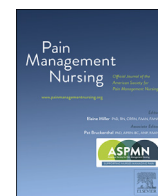




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Original Article

The effect of Therapeutic Touch on Back Pain in Adults on a Neurological Unit: An Experimental Pilot Study

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ABSTRACT

Background: Chronic back pain affects many aspects of everyday life and is a common reason for medical visits, leading to high direct and indirect health care costs. Innovative and cost-effective non-pharmacologic pain management methods should be promoted to ensure adequate treatment.

Aims: The aim of this pilot study was to investigate the pain-relieving effect of Therapeutic Touch in adult neurologic patients with back pain.

Design: A pretest–post-test randomized controlled trial.

Settings: A university hospital in Austria.

Participants/Subjects: Patients with back pain diagnosis (N = 29) on hospital admission.

Methods: A pilot study was conducted for 3 months. The control group (n = 14) received the pharmacologic pain management recommended by the World Health Organization; patients in the intervention group (n = 15) received additionally four Therapeutic Touch treatments on 4 consecutive days. The Quebec Back Pain Disability Scale and the Numeric Pain Rating Scale were used as outcome measures to evaluate activity domains affected by back pain and pain intensity.

Results: Pain improvement was found in the intervention group according to the mean score of the Quebec Back Pain Disability Scale (day 1: 72.53, standard deviation [SD] ± 14.10; day 4: 39.47, SD ± 8.77; $p < .001$). The Numerical Pain Rating Scale score averaged 4.33 points (SD ± 2.09) on the first day and 2.47 points (SD ± 1.12) on the fourth day. The long-term effect of Therapeutic Touch was significant and indicated a major effect (Pillai's trace = .641, $F_{(3,12)} = 7.1$, $p = .005$, $\eta_p^2 = .641$).

Conclusions: Therapeutic Touch seems to be a noninvasive nursing intervention for back pain management to provide more professional patient care.

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Chronic back pain is the most common and expensive health problem of the 21st century (Smith, Arnstein, Rosa, & Wells-Federman, 2002) and is defined as pain lasting longer than 3 months (Airaksinen et al., 2006). It therefore affects many aspects of everyday life (Hoy et al., 2014). In Austria, 1 in 10 teenagers or young adults and 1 in 3 people aged 60–74 has suffered from back pain in the last 12 months (Statistik Austria, 2015). Lower back pain ranked sixth among 291 medical conditions; the global prevalence was 9.4% (95% confidence interval [CI] 9.0–9.8), which increased

with old age (Hoy et al., 2014). From 2000 to 2012, 74.7% of U.S. citizens (N = 6,575,999) had a back pain diagnosis. Other pain diagnoses were degenerative spine disease (63.6%) and post-laminectomy syndrome (14.8%) (Murphy et al., 2017).

Approximately 10% of the entire U.S. population is not able to work or perform activities of daily life independently because of the severity of their pain (Murphy et al., 2017). Psychological conditions, such as anxiety or depressive disorders, are also known to support the development of chronic back pain (Lin & Taylor, 1998). Even past traumatic experiences or current problems in relationships and in the workplace may be the reason for complaints (Airaksinen et al., 2006). In addition, pain intensity is related to other symptoms such as fatigue, exhaustion, and loss of appetite (Aghabati, Mohammadi, & Pour Esmaiel, 2010), which stimulates the sympathetic nervous system, leading to an increased heart rate

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and blood pressure and hyperfunction of the endocrine system (Edwards et al., 2007). Furthermore, back pain is a common reason for medical visits, leading to high direct and indirect health care costs of approximately \$635 billion for treating pain disorders in the United States alone (Murphy et al., 2017).

The growing burden of back pain warrants the need for innovative and cost-effective nonpharmacologic methods to help affected persons (Smith et al., 2002). These nonpharmacologic methods or complementary and alternative medicine (CAM) modalities exist in form of energy field therapies such as Therapeutic Touch, although the exact mechanism of action is still unclear (Midilli & Eser, 2015).

