

Massage to Reduce Pain in People with Spinal Cord Injury

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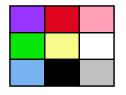
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Conducted at Craig Hospital, Englewood, CO – not-for-profit, stand-alone hospital specializing in rehabilitation for people with spinal cord and brain injuries.

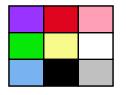


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Rationale

Test an inexpensive, low-risk treatment for treating pain in people undergoing rehabilitation following spinal cord injury.

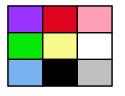


SPECIFIC AIM

To evaluate the efficacy of Massage Therapy for

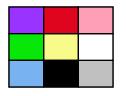
- decreasing pain,
- reducing fatigue,
- decreasing analgesic medication use, and
- increasing participation in rehabilitation modalities

among patients with spinal cord injury during acute inpatient rehabilitation.



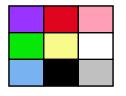
Spinal Cord Injury (SCI)

- Typically results in neurologic damage resulting in temporary or permanent loss of motor, sensory, and/or bowel and bladder function.
- Many concomitant injuries
- Pain has been shown to be one of the most significant and disabling complaints following a SCI.
- Pain is often treated with pharmaceuticals, many of which have undesirable side effects that also interfere with rehabilitation participation.



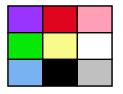
Massage

Although the exact mechanism of action of massage remains uncertain, there is evidence massage is effective in pain management, and is beneficial in reducing anxiety and depression, fatigue, alleviating stress, and improving sleep.



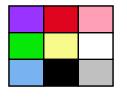
Primary Hypothesis

Massage will decrease the *pain intensity* of all etiologies among SCI patients during acute inpatient rehabilitation, regardless of the etiology of the pain.



Inclusion Criteria N = 40

- Admitted to Craig Hospital immediately following initial acute care hospitalization with a primary diagnosis of acute SCI
- age \geq 16 years
- Report pain
- Medical clearance from their attending physician
- Able to answer questions as part of the baseline and follow-up data collection
- Able to participate in treatment sessions and daily interviews
- Not currently involved in other clinical trial
- Expected to remain hospitalized at Craig for the duration of the study – five weeks



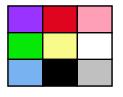
Design Challenges and Solutions

<u>CHALLENGE</u>

- Positioning
- Vulnerability
- Rehab setting
- Control
- Intention to treat

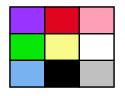
RESPONSE

- Supine (vs. prone)
- Broad Compression Massage (BCM) (vs Swedish)
- Train rehabilitation nurses to deliver treatment
- Touch treatment providing the lightest contact possible
- Nurses listen to "books-on- tape" during control treatment



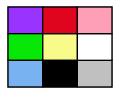
Study Design

- Randomized, cross-over, clinical trial comparing massage treatment plus usual hospital care to a "control" treatment plus usual hospital care.
- Worked with an qualified massage therapist with extensive knowledge and 20 year history of working with vulnerable populations including hospice patients



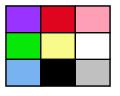
Study Design

	Week 1	Week 2	Week 3	Week 4	Week 5
Massage Group	Massage M – W – F	Massage M – W – F	Washout	Touch M – W – F	Touch M – W – F
Touch Group	Touch M – W – F	Touch M – W – F	Washout	Massage M – W – F	Massage M – W – F
Interview	Daily	Daily	Daily	Daily	Daily
PHQ-9, Blinding Assessment, Satisfaction Survey	Baseline	End of two week Treatment	End of Washout		End of two week Treatment
Medication Review					End of study
Therapy Review					End of study



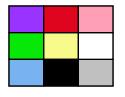
Outcome Measures

- The Brief Pain Inventory Short Form(BPI-SF) measures quality, location, intensity, and the interference of pain on daily living.
- Fatigue Severity Scale (FSS)
- Patient Health Questionnaire (PHQ-9)
- Blinding Assessment
- Patient Satisfaction



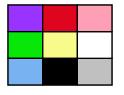
Medication Record Review

- Pharmacological Agents Abstracted from the participant's medical record and included:
 - Name of drug
 - Dosage,
 - Date of utilization,
 - Reason for use



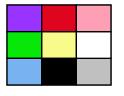
Billing Record Review

Each patient's schedule of therapies compared with the hospital billing to determine number of actual sessions received.



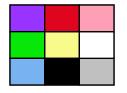
Protocols – Similarities

- Both treatments focused on identical areas of the body and were limited to the upper body including arms, hands, neck, head and face.
- Each treatment took 20 minutes.
- Treatments administered on the same schedule.



