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A Pilot Feasibility Study of Massage to Reduce Pain in People with Spinal Cord Injury during Acute Rehabilitation

Theresa Chase, MA, ND, RN[1], **Amitabh Jha, MD, MPH**[2], **C. A. Brooks, MA**[1], and **Amanda Allshouse, MS**[3]

[1]Craig Hospital, Englewood, CO

[2]Dept of Physical Medicine & Rehabilitation, University of Colorado, Denver, CO

[3]Dept of Biostatistics & Informatics, University of Colorado, Denver, CO

Abstract

Objective—To determine the feasibility of conducting a randomized controlled trial of massage therapy for patients with new spinal cord injury (SCI) during acute inpatient rehabilitation.

Design—A pilot single-center, randomized, single-blind, cross-over clinical trial.

Setting—Free-standing, not-for-profit, comprehensive rehabilitation center specializing in SCI rehabilitation

Participants—Forty adults ages 18 years and older undergoing acute rehabilitation following spinal cord injury reporting any type of pain.

Intervention—Rehabilitation nurses trained to give broad compression massage (BCM) and a control light contact touch (LCT) treatments. Participants were randomized to receive either BCM or LCT first, in six 20 minute treatment sessions over two weeks, with a one week wash-out between the two-week treatment periods.

Main Outcome Measures—Primary outcomes were changes in pain intensity and in fatigue, measured daily. Secondary outcomes included depressive symptoms measured by the Patient Health Questionnaire-9 (PHQ-9) and an assessment of pain medication usage.

Results—Pain intensity was higher at baseline and reduced more in the LCT-first group compared to the BCM-first group in period 1 (p=0.014); although this pattern was not found in period 2 (p=0.58). LCT and BCM groups did not significantly differ on any secondary measures except PHQ-9.

Conclusions—This study demonstrates the feasibility of using rehabilitation nurses to provide tactile therapy to patients with SCI and suggests a model for controlled clinical trials examining

Address correspondence to: Theresa M. Chase MA, ND, RN, Craig Hospital 3425, South Clarkson Street, Denver, CO 80113, Phone: (303) 789-8211, Fax (303) 789-8441, tmchase@craighospital.org.

CONFLICT OF INTEREST

We certify that no party having a direct interest in the results of the research supporting this article has or will confer a benefit on us or on any organization with which we are associated.

the efficacy of massage therapies. While efficacy was difficult to assess, broad compression massage was safe and well tolerated.

Keywords

spinal cord injury; massage; randomized clinical trial

INTRODUCTION

Massage has been used extensively in Western cultures as different forms of touch to soothe and relieve pain and to promote healing and relaxation, and pre-dates most accepted medicine practices. In spite of the uncertainty and possible unknown factors of the specific mechanisms of action with massage therapy for both non-disabled and disabled populations, massage is thought to reduce lactic acid levels in the muscles, stimulate healing of the connective tissues and increase lymphatic and venous circulation[1]. The demonstrated benefits of massage include reducing anxiety and depression, fatigue, alleviating stress, improving sleep, and reducing pain.[2] Pain has been shown to be one of the most serious and disabling complaints following spinal cord injury (SCI), with potential sources ranging from fractures and other injuries, post-surgical pain, neurogenic and/or neuropathic pain, and pain resulting from immobility, positioning, muscle imbalance and/or abnormal tone.[3–8] Pain is not only a problem in itself, but may contribute to other conditions, such as negative mood states, depression, anxiety, sleeplessness, and poor sleep quality and these in turn may interfere with participation in rehabilitation therapies and overall general well-being. While a variety of pharmacological and non-pharmacological approaches to treat pain after SCI have been studied,[9] including massage,[10,11] the use of massage in the inpatient rehabilitation setting has not been studied.

Motivated to find a low-risk treatment for pain for our SCI patients, and encouraged by the potential of massage therapy, we worked collaboratively with an experienced licensed massage therapist to explore the feasibility of integrating massage therapy into the rehabilitation program while evaluating the efficacy of broad compression massage (BCM) compared to light contact touch (LCT).