Background

The use of CAM modalities has increased in U.S. hospitals over the last 10 years because 85% of the responding facilities indicated a patient demand for these services (American Hospital Association, 2011). Kanodia, Legedza, Davis, Eisenberg, and Phillips (2010) evaluated the perceived helpfulness of 17 CAM modalities for back pain in the 2002 National Health Interview Survey: acupuncture, ayurveda, biofeedback, chelation, chiropractic, energy healing/reiki, folk medicine, homeopathy, hypnosis, massage, naturopathy, natural herbs, prayer, relaxation techniques, special diets, vitamins, and yoga/tai chi/qi gong. The top six CAM modalities reported by 60% of the survey participants ($n = 31,044$) were chiropractic, massage, herbal therapies, relaxation techniques, yoga/tai chi/qi gong, and acupuncture. No results concerning energy healing/reiki were published by the authors.

The CAM modality of Therapeutic Touch was developed as a nursing intervention of laying on of hands by Krieger (1975), with the intention to help or even heal the client by balancing the energy field (Keller & Bzdek, 1986; Krieger, 1975). Therapeutic Touch aims to harmonize, replenish, and improve the flow of the human energy field (Kunz, 2004) by removing blockages of a person's biofield (Hart, Freel, Haylock, & Lutgendorf, 2011). Hereby the healing energy of the life force Qi is directed through the practicing nurse's hands to promote healing and well-being of the patient (Anderson et al., 2016). The Therapeutic Touch treatment begins with centering, in which the nurse focuses consciously on the client with the sincere intention of wanting to help while at the same time activating mental and physical relaxation and establishing a state of expanded awareness. This is followed by the assessment of the current state of the client's energy field. The nurse guides his or her hands a few inches above the client's body from head to toe tips. During the treatment of imbalances, the flow of energy is directed and harmonized by calm and rhythmic hand movements, which supports the energetic balance. Next the energy field of the client is reassessed, and the treatment is repeated if needed. Finally an evaluation of the change in the energy field is carried out, and the client should rest (Therapeutic Touch International Association, 2014). If Qi is allowed to flow evenly and without blockages through the body's channels, a person feels emotionally and physically balanced (Kunz, 2004) and the pain experience can be positively supported (Anderson et al., 2016).

Some nurses feel inept, frustrated, and unsatisfied if they cannot manage chronic pain effectively (Matthias et al., 2010). Yet adequate pain management is of utmost important to elevate pain symptoms and support patients (Martin et al., 2016). Thus Therapeutic Touch is a patient-centered and mindful approach that fosters the nurse-patient relationship (Anderson et al., 2016). Keller and Bzdek (1986) investigated the pain-reducing effect of Therapeutic Touch in 60 participants with tension headache pain. Therapeutic Touch was compared with a placebo stimulation version of Therapeutic Touch, and a significant reduction in tension headache pain levels

was found from pretest to post-test in the intervention group ($n = 30, 90\%, p < .0001$). A study with 90 elderly residents from seven different facilities reported the effect of Therapeutic Touch in relieving chronic musculoskeletal pain. Pain intensity was measured with the numeric rating scale before and after the Therapeutic Touch treatment, and the mean difference was 5.93 (standard deviation [SD] ± 2.63) compared with the mimic Therapeutic Touch group ($1.83, SD \pm 2.55$) with a significant major effect size of .92 ($p < .001$) (Lin & Taylor, 1998). Another randomized controlled study (McCormack, 2009) investigated the effect of Therapeutic Touch in 90 elderly postoperative participants receiving occupational therapy after total knee or hip replacement. The intervention group ($n = 30$) had significant pain reduction after receiving a 10-minute Therapeutic Touch treatment. The mean (M) pain intensity scores decreased from 44.57 to 30.97 ($t_{(7)} = 7.24, p < .01$) compared with a control group receiving no treatment ($M = 45.23-45.30$) and a placebo group listening to the beat of a metronome for 10 minutes ($M = 22.70-25.23$) (McCormack, 2009). These results were also observed in a study with 21 post-vascular surgery patients (Coakley & Duffy, 2010). The effect of Therapeutic Touch ($n = 12$) was compared with a control group ($n = 9$) receiving standard care. Therapeutic Touch reduced postoperative pain levels ($F = 8.6, p < .0001, \eta_p^2 = .997$) and cortisol levels ($F = 10.0, p < .0001, \eta_p^2 = .999$) significantly in the intervention group (Coakley & Duffy, 2010). Therapeutic Touch also had significant pain relief in patients with cancer according to visual analog scale scores for the pre- and postintervention test for 5 days ($n = 90, F_{(8)} = 2.01, p = .04$). A significant reduction in fatigue was also identified ($F_{(8)} = 3.18, p = .002$) (Aghabati et al., 2010). The effects of Therapeutic Touch on pain was summarized in a published literature review (Monroe, 2009) and in a review of different energy field therapies including Therapeutic Touch (Fazzino, Griffin, McNulty, & Fitzpatrick, 2010). The authors concluded that Therapeutic Touch is a useful nursing intervention for pain management. Additional effects of Therapeutic Touch include reduction of anxiety (Krieger, 1975; Lin & Taylor, 1998) and supporting the overall healing processes (Krieger, 1975). Yet the effect of Therapeutic Touch on back pain has not been studied to date, and there are no published studies conducted in Austria evaluating the effect of Therapeutic Touch on back pain.