Protocols – Similarities

- Protocol addressed specifics including patient positioning, clothing, lighting, temperature, noise, and control of environment
- 10 registered nurses were trained in research methods and to deliver both treatment arms



Protocols – Differences

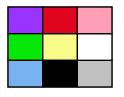
Broad Compression Massage

 "Intention to Treat" consistent with typical massage treatment

Touch Treatment

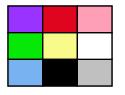
 Intention to treat interrupted – Nurses wore headsets and listened to "books on tape"

 Pressure - 2-3 pounds Pressure – 2-3
ounces



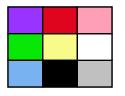
Results

- Forty subjects were randomized to receive either massage first (n=20) or light touch first (n=20).
- All forty individuals completed the entire study and were included in the per protocol analysis; however the number of participants included in each analysis varied due to incomplete data.

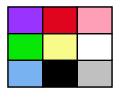


Preliminary Results Demographics

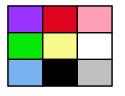
- Average age = 40.24 years (SD=13.80)
- Thirty-three participants were male (82.5%), 7 were female (17.5%)
- All but 1 were Caucasian.
- Average time post-injury was 69.35 days (SD=31.11)
- Motor vehicle accidents and sport injuries combined accounted for over 50% of the cases.



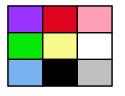
- Cross over study each person serves as their own control
- Improvements in a majority of the outcomes from the beginning of the study to the end of the study
- Irrespective of the treatment received, there was a consistent pattern of significantly less improvements during period 2 than period 1.



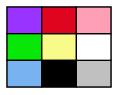
- When comparing improvements when receiving massage verses receiving light touch, <u>only two outcome</u> <u>measures</u> showed statistically significant changes
- The <u>pain intensity</u> and <u>depressive symptoms</u> improved significantly more when receiving **light touch**.
- They improved more, if they received light touch in the first period rather than in the second.
- In period 1, the light-touch group <u>started with more</u> <u>intense pain and depressive symptoms</u> and experienced a significantly greater reduction in both so that the pain intensity and depression for the two groups were not significantly different at the end of period 1.



- Pain <u>interference</u> did not show a similar pattern.
- No significant differences were found between light touch treatment and massage treatment for pain interference.

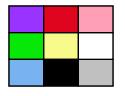


- Analysis of pain medications showed no differences between massage and light touch.
- Participation in rehabilitation was not analyzed due to incomplete data.



Preliminary Results Blinding

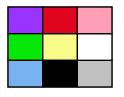
- 100% of individuals in the light touch first group correctly identified their treatment group at the end of period 1
- Most correctly identified at the end of period 2 in both groups.



 No differences were found in patient satisfaction either between groups or between period 1 and period 2.

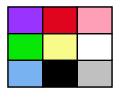
Preliminary Results Patient Satisfaction – Period 1

- 50% (Massage First) and 26% (Lt Touch) reported treatment had improved their pain
- 83% (Massage First) and 63% (Lt Touch) reported being either somewhat or very satisfied with treatment
- 83% (Massage First) and 58% (Lt Touch) said they would recommend their treatment to others



Limitations

- Defined protocol upper body only not individualized
- Patient expectations Swedish massage
- No control (no treatment) group
- Variations in practitioners

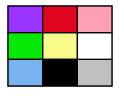


Challenges

- Accurately describe and evaluate the effect of prescription medications
- Inability to definitively describe and measure pain
- Effect of "intention to treat" effect of human contact.
- Incorporating treatment into real world setting
- What's more important pain intensity or how it interferes in our lives?

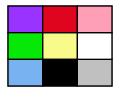
Pain does not equal Suffering

- "Both treatments helped me relax and get my mind off it (SCI), even if my pain did not change."
- "I really liked both treatments for the relaxation, but neither helped my pain."
- "Sometimes it helped my pain, not always. It always helped me relax."



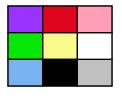
Participant Comments

- "I appreciate being touched...I don't get touched very much. People shower me and dress me, but they don't touch me."
- "It was nice to have 20 minutes of peace with no interruptions."
- "Both treatments helped but were different, like comparing apples and oranges. The pressure of massage relieved pain but the touch was soothing and made me fall asleep, almost every time."



Participant Complaints

- "I would have liked it to cover my whole body"
- "The technique is the same, but some nurses go faster or slower than others"
- "The treatments make me too relaxed and I fall asleep."



Conclusions

- This study demonstrated in a small population of people with new SCI, broad compression massage is safe and well tolerated, but is not more effective than light touch in treating pain
- Pain symptoms decreased significantly during rehabilitation for both groups
- There was a statistically significant improvement in *pain intensity* favoring light touch; however, the clinical significance is unclear, because the differences in *pain interference* were not statistically significant between the two treatments and the light touch-first group started with higher levels of pain intensity.

Thank You

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