MATERIALS AND METHODS

Design, Setting and Participants

We introduced a massage therapy protocol into a comprehensive rehabilitation facility and evaluated its efficacy by conducting a single center, randomized, controlled, crossover study over an 11 month period. Notable eligibility criteria included a diagnosis of SCI, any level of pain, medical stability, an expected length of stay of at least 5 weeks and the ability to consent. Patients were excluded if unable to answer questions secondary to cognitive impairment or understanding of the English language or if currently involved in any other clinical trial. Participants were randomly assigned to one of two groups, BCM-LCT or LCT-BCM, receiving either BCM or LCT first. Each session included 20 minutes of hands-on treatment with limited conversation between the massage nurse and patient. Participants received treatments three times a week for two weeks for a total of 12 treatments (6 of each

modality), separated by a one-week “washout period”. The local Institutional Review Board approved the research protocol and informed consent was obtained from all study participants. The authors certify that all applicable institutional and governmental regulations concerning the ethical use of human volunteers were followed during the course of this research.

Interventions and training

Both the BCM and the LCT protocols were developed by a licensed massage therapy consultant who specialized in bodywork for people for whom conventional massage might be unsafe or contraindicated, including people with limited mobility and special health considerations. One advantage of BCM is that a trained practitioner can control and apply the right pressure for the patient more accurately by using broad compression. This method also allows for testing the amount of pressure as the key active ingredient. The LCT was patterned after the BCM protocol using only two to three ounces of pressure vs. the two to five pounds of pressure required for the BCM protocol. Both treatments focused on identical areas of the body and were limited to the upper body including arms, hands, neck, head, face and upper back. Participants wore comfortable clothing in a supine position in bed or in a reclined wheelchair. The supine position was selected over the more traditional prone position since the prone position may be contraindicated for those with SCI and evidence suggested a supine position results in similar responses as a prone position.[12]

Ten registered nurses with experience working with patients with SCI were trained to administer the two protocols during an 8-hour training session which included hands-on practice. The Licensed Massage Therapist who designed the intervention protocols served as trainer and study monitor observing treatments on a regular basis.

Data Collection and Outcomes

A research assistant interviewed participants, including assessments of primary and secondary outcomes and queries about adverse events and pain treatments received in the previous 24 hours. The primary study endpoint of reduced pain was calculated as the average of three of the four pain intensity scales (worst pain, average pain and pain now) measured using the Brief Pain Inventory Short Form (BPI-SF, modified to assess symptoms in the last 24 hours) which assesses quality, location, intensity, and the interference of pain on daily living.[13,14] Secondary outcomes included the Fatigue Severity Scale (FSS),[15] and depressive symptoms using the Patient Health Questionnaire-9 (PHQ-9).[16] A variety of other data were abstracted from medical charts including demographics, injury severity with the International Standards for Neurological Classification of SCI[17] and analgesic medication use with the Medication Quantification Scale (MQS-III).[18] Side effects, complications or other adverse events were monitored by the treating nurses and by the research assistant during daily interviews as well as monitoring of the medical chart.

Statistical Analysis

Demographic and injury characteristics and baseline outcomes between randomization groups were compared using two-sample t-tests to assess whether randomization created balance on these variables. Unfortunately there were baseline differences in the primary

outcome and carry-over effects were present, with a failure to return to baseline during the washout period. For these reasons, formal analyses of the cross-over design were difficult to interpret and are not presented. Instead, changes in BPI Intensity Scale were compared for the two groups *within* each treatment period using two sample t-tests. These comparisons were repeated for all six other outcomes in Tables 2 and 3.

RESULTS

Table 1 shows demographic and clinical characteristics of all study participants and comparisons by group assignment. Average age was 40.24 years (SD=13.80); 33 participants were male (82.5%); 7 were female (17.5%); and all but one were Caucasian. At the time of enrollment, average time post-injury was 69.35 days (SD=31.11). Motor vehicle crashes and sport injuries combined accounted for over 50% of the cases. Neurologically over 50% were classified at discharge as having neurologically complete injuries - ASIA Impairment Scale (AIS) A, with the remainder almost equally split between AIS B and C, with only one AIS D. Thirty-three participants (82.5%) had tetraplegia and seven (17.5%) had paraplegia. All 40 individuals were randomly assigned to one of two study groups. One participant was discharged from the hospital in the final study week and did not receive the final treatment; one participant withdrew during week 4, citing interference with family activities; and one participant withdrew in the second week saying she did not want to comply with the study requirements. The number of participants included in each analysis varied due to incomplete data.

