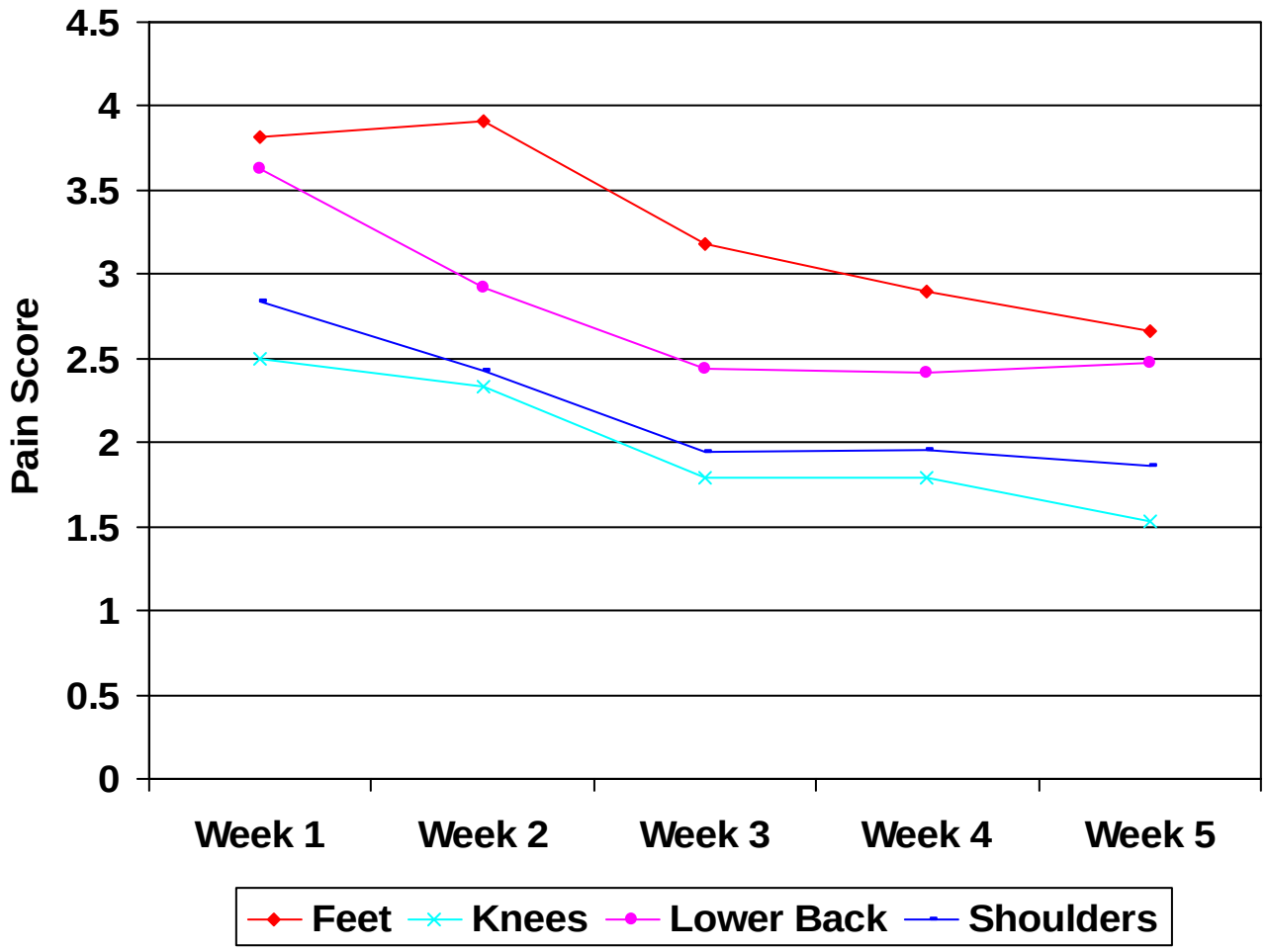

Figure 2: Tiredness Scores for Participants who Completed the Study

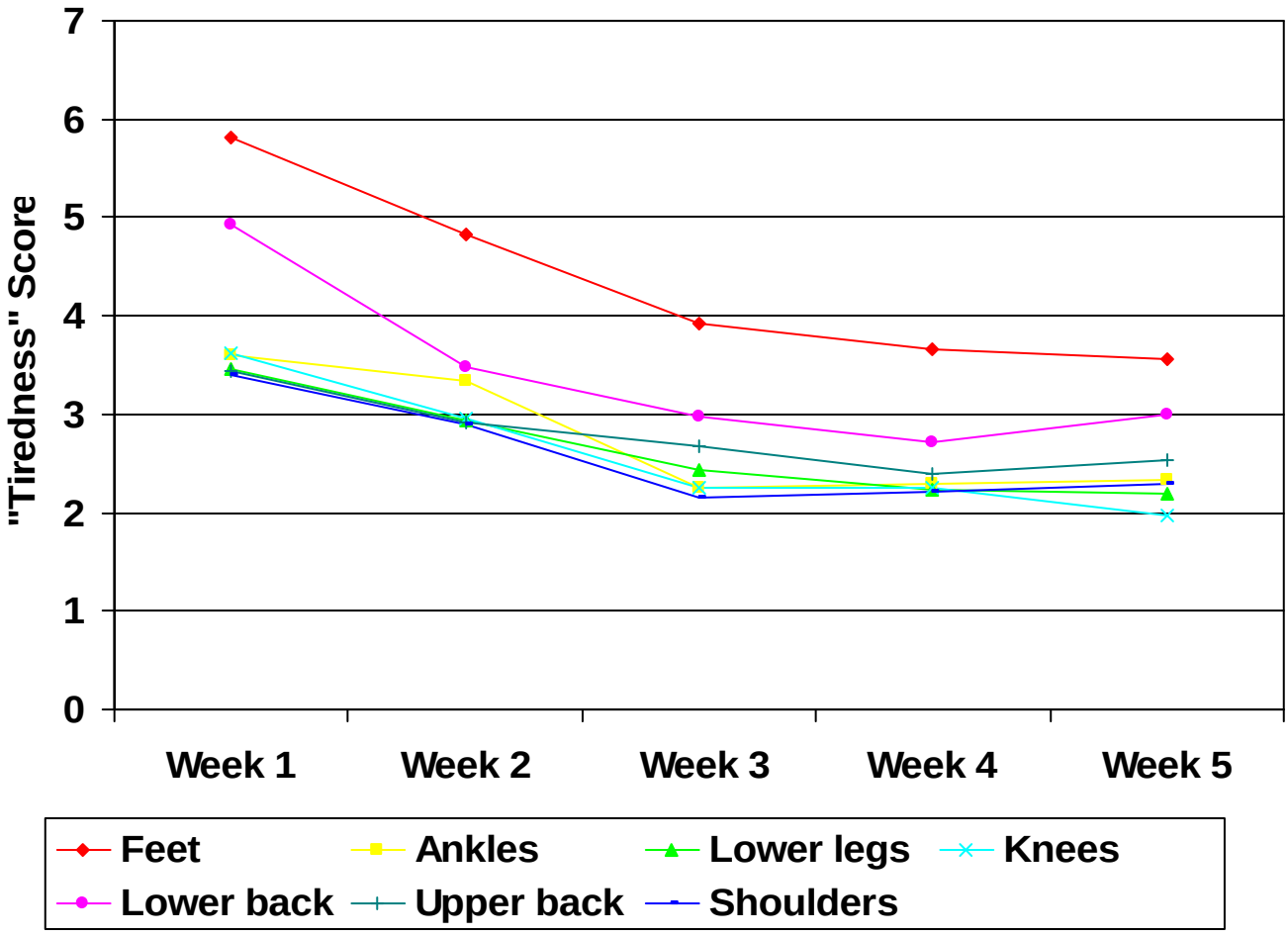

Table 1: Week 1 Mean Pain Score by Study Status

Part of Body	Left Study (n=12) Mean (sd)	Stayed in Study (n=29) Mean (sd)	Independent T-test *p*
Feet	2.28 (1.18)	4.07 (2.52)	.004
Knees	1.05 (0.97)	2.21 (2.42)	.036
Legs	1.54 (2.08)	2.21 (2.71)	.450
Ankles	1.53 (1.88)	2.08 (2.51)	.500
Hips	0.61 (0.74)	1.79 (2.26)	.020
Shoulders	1,09 (1.42)	2.96 (2.69)	.007
Lower back	1.76 (1.82)	3.88 (2.83)	.008
Upper back	0.96 (1.22)	2.70 (2.96)	.011

Table 2: Mean Pain, Weeks 1 and 5

Part of body	Week 1	Week 5	Mean difference (95% CI)	% Change Wk 5 from Wk 1	Paired t-test
Both feet (n=26)	3.964	2.746	1.218 (0.479, 1.956)	-30.7%	.002
Both ankles (n=25)	2.327	1.690	0.637 (-0.245, 1.519)	-27.4%	.149
