Management of Chronic Neck and/or Low Back Pain With a Multimodal Nonpharmacological Pain Relief Kit

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Background: Chronic neck and back pain lasting over 3 months is a significant source of disability. Recent recommendations for treating chronic pain indicate nonpharmacological interventions be initially prescribed. Topical menthol, elastic therapeutic tape, thermal therapy, and exercise have been found to be effective in reducing musculoskeletal pain. The pain relief kit described here includes these nonpharmacological interventions for patients to self-select their pain management.

Purpose: The purpose of this 3-week study was to determine the effect of a multimodal, nonpharmacological pain relief kit on pain, functioning, and pain medication consumption in individuals experiencing chronic neck and/or low back pain.

Study Design: This is a repeated measures single observational cohort study.

Methods: Study participants included 25 volunteers with moderate intensity (>3/10) chronic neck and/or low back pain. Subjects completed baseline data collection and then received a pain relief kit. This kit included a brochure, product samples, and a description of how to use the four nonpharmacological interventions, including topical menthol, kinesiology tape, thermal therapy, and 3 stretching and 3 strengthening exercises to be performed using elastic resistance. Data were collected at 3 points—before giving the kit (baseline) and at 1 week (T1) and 3 weeks (T2) after giving the kit—using the Modified Patient Specific Functional Scale (MPSFS), Medical Outcomes Survey (MOS)-36, and by assessing their ability to complete 4 functional tasks and pain intensity while completing the tasks. Furthermore, all participants used a daily log to enter the rating of their pain, document the interventions used from the kit, and the number of pain medications they consumed.

Results: There was a significant (P < .05) improvement between baseline to T2 in MPSFS and the MOS Physical Functioning and Energy/Fatigue scale. Also, between baseline to T2, the subjects reported improvement in performing 2 functional tasks and significantly less pain while completing all of the functional tasks. Finally, over the duration of the study, subjects reported significantly less daily pain, fewer days of pain per week, and less pain medication consumed per day.

Conclusion: The use of nonpharmacological interventions provided in the pain relief kit allow chronic neck and low back pain patients to effectively self-manage their pain, improve their ability to perform functional tasks, and reduce their pain medication consumption.

Keywords: Neck pain; low back pain; pain management

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INTRODUCTION

Chronic musculoskeletal pain, defined as pain lasting longer than 12 weeks, is a persistent, debilitating condition that reduces an individual’s functional ability, and commonly presents in the neck and low back. Low back pain (LBP) is the second leading cause of disability in the United States, affecting 17% of the Americans. The estimated lifetime prevalence of LBP is as high as 84%, with the point prevalence of chronic LBP being approximately 23%. More recent studies indicate that LBP causes more years lived with disability than any other health condition. Reports of annual prevalence of chronic NP in the general population worldwide averages between 23.1% to 37.2%.

Treating chronic LBP and NP is a challenge for primary care providers. Until recently, opioid medications were commonly prescribed to treat chronic pain, with the clinical objective of eliminating pain. This widespread use of opioids led to a fourfold increase in the sales of prescription opioid analgesics from 1999 to 2010, and as of 2011–2012, 6.9% of adults reported using a prescription opioid in the last 30 days. This rise in opioid use has been accompanied by a 200% increase in the rate of overdose deaths involving opioids between 2000 and 2014. Other researchers have reported that 1 in 4 people who receive prescription opioids for over 3 months for noncancer pain in primary care settings may struggle with addiction.

This rise in opioid (ab)use to treat chronic pain is inconsistent with the lack of evidence proving the effectiveness of opioids in treating chronic pain and presence of significant evidence for the harmful effects of opioid. The recent expanding and unsubstantiated use of opioids (or what is now referred to as the “opioid crisis”) has resulted in the American College of Physicians recommending nonpharmacological interventions as the first-line treatment for chronic musculoskeletal pain, with opioids being indicated as a last resort only if the benefits of their use outweigh their risks. Currently, the primary goal for managing patients with chronic pain is not the elimination of pain, but the improvement of function to an acceptable level of pain.