The BPI Pain Intensity Score was significantly higher at baseline 1 in those randomized to LCT-BCM (5.42 vs 4.22; difference 1.20, p=.0306, Table 2) and this pain score did not return to a similar level in baseline 2 (5.42 vs 3.77; p=0.0003). Nonetheless, BPI pain intensity was reduced more in the LCT-BCM group compared to the BCM-LCT group in period 1 (p=0.0139). Table 3 shows that this pattern was not found in period 2 (p=0.5825).

Tables 3 and 4 also show the LCT-BCM and BCM-LCT groups did not significantly differ on any secondary measures except the PHQ-9, which exhibited a similar pattern to the BPI Pain Intensity scale. The PHQ-9 score was reduced more in the LCT-BCM group compared to the BCM-LCT group in period 1 (p=0.0085), but this pattern was not seen in period 2 (p=0.0747). As with the BPI Pain Intensity scale, the LCT-BCM group had a higher baseline 1 PHQ-9 score that is marginally higher than the BMC-LCT group (8.45 vs 5.11; difference 3.34, p=0.0893, Table 2) and did not return to baseline after the washout period (8.45 vs 4.22, p=0.0015).

Many outcome values did not return to baseline during the washout period before cross-over, either due to a carry-over effect or natural history of the outcomes (e.g. pain intensity decreases over the course of rehabilitation, regardless of treatment received). Thus, analyses combining the 2 periods were difficult to interpret and are not presented. No adverse events were reported by participants, massage nurses or abstracted from patient medical records.

DISCUSSION

We demonstrated the feasibility of integrating a study protocol of massage therapy administered by nurses into the acute rehabilitation program for acutely injured patients with SCI. Pain after SCI can be multi-factorial, and the results of this study confirm the refractory nature of pain after SCI seen in many studies.[5] Massage therapy is gaining ground in use by people with SCI partially due to a lack of success of traditional forms of pain relief.[19] Beyond demonstrating that such experimentation may be safe, with no adverse events being reported during our study, our study also showed the feasibility of conducting rigorous randomized controlled studies of massage to help establish an evidence base for its effectiveness.

Our limited results contrast with prior literature which generally shows a beneficial effect of massage.[2] Almost no participants demonstrated a clinically significant reduction (i.e. >30% reduction from baseline)[20] of pain intensity over the 5 week study. In period 1, participants receiving LCT had more intense pain and experienced a significantly greater reduction in pain intensity. It is not clear whether this suggests that tactile therapy is more effective in more intense pain, or whether the group randomly had unusually intense pain and the data demonstrate a regression to the mean phenomenon.

Our contradictory findings may be explained by a variety of factors. First, many studies lack methodological rigor[21] and it is possible that massage has only non-specific, or placebo, benefits. To address this concern, our technique was strict in application and method for reproducibility. As a result, the treatments were not tailored to the individual and their immediate concerns of aches and pains of the day. Moreover, the massage treatment used in this study was different than most massage therapies in that it uses broad compression strokes and holding patterns versus trigger points, techniques and patterns. It is possible that a less strict protocol, giving practitioners leeway to tailor the massage to individual patients' problems, may have resulted in different findings. Finally, we chose to test the effects of massage on undifferentiated pain, and it is possible that massage is only beneficial for specific types or locations of pain, such as the low-back.[22]

Study Limitations

The feasibility study also highlighted several other factors that should be considered in future research of massage and pain acutely after SCI. A crossover design was used to both increase enrollment (by ensuring that all participants would receive the "active" treatment) and increase the power of the study. We do not have data to demonstrate impact on enrollment rates, but several of the outcomes did not return to baseline during the washout period, possibly related to natural course of pain after SCI, limiting the analysis and interpretation of the cross-over design. Another consideration may be the lack of specific testing tools and assessments for the effect of massage therapy and human touch, and the timing of assessments. Scheduling pain and fatigue assessments during patient interviews the day following the treatments may have contributed to a lack of capturing the immediate effects of the treatments, whether LCT or BCM. Additionally, due to the applications of BCM and LCT massage applied across types of pain (i.e., musculoskeletal, neuropathic)

with no attempt to differentiate; future research may work to distinguish the various types of pain and provide a depth of analysis not included in this study.