Study Aim

The primary aim of this study was to evaluate the effect of Therapeutic Touch on activity domains affected by back pain after 4 days of treatment. The secondary aim was to identify the direct pretest and post-test effect of Therapeutic Touch on reducing back pain in adult neurologic patients over a 4-day treatment period.

Methods

Study Design and Ethical Considerations

This was an experimental pilot study conducted with a pretest–post-test randomized controlled design. The study protocol was approved by the Ethics Committee of the Medical University Graz, Styria, Austria (EC-Number 26-271ex13/14). Before enrollment the patients received an information letter containing the voluntary nature of participation and a guarantee of anonymity. Patients signed the informed consent before voluntary participating in the study.

Setting and Participants

This study was undertaken at the University Hospital Graz in Styria, Austria, between February and May 2014. Included were

neurologic patients with an admission diagnosis of back pain on hospitalization. Excluded were patients younger than age 18, patients with perception problems, patients incapable of judgment and unable to give informed consent, and pregnant patients.

Sample Size

The sample size was determined with power analysis by a biostatistician based on the study results of Lin and Taylor (1998). The determination of the expected difference (Δ) was based on a previous study (Lin & Taylor, 1998). Based on 5% error, 95% power, and $\Delta = 3$ points, the sample size required 30 patients per group with a dropout rate of 10%. It was assumed that pain relief as a result of non-medical interventions with differences in the range of half a standard deviation ($\Delta = 3$) was considered a minimal clinically relevant result.

Randomization

Patients were allocated into control and intervention groups after simple randomization. Patients with the admission diagnosis back pain on hospitalization were informed of the study. After providing verbal and written informed consent, the patient chose between two sealed envelopes containing assignment to the intervention or the control group. Figure 1 presents the allocation process in a flow chart.

Outcome Measures

The German Quebec Back Pain Disability Scale (QBPDS) (Riecke, Holzapfel, Rief, Lachnit, & Glombiewski, 2016) evaluates functional limitations when performing different activities and is recommended as an outcome measure to evaluate the treatment effect (Kopec et al., 1995). This recommendation led us to use the QBPDS to measure the primary outcome. The QBPDS contains 20 basic daily activities and identifies a broad spectrum of a patient's back pain experience for various activities. Each of the 20 activities can

be rated from 0 to 5 (0 = not difficult at all; 1 = minimal difficult; 2 = somewhat difficult; 3 = fairly difficult; 4 = very difficult; 5 = unable to do) with a maximum of 100 points. The higher the score, the more physical limitations a person has (Kopec et al., 1995). The German QBPDS was tested with an online sample ($n = 105$) and inpatient participants ($n = 75$). The QBPDS had high internal consistency for the full scale ($\alpha = .94$) and for the individual four items: $.76 \leq \alpha \leq .90$. The factor analysis for a four-factor solution explained 57.43% of the total variance. The convergent validity was established with the Pain Disability Index ($r = .78$), the Roland-Morris Disability Questionnaire ($r = .54$), and pain intensity ($r = .46$) (Riecke et al., 2016).

The 11-point numeric pain rating scale (NPRS) (Childs, Piva, & Fritz, 2005) measures the intensity and extent of back pain (0 = no pain; 10 = worst pain ever) and was the secondary outcome. The scale has been reported to have concurrent and predictive validity in measuring pain intensity in adults (Jensen, Turner, Romano, & Fisher, 1999). The responsiveness of the NPRS to detect change of pain intensity in patients was also established (Childs et al., 2005).