Lower legs (n=24)	2.115	1.490	0.625 (-0.037, 1.287)	-29.6%	.063
Both knees (n=25)	2.391	1.406	0.985 (0.421, 1.549)	-41.2%	.001
Both hips (n=24)	1.867	1.574	0.293 (-0.148, 0.735)	-15.7%	.183
Lower back (n=26)	2.399	2.329	0.070 (0.286, 2.054)	-48.8%	.012
Upper back (n=26)	2.628	1.909	0.718 (-0.054, 1.491)	- 2.9%	.067
Upper back and shoulders (n=26)	2.734	1.798	0.935 (0.194, 1.677)	-34.2%	.016
Overall fatigue (n=26)	5.295	4.246	1.050 (0.330, 1.770)	-19.8%	.006

Table 3: Mean Pain Scores, Weeks 1 through 5

Part of body	Week 1 Mean (SD)	Week 2 Mean (SD)	Week 3 Mean (SD)	Week 4 Mean (SD)	Week 5 Mean (SD)	% Change Wk 5 vs Wk 1	*p* (RM ANOVA)
Feet	3.811	3.916	3.185	2.903	2.661	-30.2%	<.001
Both ankles	2.137	2.422	1.793	1.794	1.576	-26.3%	.089
Both legs	2.195	2.216	1.963	2.006	1.580	-28.0%	.192
Both knees	2.501	2.334	1.787	1.789	1.531	-38.8%	<.001
Both hips	1.944	2.048	1.815	1.790	1.717	-11.7%	.482