Literature indicates that a number of nonpharmacological interventions, including topical menthol, kinesiology tape, thermal therapy, and various forms of exercises, when selected using an individualistic approach, are effective in reducing chronic pain. Menthol is commonly used in topical analgesics and is known to reduce pain in patients with LBP, carpal tunnel syndrome, osteoarthritic knee pain, chemotherapy-induced peripheral neuropathy, and neck pain. A recent systematic review concluded that menthol applied topically provides clinically significant reductions in musculoskeletal pain.

Kinesiology tape (KinTape) is a thin cotton and elastic tape. Early on, KinTape was hypothesized to promote normal muscular function, increase lymphatic and vascular flow, and reduce pain; however, research has only substantiated its pain-relieving effects. Similar to the pain-relieving effects of topical menthol, KinTape has been effectively used to treat musculoskeletal pain, including knee bursitis and chronic LBP. A systematic review and meta-analysis of 17 randomized control trials focusing on chronic musculoskeletal pain reported that KinTape is superior to control conditions in pain management.

Two review articles on thermal therapy concluded that either heat or cold therapy applied to a painful area has limited short-term efficacy to treat a variety of sources of musculoskeletal pain, including LBP. As both these reviews reported low-quality studies that used thermal therapy to treat pain, more empirical studies are needed in this area.

Different types of exercise therapies have been used to treat chronic NP and LBP. An early Cochrane review concluded exercise to be slightly effective at decreasing pain and improving function in adults with chronic LBP. According to a more recent review, moderate-quality evidence suggests that exercise programs can prevent recurrences of back pain, but conflicting evidence was found for exercise being a beneficial treatment for LBP.

Consider these findings, the literature supports nonpharmacological interventions for reducing chronic musculoskeletal pain when prescribed using an individualistic approach, including topical menthol, kinesiology tape, thermal therapy, and various forms of exercise.

Pain is an individualized experience and patients respond differently to different interventions intended to relieve pain. Multiple physiological pathways contribute to both acute and chronic pain, and optimal pain control may involve using multiple therapies that disrupt different pain pathways. These individualized responses to pain management and the multiple physiological pathways where pain sensations can be
interrupted indicate that effective pain management involves trying different interventions until individual pain management can be achieved. Enfranchising the patient into individual management of their pain by offering them several therapeutic options to choose from is reportedly effective in reducing pain. More recently the Clinical Practice Guidelines from the American College of Physicians recommends that patients contribute to identifying effective nonpharmacological intervention to manage their chronic pain. This empirical evidence and clinical recommendation support the purpose of this study.

This 3-week study aimed to determine the effect of a multimodal nonpharmacological “pain relief kit” on pain, functioning, and pain medication consumption of individuals experiencing chronic NP or LBP. This purpose was achieved by addressing the following research question and hypotheses:

**Research Question:** Does providing the multimodal nonpharmacological pain relief kit for 3 weeks affect pain medication consumption in patients with chronic NP and/or LBP?

**Hypothesis 1:** Three weeks after providing the multimodal nonpharmacological pain relief kit to patients with chronic NP and/or LBP, they will report significant reductions in their pain.

**Hypothesis 2:** Three weeks after providing the multimodal nonpharmacological pain relief kit to patients with chronic NP and/or LBP, they will report significant improvements in their functioning.

**METHODS**

A convenience sample of 25 subjects who reported experiencing chronic NP and/or LBP for 4 weeks or more were recruited from an outpatient chiropractic/physical therapy clinic. Patients attending this clinic for treatment of their chronic NP and LBP were provided with a recruitment flier that instructed them to contact a member of the research team, if interested. Following phone screening for inclusion and exclusion criteria, eligible individuals were invited to attend a baseline data collection visit at the outpatient clinic. During this baseline visit, subjects provided their informed consent for study participation (IRB#: SSR.2016.9) and then completed baseline data collection. Next, all participants received the Safer Pain Relief kit (Performance Health; Akron, Ohio), the instructions on how to use the kit, and how to complete a daily diary for the next 3 weeks. The kit included samples of nonpharmacological pain relief products and information on how to manage their pain. Participants were also instructed to continue to follow their physician’s instructions for the management of their pain over the duration of the study. Subjects completed the data collection protocol again at 1 and 3 weeks following baseline data collection (T1 and T2, respectively). In addition, all participants provided a daily numerical rating of their pain, number of pain medications consumed, and documentation of pain management interventions they used from the kit. This resulted in a one group repeated measures design in which subjects were provided with a pain relief kit for 3 weeks, and data were collected at baseline and at 1 and 3 weeks following baseline data collection.