Data Collection

Demographic information of the patients (age and sex) was obtained from medical records. On the first day after admission, all participating patients filled out the QBPDS questionnaire and were asked their NPRS pain score. These data were used as baseline measurement (t_0) for the intervention and control group. For pain control, all participating patients received conservative therapy according to the World Health Organization three-step pain relief ladder as needed (World Health Organization, 1996). The intervention group received four additional Therapeutic Touch treatments; the control group only received pharmacologic pain management. The four Therapeutic Touch treatments took place in the patient's room on 4 consecutive days, preferably at the same time between 1 p.m. and 3 p.m. Furthermore, patients in the intervention group

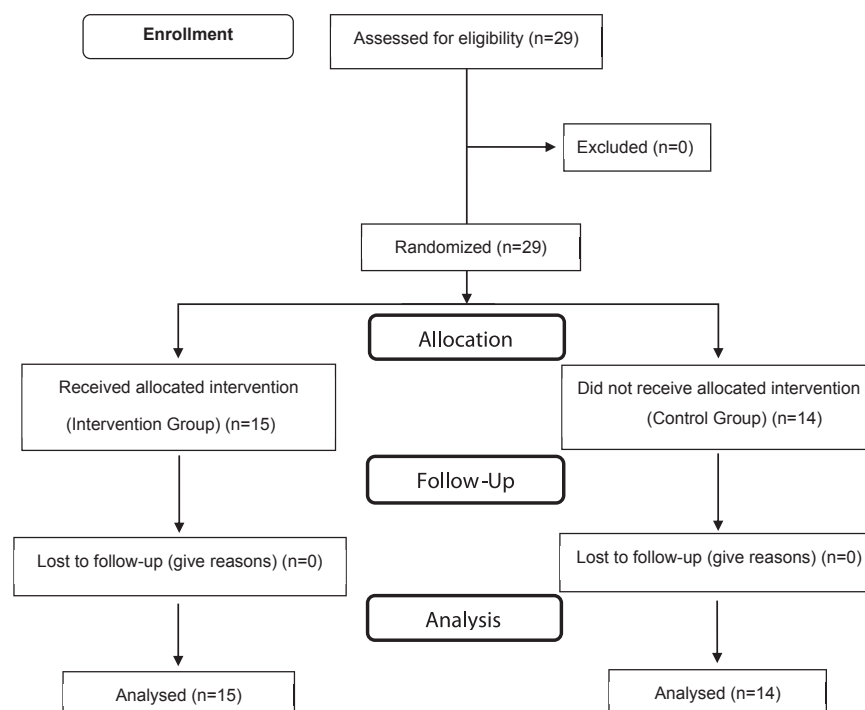


Figure 1. Flow diagram of participant enrollment (CONSORT 2010).

were asked their NPRS pain score before and after each treatment. The same measurements (QBPDS and NPRS) were repeated after 4 days (t1) (Fig. 2) in the intervention and control group. For pain control, all participating patients received conservative therapy according to the World Health Organization three-step pain relief ladder as needed (World Health Organization, 1996).

Intervention

Nine nurses from the neurologic unit with Therapeutic Touch basic training (60 lessons over 6 days) (Therapeutic Touch ooe, 2018) applied the Therapeutic Touch intervention. The treatment steps were standardized and took about 20 to 30 minutes to complete. The nurse used her hands to assess and rebalance the patient's entire energy field according to the following steps: (1) centering by consciously focusing on the patient and thereby activating a state of extended perception; (2) assessing the energy field by keeping the hands at a 5- to 10-cm distance from the patient's body to explore for energy deficits or increases and negative energy; (3) treatment of affected areas by modulating, balancing, and directing the energy in its flow and symmetry, treating the person holistically with the aim of promoting free energy flow; and (4) evaluation of the energy field and completion of the treatment (Therapeutic Touch ooe, 2018).

Outcomes

The study's primary endpoint was to present a change of the QBPDS score between the baseline measurement (t0) and the measurement after 4 days treatment (t1) compared with the control group. The secondary endpoint was to identify the direct pre-test and post-test effect of Therapeutic Touch by a change of the NPRS score over a 4-day period in the intervention group.

Statistical Analysis

Statistical analysis was carried out with the statistic program SPSS (Version 21; IBM Corp., Armonk, NY, USA). Absolute and

relative frequencies and central tendencies and statistical dispersions were disclosed according to the level of measurement. The Shapiro-Wilk test was used to test for normal distribution and the χ^2 test was used to test for homogeneity of the population sample. Repeated-measure analysis of variance (ANOVA) was used to calculate the effect of the Therapeutic Touch treatment versus no intervention and to compare the mean total score of the QBPDS and NPRS. The t test was used to compare the baseline measurement between the control and intervention group. The significance level was set at $p < .05$.