Lower back	3.630	2.916	2.444	2.412	2.474	-31.8%	<.001
Upper back	2.633	2.505	2.378	2.124	2.105	-20.0%	.164
Shoulders	2.842	2.424	1.948	1.956	1.863	-34.4%	.001
Upper back and shoulders	2.749	2.475	2.168	2.049	1.989	-27.6%	.006

Table 4: Mean Perceived "Tiredness," Weeks 1 through 5

Part of body	Week 1	Week 2	Week 3	Week 4	Week 5	% Change Week 5 vs. Week 1	*p* (RM ANOVA)
Both feet	5.815	4.825	3.919	3.66	3.565	-38.7%	<.001
Both ankles	3.610	3.331	2.247	2.296	2.332	-35.4%	.008
Both legs	3.452	2.937	2.427	2.229	2.190	-36.6%	.042
Both knees	3.619	2.948	2.259	2.243	1.972	-45.5%	<.001
Both hips	2.881	2.455	2.183	2.004	2.247	-22.0%	.217
Lower Back	4.932	3.480	2.970	2.706	2.990	-39.4%	<.001
Upper Back	3.434	2.916	2.668	2.401	2.530	-26.3%	.034
Both shoulders	3.401	2.891	2.152	2.220	2.291	-32.6%	.002
Upper back and shoulders	3.429	2.916	2.410	2.326	2.411	-29.7%	.004

