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ORIGINAL ARTICLE

Managing pain and fatigue in people with spinal cord injury: a randomized controlled trial feasibility study examining the efficacy of massage therapy

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Study design: A randomized controlled trial (RCT).
Objectives: To determine the efficacy of massage therapy (MT) as a treatment that could be implemented to reduce pain and fatigue in people with chronic spinal cord injury (SCI).
Setting: Laboratory setting in Sydney, Australia.
Methods: Participants included 40 people with SCI living in the community who were randomly assigned into one of two RCT arms: MT (Swedish massage to upper body) or an active concurrent control (guided imagery (GI) relaxation). All participants received 30 min once a week of either massage or GI over 5 consecutive weeks. In addition to sociodemographic and injury factors, assessments and reliable measures including the short-form McGill Pain Questionnaire and Chalder's Fatigue Scale were validated.
Results: Chronic pain and fatigue were significantly reduced in the massage group when assessed at the end of 5 weeks ($P<0.05$), with large effect sizes. Interestingly, GI was as effective as MT in reducing pain and fatigue. Pain scores were reduced significantly over time in both MT and GI groups ($P=0.049$ and $P=0.032$, respectively). Total fatigue scores were also reduced in both MT and GI groups ($P=0004$ and $P=0.037$, respectively.)
Conclusions: Massage and GI are both active treatments that provide potential clinical benefits for adults with SCI. Future research should clarify the role of massage and GI in managing pain and fatigue in SCI and assess outcomes into the longer-term.
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INTRODUCTION

Spinal cord injury (SCI) results in the loss of sensory input and motor control and is often associated with debilitating secondary conditions such as chronic pain and chronic fatigue that have substantial negative impacts on quality of life.[1–4] Chronic pain and fatigue are prevalent and potentially incapacitating.[1–3] For instance, it has been estimated that up to 75% of adults with SCI will suffer ongoing pain, with about one-third indicating that their pain is severe to excruciating.[2] Common types include musculoskeletal, visceral and neuropathic pain.[2] In addition, it has been estimated that up to 50% of adults with SCI will experience severe levels of fatigue,[3] with consequent disruptions to autonomous daily participation.[4–8] Fatigue has been defined as a state of excessive chronic physical and mental tiredness involving pervasive feelings of exhaustion and negative emotions such as anxiety and depressed mood.[3,7,9] It is the excessive and chronic nature of fatigue that distinguishes it from commonly experienced 'tiredness' related to daily physical or mental exertion, sometimes called acute fatigue.[9]

The management of conditions such as chronic pain following SCI is considered difficult and challenging, necessitating complex management algorithms,[10] although pharmacological treatments are known to provide some benefit.[10,11] The management of chronic fatigue is equally challenging,[3] and there are very few studies investigating benefits of medications for muscular or acute fatigue in SCI.[7] Physical activity has been shown to be beneficial for adults with SCI,[12] with higher levels of physical activity in individuals with SCI related to lower levels of chronic pain and fatigue.[13] Cognitive behavioral treatments have also been shown to provide some benefit, especially for chronic pain in adults with SCI.[14–16]

Massage therapy (MT) is the manual manipulation of soft tissue with the intention of promoting health.[17] A meta-analysis of 37 randomized studies investigating the benefits of MT suggested that it is effective in addressing conditions such as elevated anxiety and negative mood, as well as ongoing pain (but not acute pain).[17] A systematic review of MT for low back pain concluded that massage was inferior as a modality in reducing chronic low back pain compared with manipulation and transcutaneous electrical nerve stimulation, but superior to a sham laser control, relaxation therapy and self-care education, and equal to corsets and exercise.[18]

In a search of the literature, there is very preliminary evidence that MT can provide some benefit for managing pain in SCI. In a small opportunistic sample employing a telephone survey and investigating the use of complementary therapies (CTs) in people with SCI, ~40% reportedly used at least one CT to manage chronic pain.[19] Massage was reported as the second most frequently used CT

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(with acupuncture first), and was rated highest for pain relief.[19] In an exploratory sequential controlled design study, the effects of massage ($n=15$) were compared with those of acupuncture ($n=15$) in 30 adults with SCI. Results suggested that MT (and acupuncture) held promise as a treatment for chronic pain.[20] In addition, the benefits of MT versus upper trunk exercise in 20 adults with C5–C7 tetraplegia were investigated.[21] Half of the participants were randomly assigned to a MT group (40 min of remedial massage on the upper body twice a week for 5 weeks) or an exercise group (motion exercise routines targeting arms, neck, shoulders and back, twice a week for 5 weeks and performed by themselves). Only the massage group reported reduced levels of anxiety and depressive symptoms, as well as increased muscle strength.[21] Finally, pilot research was conducted, testing the feasibility of using MT in the acute phase of SCI as a management of pain and fatigue.[22] Patients with SCI were randomized to either MT or light touch where they received a 20-min session three times a week for 2 weeks. This study was a cross-over trial, where eventually patients received the alternative treatment. Reductions in pain and fatigue were found for both conditions, with the investigators concluding that MT was a feasible treatment for pain and fatigue in the acute phase.