**Sample**

In response to recruitment efforts, potential participants contacted a member of the research staff, who discussed the study and screened for inclusion/exclusion criteria. Subjects were included in the study if they were over age 18 and experienced average daily musculoskeletal pain of moderate intensity (≥3/10) in the neck or low back for more than 4 weeks. Individuals were excluded from the study if they reported any contraindication for medical clearance before engaging in moderate intensity exercise or if they had any other health limitations restricting them from moderate exercise. Additional exclusion criteria were inability to complete any of the data collection protocols, previous diagnosis of schizophrenia or dementia, inability to provide informed consent, and a previous allergic reaction to adhesive tape or menthol.

**Data Collection**

All participants completed a data collection protocol at the 3 data collection points (baseline, T1, and T2). Demographic information (age, gender, acceptable level of pain, and if they engage in regular exercise) was collected from all participants at baseline only, as this information was not expected to change over the duration of the study. The other information collected at all 3 data collection points included reporting of their pain, and functioning and performance of the four functional tasks by using paper and pencil instruments. In addition, all subjects completed a daily pain and treatment diary over the 3-week study duration and were reimbursed $25 at T2 for completing every line on the diary. This approach resulted in over 95% of the diary entries being completed.

The paper and pencil instruments used were the Modified Patient Specific Functional Scale (MPSFS) and the Medical Outcomes Survey (MOS-36). The MPSFS measured the subject’s self-reported functional limitations. At baseline, this instrument asked the subject to identify 3 important activities that they had difficulty in performing because of their chronic LBP and/or NP and to rate the severity of their reduced functioning while performing that activity. At T1 and T2, the subjects were asked to rate the severity of their reduced functioning while performing these same activities. Subjects rated the difficulty in performing each task on an 11-point scale (0 indicating being unable
to perform the activity and 10 indicating being able to perform the activity with no difficulty at all). An average functional limitation score was calculated as the sum of the reduced functioning scores divided by 3; lower scores indicated a greater degree of self-reported functional limitations. The concurrent validity, sensitivity to change over time, and reliability of the MPSFS was deemed adequate for use as a tool in clinical practice.35

The MOS-36 includes 36 multiple choice items that assess 8 health concepts: physical functioning, bodily pain, role limitations due to physical health problems, role limitations due to personal or emotional problems, emotional well-being, social functioning, energy/fatigue, and general health perceptions.36 The recipient needs 5 min to complete this instrument, which has established acceptable psychometric properties.37

The subjects’ level of functioning was measured as their ability to complete the four functional tasks, namely, ascend and then descend a stairway, sit-to-stand, and raise a 10-lb weight from the floor. Following a demonstration of the functional tasks by a researcher, a single trial of each of the functional tasks was completed to minimize subject fatigue and pain. The ordering of the functional tasks was consistent across all data collection points.

The stairway task was measured as time in seconds the subject took to ascend and then descend a flight of 10 steps with a 7-in. riser. The starting position for this functional task was the subject standing facing the stairway, no further than 12 in. from the first step, with hands at the side. Subjects were told to climb 10 steps and stop. After a 30-s rest, subjects were asked to descend the 10 steps and halt at the starting position. The end of the test was when both of the subject’s feet reached the top (when ascending) or the bottom (when descending) of the 10 steps. The trial was measured to the nearest 100th of a second using a stopwatch. Lower values on these assessments indicated a greater level of functioning. We have found this assessment to be sensitive to exercise interventions with patients with knee osteoarthritis in our preliminary studies.38–41