Table 4: Self-report of Change in Pain/Discomfort While Using Barefoot Science™

Part of Body:	Less Pain	More Pain	No Change	Don't Know
Feet (n=31)	18 (58.1%)	8 (25.8%)	4 (12.9%)	1 (3.2%)
Ankles (n=31)	15 (48.4%)	3 (9.7%)	11 (35.5%)	2 (6.5%)
Knees (n=30)	15 (48.4%)	1 (3.2%)	13 (41.9%)	1 (3.2%)
Lower legs (n=30)	11 (35.5%)	2 (6.5%)	16 (51.6%)	1 (3.2%)
Hips (n=30)	11 (35.5%)	1 (3.1%)	16 (51.6%)	2 (6.5%)
Lower back (n=30)	6 (19.4%)	2 (6.5%)	18 (58.1%)	4 (12.9%)
Shoulders/upper back (n=31)	5 (16.1%)	1 (3.2%)	20 (64.5%)	5 (16.1%)

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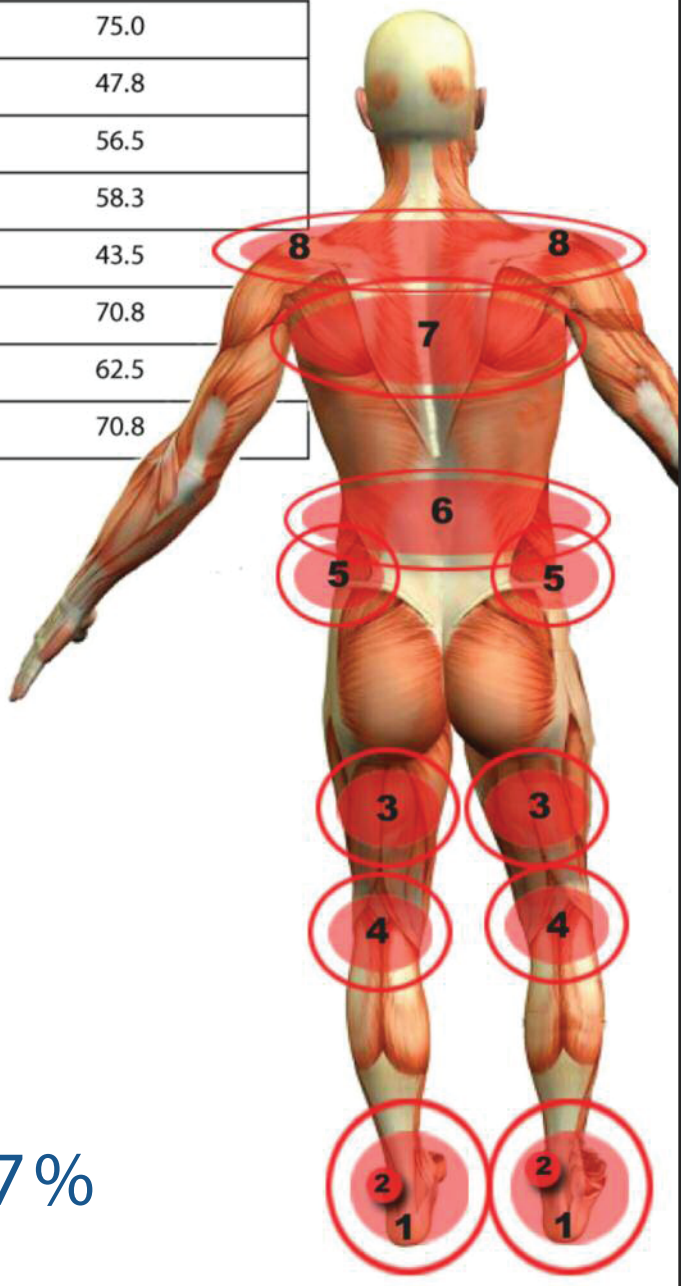
BAREFOOTSCIENCE™