Guided imagery (GI) is an internal experience of a perceived event without the actual external stimuli.[23] GI is predicated on the principle that each thought has a physiological response, and in recent years there has been an increase in the practice and research of GI as a treatment option for psychological, psychiatric and medical conditions.[24–26] To control for the effect of a therapeutic relationship between SCI participant and therapist, GI was chosen as an active control. The GI script in this study involved 30 min each week for 5 weeks of pleasant imagery to encourage a relaxation response (similar to the intervention of MT), but did not involve touch. The investigators considered that this dosage of GI was not sufficient to produce a treatment effect and therefore served as an active placebo, and by doing so, the study controlled for the effects of MT alone.

The aims of the current study were to conduct a preliminary randomized controlled study to: (a) determine the feasibility of using MT as a potential treatment for reducing chronic pain and fatigue in adults with SCI who are living in the community, and (b) compare changes in pain and fatigue in the group that received MT with those in an active control group that received GI relaxation. On the basis of prior massage studies, it was hypothesized that the group that received MT will have superior reductions in pain and fatigue.

MATERIALS AND METHODS

Study participants

Participants included 40 adults with a SCI (mean age = 46 years, s.d. = 11.6; 34 males, 4 females), the mean age at the time of the injury being 27.4 years (s.d. = 13.5) and the mean time since the injury was 18.4 years (s.d. = 12.1). Participants with SCI were recruited through advertisements and editorials about the study, placed in newsletters of SCI consumer organizations, associations, rehabilitation centers and community groups. Inclusion criteria for the participants with SCI consisted of the following: (i) male or female aged between 18 and 79 years; (ii) able to understand instructions in English; and (iii) having sustained an acute SCI at least 12 months before the study. Exclusion criteria included the following: (i) history of severe psychiatric disorder such as bipolar disorder or psychoses; (ii) history of debilitating diseases such as cancer, stroke or neurodegenerative disease; (iii) history of alcohol abuse; and (iv) having received a massage within 4 weeks before entering the study. Chronic pain was not included as an inclusion criterion as most people with SCI experience pain and fatigue.[1–4] Completeness of the lesion was assessed by a medical specialist based on International Standards for Neurological Classification of SCI (http://ais.emsci.org/). SCI participants received appropriate monetary compensation for their time and travel. Sociodemographic and injury characteristics for the total group, the massage and active control groups are shown in Table 1. The study received randomized controlled trial registration: ACTRN12615000136505.

Research ethics

Full compliance with the Code of Ethics of the World Medical Association occurred, and research ethics approval was granted by the local institutional research ethics committee. All institutional regulations concerning the ethical use of human volunteers were followed during this research. Approval was granted by the local institutional human research ethics committee. Written consent was obtained before participation in the study, and the study was conducted from 2005 to 2007.

Study design

In compliance with latest SCI intervention recommendations,[27] this study employed a randomized controlled trial design with parallel groups: that is, two arms into which participants were randomly assigned in equal numbers. The active arm involved 20 participants receiving 30-min MT sessions once a week for 5 consecutive weeks. The second arm involved an active concurrent control group that received 30-min sessions of GI once a week over 5 consecutive weeks. The active control condition had the same amount of therapist–participant interaction time during the five sessions as the MT group, and therefore, theoretically controlling for extraneous factors such as therapeutic relationships. However, the GI condition did not control for touch as did a prior study.[22] It has also been recommended that double-blind methodology is optimal for clinical trial studies,[27] although it was not possible

Table 1 Demographic characteristics by the group of SCI participants ($N=40$)