The sit-to-stand assessment determined the subject’s capacity to repeatedly arise from a chair over a 30-s period. Subjects began this assessment by being seated in a chair without armrests. Subjects were told to assume an upright standing position followed by a seated position as many times as possible within 30 s. The time counter was started on the subject’s first movement and ended 30-s later. The number of complete sit-to-stand and stand-to-sit movements (up from and down to the chair) was recorded as the subject’s score, with a higher score indicating a greater level of functioning. This assessment has demonstrated high validity by being correlated with a 1RM leg press and strong test-retest reliability \( r = .89 \).42,43

The functional assessment of raising a 10-lb weight from the floor to a mark on the wall 5 feet above the ground, which involved bending and straightening of the back, assessed the subject’s capacity to coordinate the strength in their upper and lower body. Each subject was instructed to raise a standard 10-lb kettlebell from the floor to a position above the 5-foot mark on the wall. Subjects began the assessment standing upright with the kettlebell between their feet on the ground. The researcher instructed the subject to move the kettlebell from the floor so that the bottom of the weight was above the mark as “quickly and safely” as possible and then place it back on the ground. The test began on the subject’s first movement and ended when the weight was placed at the 5-foot mark. The duration of time to complete this activity was measured by the research assistant to the closest 100th of a second.

Back and neck pain while performing functional tasks were also measured immediately following completion of each of the four functional tasks. Subjects were asked to place a mark on a 10-cm visual analog scale (VAS) indicating the severity of their back and neck pain while performing each of the functional tasks assessments. The VAS was anchored at the terminal points of the scale by the terms “No Pain” and “Extreme Pain.” The distance (mm) between the subject’s mark indicating their pain and the “No Pain” anchor was considered their pain score while performing the specific functional task, with higher scores indicating a greater degree of pain. The VAS has been demonstrated to correlate well44 with physician assessments of pain \( r = .70 \) and to have high test-retest reliability \( r = .97 \).45

The brief daily pain and treatment diary required the subject to document the average level of pain they experienced during the previous day by providing a numerical rating of their pain, with 0 indicating “No Pain” and 10 indicating “Extreme Pain.” In their diary, subjects also recorded daily the number of pain medications they consumed during the previous 24 h. No attempt was made to identify the type of pain medication the subjects consumed and no subject’s prescriptions for pain medications changed during the study period. Subjects were asked to simply record the number of “pain pills” they consumed in the previous 24 h. The subject’s daily pain rating and number of pain medications were averaged over each week of the 3-week trial. Finally, the subjects were also asked to record on the daily diary whether or not they used any of the four modes of nonpharmacological interventions included in the pain relief kit during the previous 24 h.

**Intervention**

Immediately following baseline data collection, a research staff provided, to all participants, the pain
1. Exercise Training: (Strengthening, flexibility, cardiovascular) TheraBand CLX exercises for neck and/or low back pain up to (either given by provider or general recommendation)
2. Biofreeze (applied with roll on applicator): Apply during your morning hygiene routine and as needed throughout the day in response to pain. Apply 5 minutes prior to and/or following engaging in resistance training exercises or any other moderate intensity activity.
3. Kinesiology Tape: Apply to the affected area at 25% elongation and reapply every 3 days or as needed when 20% of the tape fails to adhere.
4. Thermal Therapy (Warmed or cool TheraPearl, or other ice/heat pack): Apply during your morning hygiene routine and as needed throughout the day in response to pain. In general, Apply heat 30 minutes prior to and cold following engaging in resistance training exercises or any other moderate intensity activity.

Figure 1. Recommended use of the 4 of nonpharmacological interventions in the pain relief kit.

RESULTS

Descriptive statistics revealed that of the 25 subjects completing the trial, 18 (72%) reported LBP, 4 (16%) reported NP, and 3 (12%) reported a combination of LBP and NP. The sample comprised 15 women (60%) and 10 men (40%). The average age of the sample was 39.48 ± 13.08 years; the average duration of LBP or neck pain was 19.28 ± 33.59 months, and the sample’s average level of acceptable pain was 3.73 ± 1.77.