Proven Effective Rehabilitation for Foot, Leg, Knee, Hip, Back and Shoulder Pain

Part of body	Percentage of Pain Reduction at week five (%)	Percentage of Subjects having significant pain Reduction at week five? (%)
1. Both feet	***-33.0%***	75.0
2. Both ankles	***-30.3%***	47.8
3. Lower legs	***-30.7%***	56.5
4. Both knees	***-42.9%***	58.3
5. Both hips	***-19.0%***	43.5
6. Lower back	***-34.0%***	70.8
7. Upper back	***-21.9%***	62.5
8. Both shoulders	***-38.9%***	70.8



In a study conducted in a clinical environment over 96% of the ER Doctors and Nurses reported pain reduction in at least one of 8 body parts studied

96%
REDUCTION IN PAIN

Overall pain reduction score for all 8 body parts was **83.3%**

Overall reduction in fatigue **-22.7%**

WHAT IS BAREFOOT SCIENCE?

DOCTOR RECOMMENDED

HOSPITAL TESTED

PROVIDES LONG-TERM PAIN RELIEF

ADDRESSES THE CAUSE NOT JUST THE SYMPTOM

DID YOU KNOW?

- 85% of North Americans seek medical help for foot-related ailments. 54% report tired or sore feet on a regular basis.
- Chronic shoe wearing can cause our arches to weaken and also result in rolling onto the sides of the feet, giving rise to ankle, knee and back pain.
- Footwear, insoles, or orthotics that cushion and/or support your feet can actually inhibit natural healthy foot function including flexibility and movement.

THE BAREFOOT SCIENCE DIFFERENCE

- Works Like a Rehabilitative Exercise Program right in your shoe.
- Patented Barefoot Science Arch Activation® insoles mimic the physics of being barefoot to help restore natural foot function and strengthen weakened arches.
- Safe, Gentle, and Natural Long-Term Relief.
- Used by Professional and world-class athletes in Track & Field, Professional Football, Strong Man competitions, Figure Skating, and Ballet for maximum comfort and enhanced performance.
- Effective for a wide range of foot-related problems, such as flat feet, plantar fasciitis, high arches, achilles tendonitis, knee, hip and back pain, and much more.

BAREFOOT SCIENCE FACTS

The BAREFOOT SCIENCE® patented Arch Activation Foot Strengthening Insole System™ is designed to gently work and rehabilitate the weak foot muscles and lazy arches that are often the cause of foot-related problems and pain.

Working in your shoes as you go about your daily routine, BAREFOOT SCIENCE® stimulates, strengthens and restores optimal foot function, enabling you to be as active as you want to be.

FACT: BAREFOOT SCIENCE® is up to10 times more effective than custom orthotics at improving alignment and strength.

FACT: BAREFOOT SCIENCE® is a fraction of the cost of custom orthotics, which can cost up to $300.00, $400.00 or even $500.00.

FACT: The BAREFOOT SCIENCE® System features a pair of insoles and a series of progressively denser "activating inserts" that effortlessly fit into the underside of the insole. These inserts are adjusted over a period of weeks to increasingly challenge weak foot muscles in order to strengthen lazy arches and address foot problems at the source. It is like an exercise program for your feet. It feels like a mini-foot massage, which is actually your foot muscles waking up, getting stronger and working the way nature intended. The more you use them, the stronger your foot muscles become.

FACT: BAREFOOT SCIENCE® features patented technology with a series of activating inserts that work differently than prescribed custom orthotics that are rigid and simply brace or support the foot. BAREFOOT SCIENCE® rehabilitates rather than merely providing short term, unsustainable relief of foot-related problems. Unlike custom orthotics that restrict the motion of your foot so that your muscles are inhibited from working naturally, BAREFOOT SCIENCE® actually stimulates your natural foot reflex action. This gets the muscles working and they become stronger, restoring a healthy domed arch that supports the feet, which in turn, can improve posture and align the entire body from the ground up.