It is difficult to capture the effects of human touch on the mind, body and spirit and it may be equally difficult to design a control that truly eliminates the effects of human touch. The satisfaction results suggest there were unmeasured benefits with both treatments. Massage therapy has had few controlled studies and is considered an alternative modality and not a usual part of the rehabilitation program for people with SCI. This study addresses the possibility of using massage therapy in the rehabilitation program as an adjunct to usual hospital care. Anecdotally, patients were found to be asleep in deep relaxation at the conclusion of both LCT and BCM treatments. Patients reported high satisfaction with the treatments, especially with the time and attention of a nurse for a full 20 minutes without interruption and distraction. Nurses also reported that the time spent with patients was often the most undisturbed period of patient care allowed in a busy day. Although results show no significant difference in response to either treatment, researchers on this study believe there were beneficial effects and improvements in patient condition regardless of treatment.

CONCLUSION

This study demonstrated the feasibility of implementing a randomized, controlled research protocol to evaluate the effectiveness of massage therapy using rehabilitation nurses in the acute rehabilitation setting. Findings from the pilot study suggest that the group with higher pain intensity showed significantly more improvement, and efforts to otherwise differentiate types of pain, may suggest areas for future research.

Acknowledgments

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Table 1

Participant Characteristics

Characteristic	BCM First *(n= 20)*	LCT First *(n= 20)*	All Participants *(n=40)*
Men *n (%)*	14 (70)	19 (95)	33 (82.5)
Mean Age (SD)	41.80 (14.27)	38.67 (13.49)	40.24 (13.8)
White race *n (%)*	20 (100)	20 (100)	40 (100)
Etiology of Injury *n (%)*			
Vehicular	9 (45)	6 (30)	15 (37.5)
Sports	4 (20)	6 (30)	10 (25)
Fall	3 (15)	4 (20)	7 (17.5)
Hit by object	0	3 (15)	3 (7.5)
Violence	0	1 (5)	1 (2.5)
Disease	4 (20)	0	4 (10)
Mean Days Post Injury *(SD)*	76 (34.44)	62.70 (26.61)	69.35 (31.11)
Neurological Level n (%)			
Tetraplegia	18 (90)	15 (75)	33 (82.5)
Paraplegia	2 (10)	5 (25)	7 (17.5)
ASIA Impairment Scale at Rehabilitation Discharge n (%)			
A – Complete Injury	10 (50)	13 (65)	23 (57.5)
B – Incomplete Injury	6 (30)	3 (15)	9 (22.5)
C – Incomplete Injury	3 (15)	4 (20)	7 (17.5)
D – Incomplete Injury	1 (5)	0	1 (2.5)
Educational Level n (%)			
Less than high school	2 (10)	3 (15)	5 (12.5)
High school/GED	10 (50)	6 (30)	16 (40)
Trade/Voc/Tech	2 (10)	4 (20)	6 (15)
Some College	2 (10)	5 (25)	7 (17.5)
Bachelor’s Degree and higher	4 (20)	2 (10)	6 (15)
Marital Status n (%)			
Single	5 (25)	11 (55)	16 (40)
Married	13 (65)	5 (25)	18 (45)
Divorced	2 (10)	2 (10)	4 (10)
Widowed	0	1 (5)	1 (2.5)
Separated	0	1 (5)	1 (2.5)