Table 1 presents the mean and standard error for each of the outcome variables measured at the 3 data collection points, and the results of the RM-ANOVA statistic that addressed the hypotheses. The analysis presented in Table 1 indicates that the sample significantly increased their functioning as evidenced by the scores on the MPSFS and the MOS-36 measures of Physical Functioning and Energy/Fatigue, which were significantly higher at T2 than at baseline and T1. None of the remaining six health concepts assessed by the MOS-36 changed throughout the study. Similarly, the sample improved their performance on the sit-to-stand and 10-lb weight tasks between baseline and T1 and maintained these improvements over baseline at T2. The sample did not change their time to ascend or descend a flight of 10 steps. Pain while performing each of the four functional tasks significantly decreased between baseline and the end of the 3-week protocol (T2).

Table 1 also presents the weekly average of the daily pain rating and daily pain medication consumption documented by the subjects in their daily pain and treatment diary. RM-ANOVA of these weekly averages indicated that the average daily numerical rating of pain significantly declined from 4.50 ± .29 at baseline to 3.50 ± .34 at T1 and declined significantly again between T1 and T2 to 2.81 ± .43. The number of days per week that the subjects reported being in pain declined from 6.56 ± .24 during the first week of the study to 5.76 ± .40 during the second week, and decreased again to 4.92 ± .55 during the third week of the study. Finally, the average number of pain medications consumed per day during Week 1 (1.04 ± .39)
was significantly higher and almost double the average number of pain medications consumed per day by the sample during Week 3 (.56 ± .32) of the study.

**DISCUSSION**

The study results support the two study hypotheses and answer the research question. The results indicate that providing chronic NP and/or LBP patients with the multimodal, nonpharmacological pain relief kit may result in substantial reductions in their pain. Additionally, the pain relief kit may improve their self-reported and objective measures of function, as well as a decrease in the number of pain medications they consume.

These findings are consistent with those of previous investigators who reported that components of the pain relief kit including topical menthol, KinTape, thermal therapy, and exercise when used in an individualistic

| Table 1. Outcomes over time |
|----------------------------|
| **Outcome**                 | Baseline Mean* ± SE | 1 week (T1) Mean* ± SE | 3 weeks (T2) Mean* ± SE | F-value, P < |
|-----------------------------|---------------------|------------------------|------------------------|-------------|
| Modified Patient Specific Functional Scale | 4.84 ± .42 | 4.94 ± .52 | 6.82 ± .56 | 10.67, .00 |
| Medical Outcomes Survey (MOS), Physical Functioning | 70.40 ± 4.1 | 73.20 ± 3.50 | 79.80 ± 4.04 | 6.26, .02 |
| MOS, Role Limitations due to Physical Problems | 40 ± 8.42 | 35.00 ± 7.63 | 47.33 ± 7.37 | .64, .43 |
| MOS, Role Limitations due to Emotional Problems | 78.67 ± 7.67 | 74.67 ± 8.00 | 72.13 ± 8.27 | .89, .90 |
| MOS, Energy/Fatigue | 50.00 ± 4.50 | 51.00 ± 4.56 | 56.40 ± 4.50 | 6.69, .01 |
| MOS, Emotional Wellbeing | 78.24 ± 3.20 | 78.36 ± 3.24 | 75.76 ± 4.57 | .36, .56 |
| MOS, Social Functioning | 81.00 ± 4.84 | 80.00 ± 4.02 | 80.50 ± 3.90 | .02, .90 |
| MOS, Pain | 50.2 ± 4.78 | 50.80 ± 4.03 | 59.60 ± 3.74 | 2.87, .10 |
| MOS, General Health | 70.20 ± 3.10 | 70.40 ± 3.46 | 70.40 ± 3.60 | .02, .90 |
| Time to Ascend 10 Steps | 5:18 ± .37 | 5:12 ± .37 | 4:54 ± .31 | 1.44, .24 |
| Time to Descend 10 Steps | 5:20 ± .44 | 4:54 ± .46 | 4:37 ± .34 | 3.30, .08 |
| Sit-to-stand repetitions in 30 s | 9.90 ± .62 | 12.32 ± .72 | 13.00 ± .89 | 16.02, .00 |
| Time to lift a 10-lb weight | 3:31 ± .40 | 2:36 ± .26 | 2:43 ± .34 | 11.26, .00 |
| Pain while ascending Stairway | 1.88 ± .38 | 1.28 ± .31 | .82 ± .12 | 8.01, .01 |
| Pain while descending Stairway | 1.88 ± .40 | 1.32 ± .33 | .76 ± .13 | 8.12, .01 |
| Pain during sit-to-stand | 2.12 ± .40 | 1.70 ± .29 | .96 ± .16 | 8.13, .01 |
| Pain while lifting a 10-lb weight | 2.04 ± .43 | 1.80 ± .40 | .76 ± .12 | 9.02, .02 |
| Average daily rating of pain | 4.50 ± .29 | 3.50 ± .34 | 2.81 ± .43 | 19.67, .00 |
| Average number of days in pain | 6.56 ± .24 | 5.76 ± .40 | 4.92 ± .55 | 8.67, .00 |
| Average pain medication per day | 1.04 ± .39 | .80 ± .35 | .56 ± .32 | 4.04, .02 |