FACT: Orthotics and conventional insoles merely support or cushion the foot and, therefore, only treat symptoms; they don't deal with the weak foot muscles and lazy arches that are usually the cause of most foot-related problems. BAREFOOT SCIENCE® offers a positive alternative to ineffective orthotics and traditional insole products.

FACT: BAREFOOT SCIENCE® does for your feet what squeezing a tennis ball does for your hand. Shoes can restrict your movement just like a cast. With reduced movement, the foot muscles can become weak, causing lazy, unstable arches that can lead to problems in your feet, joints and back. BAREFOOT SCIENCE® stimulates, wakes up and strengthens weak foot muscles to create a healthy domed arch. Just as you would exercise any other muscles in your body to restore healthy function, your foot muscles also need stimulation and movement to work the way nature intended.

FACT: BAREFOOT SCIENCE® is flexible, easy to use and fits your existing footwear. It's lightweight, durable, washable and has an odor resistant treatment. Once you put them in your shoes you can immediately feel them working, providing gentle pressure and stimulation under the arches of your feet, giving you instant comfort and ongoing relief.

FACT: BAREFOOT SCIENCE® was designed to offer the same freedom of movement and natural stimulation as if you were standing, walking or running barefoot. You get that barefoot feeling inside your shoes. By gently working your foot muscles the way nature intended, your feet and leg muscles don't ache at the end of the day.

FACT: BAREFOOT SCIENCE® has received over 20 years of intensive research. It is Doctor used and tested, and is recommended by leading orthopedic surgeons and chiropractors.

FACT: Over one million happy feet attest to the effectiveness and benefits of BAREFOOT SCIENCE®

Common Symptoms That Barefoot Science® Insoles Address:

* THIS IS NOT A COMPLETE LIST OF SYMPTOMS. ALWAYS REPORT ANY SYMPTOMS OR PERSISTENT PAIN TO YOUR DOCTOR.

AILMENT	COMMON SYMPTOMS*
Plantar Fasciitis	Sharp heel pain, often first thing in the morning or after resting
Hallux Valgus (Bunions)	Joint swelling in big toe. Big toe points inward toward other toes
Hammer Toes	Abnormal buckling of toes, usually second and/or third toes Painful joint and appearance of corns and calluses
Heel Spurs	Extreme pain in heel and bottom of foot, especially while walking or running
Metatarsalgia	Pain and inflammation in the ball of the foot
Flat Foot	Arch of the foot is collapsed or hasn't developed and may be tender (excessive pronation)
Tendonitis	Pain in the instep, intense pain when standing on toes
Corns and Calluses	Shell of hard, dead skin caused by friction (callus), may become red and painful (corn)
Lower Back/Knee Pain	Aches and pains located in lower back region or in one or both legs

CLINICAL STUDY FACTS

EMERGENCY ROOM STAFF STUDY

Participants in the study experienced a significant reduction in pain and tiredness when using the BAREFOOT SCIENCE® Arch Activation Foot Strengthening System.

OBJECTIVE: Staff who work in emergency departments (EDs) often spend most of their days on their feet and are physically active. A study was conducted in this "real world" environment to see if the Barefoot Science™ Arch Activation Foot Strengthening System would be beneficial.

MEDICAL OVERSIGHT / AUTHORSHIP:
Dr. Peter Fowler, MD FRCS(C), Orthopedic Surgeon, Dr. Ned Amendola, MD, Director, University of Iowa Sports Medicine Center and Corinne Hodgson, Epidemiologist

FINDINGS: The study demonstrated that the BAREFOOT SCIENCE® Arch Activation Foot Strengthening System significantly reduced foot, knee, lower back and shoulder pain. It was also effective in reducing the perception of "tiredness" of the feet, ankles, knees, lower back, upper back and shoulders and overall fatigue at work.