Table 2

Mean raw scores and differences within Period 1

	Period 1											
	Light Touch			Massage			Difference M-T					
	Baseline	Follow-up	Change	Baseline	Follow-up	Change	Baseline		Follow-up		Change	
Outcome	**est (SD)**	**est (SD)**	**est (SD)**	**est (SD)**	**est (SD)**	**est (SD)**	**est (SD)**	**p > |t|**	**est (SD)**	**p > |t|**	**est (SD)**	**p > |t|**
BPI Pain Intensity[1]	5.42 (1.46)	3.91 (2.40)	−1.51 (1.63)	4.22 (1.89)	4.03 (2.04)	−0.19 (1.60)	−1.20 (1.69)	.0306	0.12 (2.23)	.8662	1.32 (1.62)	.0139
BPI Pain Interference[1]	3.80 (2.86)	2.45 (2.43)	−1.35 (2.22)	3.37 (2.71)	2.70 (2.57)	−0.67 (2.19)	−0.43 (2.79)	.6287	0.25 (2.50)	.7548	0.68 (2.20)	.3364
FSS Sum[2]	33.63 (15.94)	29.05 (16.03)	−6.19 (7.66)	31.05 (13.54)	26.43 (17.05)	−4.62 (13.74)	−2.58 (14.76)	.5882	−2.62 (16.55)	.6199	1.58 (11.20)	.6631
PHQ-9 Sum[3]	8.45 (6.39)	5.15 (4.34)	−3.30 (3.57)	5.11 (5.52)	5.75 (4.62)	0.79 (5.46)	−3.34 (5.98)	.0893	0.60 (4.48)	.6746	4.09 (4.59)	.0085
MQS-III Pain Meds[4]	13.34 (9.37)	13.26 (10.20)	−0.08 (6.12)	11.02 (8.62)	12.63 (9.21)	1.61 (5.53)	−2.32 (9.00)	.4201	−0.63 (9.72)	.8382	1.69 (5.83)	.3659
MQS-III Other Meds[4]	8.69 (9.14)	9.28 (10.28)	0.59 (4.11)	16.46 (10.28)	15.91 (8.64)	−0.55 (7.00)	7.77 (9.73)	.0159	6.63 (9.49)	.0332	−1.13 (5.74)	.5360
MQS-III All Meds[4]	22.03 (14.86)	22.54 (17.84)	0.51 (8.44)	27.47 (13.25)	28.54 (14.46)	1.07 (8.84)	5.44 (14.08)	.2289	6.00 (16.24)	.2498	0.55 (8.64)	.8402

[1] Brief Pain Inventory

[2] Fatigue Severity Scale

[3] Patient Health Questionnaire-9

[4] Medication Quantification Scale-III

Table 3

Mean raw scores and differences within Period 2

	Period 2											
	Light Touch			Massage			Difference M-T					
	Baseline	Follow-up	Change	Baseline	Follow-up	Change	Baseline		Follow-up		Change	
Outcome	**est (SD)**	**est (SD)**	**est (SD)**	**est (SD)**	**est (SD)**	**est (SD)**	**est (SD)**	**p > |t|**	**est (SD)**	**p > |t|**	**est (SD)**	**p > |t|**
BPI Pain Intensity[1]	3.68 (1.88)	3.74 (1.97)	−0.14 (1.08)	3.77 (2.64)	4.02 (2.36)	0.04 (0.84)	0.09 (2.28)	.9041	0.28 (2.17)	.6950	0.18 (0.97)	.5825
BPI Pain Interference[1]	2.40 (2.49)	2.59 (2.43)	0.06 (1.74)	2.59 (2.54)	2.90 (2.59)	0.16 (1.79)	0.19 (2.52)	.8154	0.31 (2.51)	.7121	0.10 (1.76)	.8644
FSS Sum[2]	24.85 (13.66)	27.54 (15.26)	2.85 (5.15)	27.05 (16.21)	29.54 (17.39)	1.48 (8.48)	2.20 (14.96)	.6484	2.00 (16.33)	.7116	−1.37 (6.97)	.5541
PHQ-9 Sum[3]	5.50 (5.85)	4.72 (3.88)	−1.40 (5.19)	4.22 (4.95)	5.94 (6.23)	1.53 (3.74)	−1.28 (5.39)	.4955	1.22 (5.19)	.4844	2.93 (4.48)	.0747
MQS-III Pain Meds[4]	13.20 (9.04)	11.25 (7.63)	−1.95 (5.38)	13.21 (11.73)	10.27 (9.26)	−2.93 (7.87)	0.00 (10.47)	.9988	−0.97 (8.48)	.7187	−0.98 (6.74)	.6490
MQS-III Other Meds[4]	18.82 (10.20)	18.67 (8.92)	−0.15 (6.90)	8.18 (7.43)	10.58 (9.29)	2.40 (5.85)	−10.6 (8.92)	.0006	−8.09 (9.11)	.0078	2.56 (6.40)	.2138
MQS-III All Meds[4]	32.02 (14.46)	29.91 (12.98)	−2.11 (9.42)	21.38 (15.95)	20.85 (15.48)	−0.53 (12.02)	−10.6 (15.22)	.0332	−9.06 (14.29)	.0521	1.58 (10.80)	.6462

[1] Brief Pain Inventory

[2] Fatigue Severity Scale

[3] Patient Health Questionnaire-9

[4] Medication Quantification Scale-III