Characteristic	*Total*	*Massage*	*Active control*
Sex			
Female, *n* (%)	6 (15)	4 (20)	2 (10)
Males, *n* (%)	34 (85)	16 (80)	18 (90)
Age			
Mean years (s.d.)	46.0 (11.6)	48.9 (12.2)	43.0 (10.7)
Time since injury			
Mean years (s.d.)	18.4 (12.1)	18.1 (12.7)	18.7 (11.7)
Cause of injury, n *(%)*			
MVA	19 (47.5)	6 (30.0)	13 (65.0)
Falls	5 (12.5)	2 (10.0)	3 (15.0)
Sport	6 (15.0)	4 (20.0)	2 (10.0)
Non-trauma	9 (22.5)	7 (35.0)	2 (10.0)
Other	1 (2.5)	1 (5.0)	—
Education, n *(%)*			
High school	13 (32.5)	4 (20.0)	9 (54.0)
College	13 (32.5)	9 (45.0)	4 (20.0)
University UG	9 (22.5)	5 (25.0)	4 (20.0)
University PG	5 (12.5)	2 (10.0)	3 (15.0)
Injury level, n *(%)*[a]			
Paraplegia	30 (75.0)	14 (70.0)	16 (80.0)
Tetraplegia	9 (22.5)	5 (25.0)	4 (20.0)
Completion of lesion[a]			
Complete	20 (50.0)	10 (50.0)	10 (50.0)
Incomplete	19 (47.5)	9 (45.0)	10 (50.0)

Abbreviations: PG, postgraduation; SCI, spinal cord injury; UG, undergraduation.
[a]One participant level and completeness unknown (non-traumatic).

for the clinical investigators or participants to be blind to the intervention in a study such as this. However, a single-blind control design was utilized, in which participants were initially unaware of whether they were assigned into the massage or control group.

Procedure

The intervention for the massage group was 30 min of Swedish MT performed on the participants' back, neck and arms. Swedish massage includes four basic strokes—stroking, effleurage, kneading and friction—which were used on the MT group during each session. This protocol is similar to those used in previous intervention studies and controls the problem of the use of mixed types of massage.[28,29] Eleven female massage therapists with the highest standard of tertiary education in MT in New South Wales and a minimum of 5 years of clinical experience were trained to perform a MT protocol standardized for this study. Each participant had the same therapist for all five sessions, and therapists massaged between one and four participants, dependent on the availability of therapists and ability to coordinate suitable times. Participants received the massage while leaning forward in the wheelchair, against a comfortable, adjustable thoracic and facial support, and wheelchairs were locked for stability. The MT protocol was written in poster style and placed in a visible position for the therapists so that all massage therapists consistently used the same massage sequence and techniques. High-quality, pure sweet almond oil was used for all MT sessions, and all MT equipments were cleaned following each session.

All control participants received five 30-min sessions of GI delivered by one female therapist with tertiary qualifications and experience in stress management. A GI relaxation script and protocol were developed and used for all sessions. Each session began with the participant seated comfortably in their wheelchairs using pillows and supports when necessary. Before the first session, participants were asked to think of a favorite, peaceful, calm environment that they could then visualize during the relaxation. They were not required to discuss the location or nature of that place, but to visualize it in their mind. They were asked to close their eyes and were first instructed how to perform slow diaphragmatic breathing. In each session, the therapist gave the same concise instructions to guide participants through the GI. They were instructed to use the five senses (vision, hearing, touch, smell and taste) to visualize specific components of their favorite place. The GI protocol is similar to those used in previous studies.[30]

Assessment

Assessment occurred immediately before the start of the 5-week MT and GI sessions, and directly after the completion of the five sessions. Because this study was designed to determine the feasibility of MT as a treatment, no medium to long-term outcome measures were taken. Two primary outcome measures were employed. The primary clinical outcome measure for pain consisted of the short-form McGill Pain Questionnaire (SF-MPQ),[31] used to assess the ratings of participants of their pain severity. The SF-MPQ consists of the sum of the ranked values of 15 descriptors of chronic pain severity employing a four-point Likert scale ranked from 0 (no pain) to 3 (severe pain), providing an overall indication of pain severity.[31] Higher scores indicate more severe chronic pain. The SF-MPQ has been shown to be highly correlated with the full McGill Pain Questionnaire, to have acceptable test–retest reliability, and to have acceptable convergent and discriminate validity.[31,32] The primary outcome measure for chronic fatigue was the Chalder Fatigue Scale, a self-rating fatigue scale that provides an overall indicator of chronic fatigue, as well as domains of mental and physical fatigue.[33] In this paper, only overall fatigue scores are reported. The CSF has 14 items with four-point Likert items (0 to 3) with high scores indicating higher levels of fatigue.[33] Typical items include the following: 'Do you have problems with tiredness?' and 'Do you have difficulty concentrating?' The Chalder Fatigue Scale has acceptable internal reliability and discriminant validity,[33] and has been shown to be a sensitive measure of fatigue in SCI research.[34]