FIGURE 1: PAIN SCORES FOR PARTICIPANTS WHO USED BAREFOOT SCIENCE™ FOR 4 WEEKS

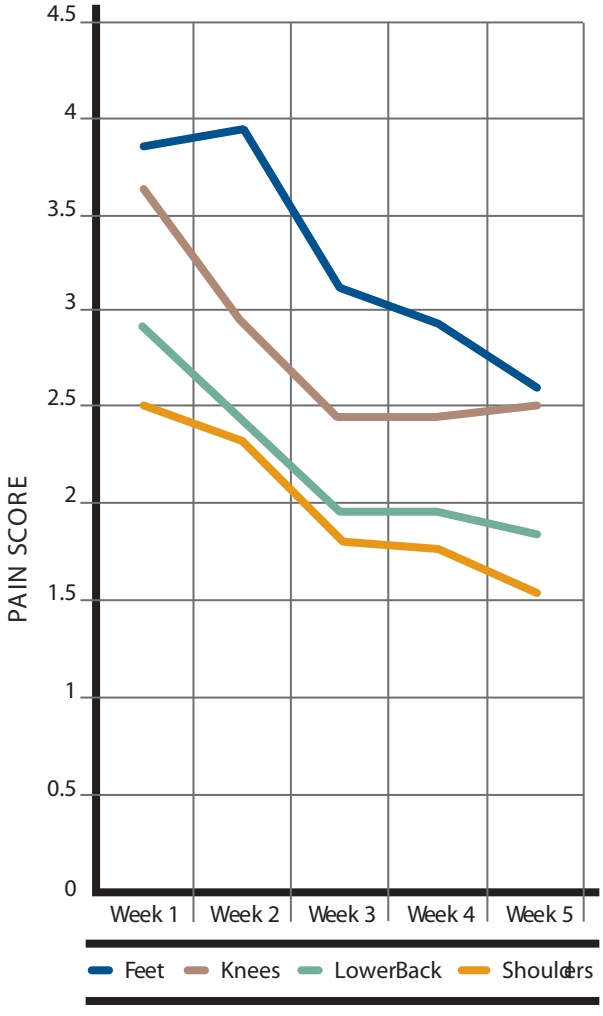
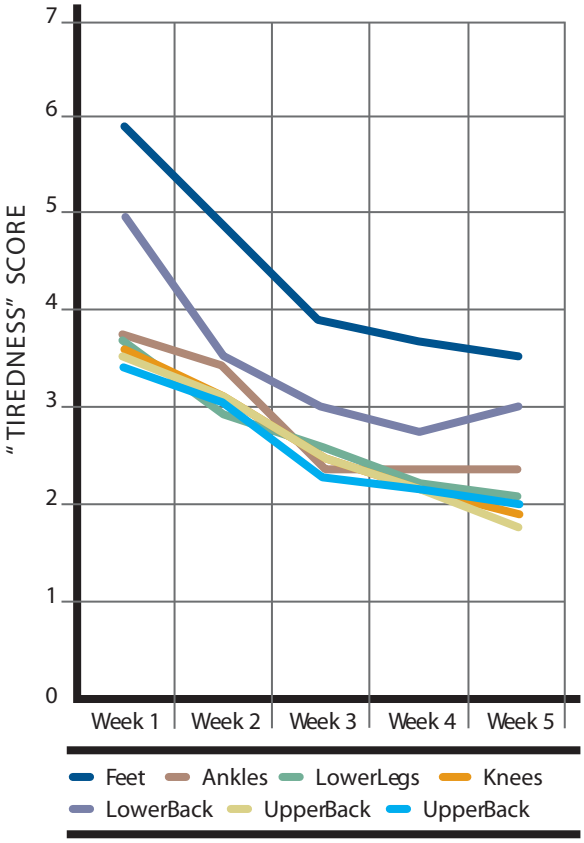


FIGURE 2: TIREDNESS SCORES FOR PARTICIPANTS WHO USED BAREFOOT SCIENCE™ FOR 4 WEEKS



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