* Means with different shading indicate the means are significantly different (P < .05).
manner resulted in less pain and improved functioning. A limitation of these previous studies was that they only examined a single nonpharmacological pain-relieving intervention at a time. Furthermore, the pain intervention protocol in each of these previous studies was prescribed by the research protocol, did not include the subject’s individual preferences, and did not allow the subject to contribute to identifying effective nonpharmacological intervention(s) to manage their pain as is recommended by the American College of Physicians.12 Table 2 indicates the average use of each of the components of the pain relief kit, with the subjects utilizing components of the kit an average of 19.48 ± 6.96 times during the 3-week trial. Thermal therapy was used on average the least (.92 ± 2.72) followed by menthol (1.68 ± 2.29) and KinTape (2.08 ± 3.15), and exercise was the most used component of the kit, with an average use of 14.80 ± 4.75 times per subject over the study duration. Although exercise was the most used component of the kit, subjects used other components of the kit, on average, five additional times per week to manage their pain over the study duration. It appears that subjects in this trial tried different components of the kit to manage their pain and that this practice resulted in substantial reduction in their pain and improvement in their function. In fact, subjects in this trial achieved a level of pain at T3 that was well below the acceptable level of pain that they had reported at baseline. These reductions in pain and improvements in function occurred while the number of pain medications they consumed decreased from an average of 1.04 to .56 pain pills per day over the 3-week trial. This is one of the first trials to indicate the efficacy of a nonpharmacological intervention to reduce pain medication consumption.

Limitations

Although encouraging, the results of this study must be interpreted with caution, as the study design is susceptible to a number of threats to validity. First, this study did not include a control group and the favorable results may be attributable to the natural progression of chronic pain conditions: 90% of these conditions resolve without any treatment after 3 months.48 This possible threat is likely minimal as subjects reported chronic pain for an average of 19.28 ± 33.59 months before enrolling in the study. A second potential threat is the heterogeneity of the small sample in the study. The sample for this study included a variety of chronic pain conditions that may have responded differently to the nonpharmacological components of the pain relief kit. The small sample did not allow a detailed analysis into which component was and was not effective for a specific chronic pain condition. Finally, no attempt was made to document the specific type of pain medication (pain pills) the subjects were consuming to manage their pain, e.g. narcotics, nonsteroidal antiinflammatory drugs, or over-the-counter analgesics. Nonetheless, over the 3-week study duration, the sample claimed to have no changes in their pain medication prescriptions. Future studies may wish to address these limitations through studying a larger, more homogenous group of patients with chronic pain and more closely document their use of components of the pain relief kit and the type and number of pain medications they consume.

CONCLUSION

Chronic neck and back pain are frequent and persistent health problems. As the treatment recommendations for these conditions move away from narcotics, practitioners need safer alternatives to medications to manage chronic musculoskeletal pain. The pain relief kit examined in this study, which includes four nonpharmacological interventions, may be used to reduce pain, increase functioning, and decrease the use of pain medications.

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