A secondary measure was employed to provide a pretreatment assessment of mood states.[35] The Profile of Mood States (POMS) was used to measure negative mood status. The POMS is a 65-item Likert-type measure (0 = not at all, 4 = extremely) of six negative mood states, including anxiety (tension), depressive mood and anger. High scores indicate elevated negative mood states. The POMS assesses mood states by requesting participants to rate themselves on adjectives related to the particular negative mood state. For example, participants rated themselves on descriptors such as 'tense', 'hopeless' and 'restless.' The POMS has been shown to have acceptable validity and a high internal reliability,[35] and has been shown to be a sensitive measure of mood states in SCI research.[34] Only the anxiety and depressive mood domains are reported in this paper to determine whether the two groups were similar for mood states when enrolled into the study.

Statistical methods

Repeated measures analysis of variance was performed to determine whether significant differences existed over time between the MT and GI groups for the pain and fatigue outcome measures. If the repeated measures analysis of variance was significant, Fisher least significant difference *post hoc t*-tests were used to determine where differences existed. On the basis of prior research in people with SCI and change related to the treatment,[36] a conservative effect size of 0.3 was assumed (Cohen's *d*), and with a statistical power of 80%, an α of 0.05 for detecting differences between two groups, the required sample size was 24 or 12 per group.[37,38] Therefore, with 20 in each group, the *a priori* statistical power was estimated to be 96%.[38] Partial eta-squared (η^2) effect size values are provided as an estimate of the size of the difference among the groups or over time. A partial η^2 of ~0.03 is considered small, 0.13 is considered a medium difference and over 0.2 is considered a large and substantial difference.[37] *Post hoc* or retrospective statistical power of the tests is also provided. All analyses were performed using the Statistica Software (Version 12, Statsoft, Dell Inc., Tulsa, OK, USA).

RESULTS

There were no significant differences found for pain severity scores between the MT and GI groups: $F_{1,38} = 0.02$, $P > 0.05$, $\eta^2 = 0.00$ and power = 5%. Pain scores were significantly reduced over time, from pretreatment to post-treatment in both groups: $F_{1,38} = 9.01$, $P < 0.01$, $\eta^2 = 0.19$, power = 83% with *post hoc* analyses revealing that pain scores were reduced significantly over time for the MT group ($P < 0.05$) as well as for the GI group ($P < 0.05$). There was no significant interaction effect between groups and intervention over time: $F_{1,38} = 0.02$, $P > 0.05$, $\eta^2 = 0.00$, power = 5%. Table 2 shows pain severity (SF-MPQ) scores for both groups.

There were no significant between-group differences in overall Chalder Fatigue Scale fatigue scores: $F_{1,38} = 0.89$, $P > 0.05$, $\eta^2 = 0.02$ and power = 15%. Within-group analyses revealed that fatigue scores were reduced significantly over time: $F_{1,38} = 18.4$, $P < 0.01$, $\eta^2 = 0.33$ and power = 99%, with *post hoc* analyses indicating that fatigue scores were reduced significantly in the MT group ($P < 0.05$) and in the GI group ($P < 0.05$). There was no significant interaction effect between groups and intervention over time: $F_{1,38} = 1.49$, $P > 0.05$, $\eta^2 = 0.04$, power = 22%. Table 2 shows Chalder Fatigue Scale scores for both

Table 2 Pain and fatigue scores for the two groups over time

	Massage			*Active control*		
	Mean	*s.d.*	*95% CI*	*Mean*	*s.d.*	*95% CI*
Pre-SF-MPQ	11.7	8.9	7.6–15.9	11.5	10.0	6.8–16.1
Post SF-MPQ	9.1	8.1	5.4–12.9	8.6	8.9	4.5–12.8
Pre-CFS	17.6	5.4	15.1–20.1	18.4	7.0	15.1–21.7
Post CFS	14.1	4.3	12.1–16.1	16.5	5.9	13.8–19.3

Abbreviations: CFS, Chalder Fatigue Scale; CI, confidence interval; SF-MPQ, short-form McGill Pain Questionnaire.
Note: no significant between-group difference in pain: $F_{1,38} = 0.02$, $P > 0.05$.
Significant reductions in pain over time in both groups: $F_{1,38} = 9.01$, $P < 0.01$.
No significant group differences in fatigue: $F_{1,38} = 0.89$, $P > 0.05$.
Significant reductions in fatigue over time for both groups: $F_{1,38} = 18.4$, $P < 0.01$.

groups. To rule out possible confounding influences of mood states, the two groups were shown to be similar for anxiety and depressive mood, with no significant differences between the MT and GI groups at the pretreatment measure for anxiety ($F_{1,38} = 3.4$, $P > 0.05$) or depressive mood ($F_{1,38} = 0.07$, $P > 0.05$).

DISCUSSION

The use of MT in the management of chronic pain and fatigue in adults with SCI has been shown to be feasible by the findings of the current study. MT was associated with reduced chronic pain severity and fatigue in adults with SCI who are living in the community, a time when their personal resources for daily functioning and participation are challenged.[34,39] Although not addressed in this paper, MT may also be beneficial for managing pain and fatigue to adults with SCI within the acute inpatient rehabilitation phase, as suggested by prior pilot research.[22] This will need clarification from future research.

However, and significantly, MT was shown to be no more effective in lowering pain and fatigue than GI. This finding supports the conclusion that MT, as delivered in this study, was as effective in treating pain and fatigue as was an active control condition such as GI. MT may decrease pain via mechanisms explained in the Gate Control Theory[40] in which tactile stimulation can reduce pain by inhibiting nociception via the release of gamma-amino butyric acid in small fibers in the spinal cord.[41] The mechanisms by which MT reduces fatigue could be via the relaxation response that reduces cortisol levels associated with distress. Reduced cortisol levels, in turn, are associated with decreased negative mood states, stress and anxiety,[42] which are known to affect sleep patterns negatively.[1] However, an alternative explanation is possible. That is, MT is at least as effective as GI, which has an increasing evidence base as an effective treatment.[43–45] For instance, GI is regarded as an efficacious treatment for reducing anxiety and chronic pain, and is thought to work by enhancing parasympathetic responses and thus evoking relaxation in people with injuries.[43] It is believed to be beneficial because of its positive influence on factors known to be active in chronic pain and fatigue, such as a person's nociceptive feedback, physical and emotional status and a person's expectations (for example, self-efficacy), appraisals and thoughts (for example, catastrophization).[44,45] Given the strong relationship between fatigue, pain and mood states,[34] it is not inconceivable that the use of GI could also result in improved vitality (that is, reduced fatigue).

The results of this study therefore provide preliminary evidence to support the implementation of MT and GI into SCI rehabilitation as strategies for addressing the complex problems of pain and fatigue. This conclusion is supported by the extent of the reductions in pain and fatigue in the two groups, given resultant effect sizes were large ($\eta^2 = 0.19$ and 0.33). This suggests that both MT and GI have value as therapeutic strategies for pain and fatigue management, with the large effect sizes suggesting that they could result in significant clinical benefits. Furthermore, MT integrated into SCI rehabilitation may result in improved management of chronic pain and fatigue during hospitalization, eventually leading to improved long-term adjustment following discharge from hospital. In addition, the findings also provide support for teaching GI strategies more widely within SCI rehabilitation. Rehabilitation centers and hospitals are increasingly incorporating GI into standard care,[46] and advantages have included reduced average length of stay as well as lower average pharmacy and medication costs.[47]

Limitations of the study include the lack of medium and long-term pain and fatigue outcomes. Also, although there was no difference between groups in pain intensity, the type of pain (that is, musculoskeletal, neuropathic or possibly both) was not controlled for. Future research will need to determine, for instance, whether MT is more effective for musculoskeletal and GI more effective for neuropathic pain. Nevertheless, the study findings served the purpose of demonstrating the feasibility of employing MT (and GI) to assist in the management of chronic pain and fatigue.

Future-controlled research is required that clarifies the role and efficacy of MT and GI in managing pain and fatigue. In conclusion, the clinical value of this study is that both MT and GI are novel, possibly efficacious SCI rehabilitation therapies that could provide substantial relief, from prevalent aversive conditions such as chronic pain and fatigue, to over 10 000 people in Australia who live with chronic SCI, not to mention many more thousands worldwide. The introduction of additional non-pharmacological, non-invasive and cost-effective treatments into multidisciplinary rehabilitation approaches for improving adjustment and daily functioning,[48] as well as challenging conditions such as chronic pain and fatigue, will increase the quality of life of people with neurological conditions such as SCI.

DATA ARCHIVING

There were no data to deposit.

CONFLICT OF INTEREST

The authors declare no conflict of interest.

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