Results

Overall 12 female patients (41%) and 17 male patients (59%) ($N = 29$) were included in the study. The patients mean age was 59.31 years ($SD \pm 11.7$). Fourteen patients were randomly assigned to the control group (CG), and the mean age was 60.86 years ($SD \pm 10.43$). The remaining 15 patients were assigned to the intervention group (IG) and the mean age was 57.87 years ($SD \pm 12.97$). Patient characteristics (age and sex) were homogeneous in both groups ($\chi^2_{(20)} = 24.28, p = .23$).

Effect of Therapeutic Touch on Back Pain

Baseline measurement with the QBPDS indicated a mean total score of 72.53 ($SD \pm 14.10$, 95% CI 64.72–80.33, range = 47–91) in the intervention group. The control group had a mean total score of 64.36 points ($SD \pm 18.5$, 95% CI 53.68–75.04, range = 21–87). The difference in the mean baseline measurement was not significant between the intervention and control group ($t_{(27)} = 1.35, p = .19$). After 4 days, the end measurement with the QBPDS had a mean total score of 39.47 ($SD \pm 8.77$, 95% CI 34.61–44.33, range = 24–56) in the intervention group. The control group averaged 61.5 points ($SD \pm 16.42$, 95% CI 52.02–70.98, range = 25–82).

The covariance comparability required for calculating and interpreting the ANOVA was given by the Box M test ($p = .196$).

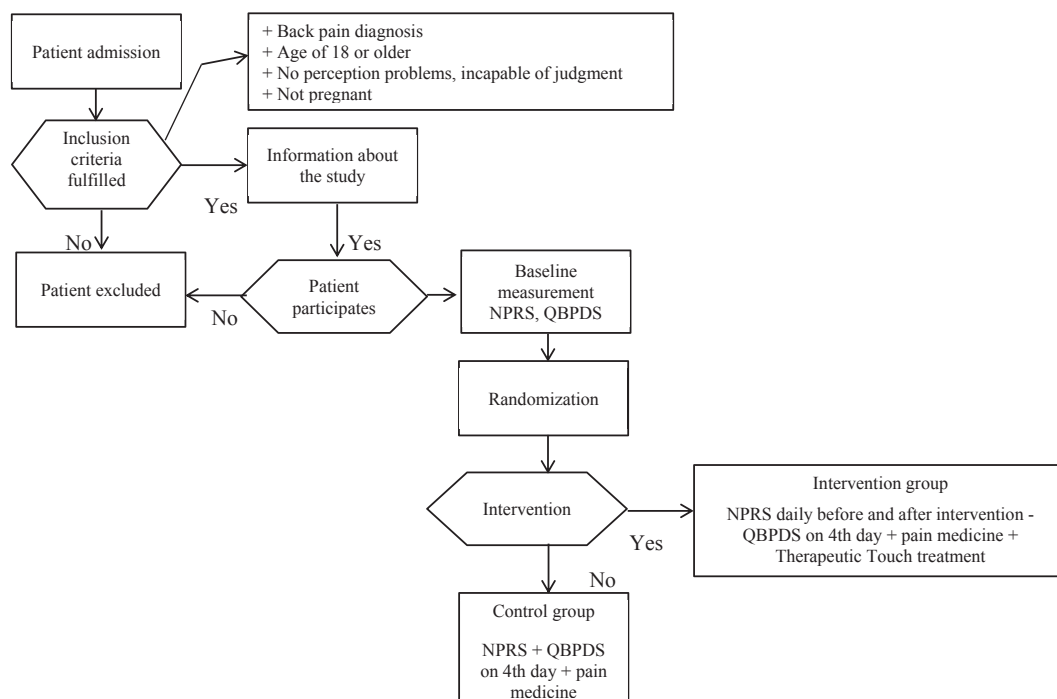


Figure 2. Study procedure.

The multivariate ANOVA tests indicated a highly significant major effect by the total score change of the QBPDS, which explained 67% of the variance (Pillai's trace = .674; $F_{(1,27)} = 55.72$, $p < .001$, $\eta_p^2 = .674$). The QBPDS baseline and end measurement was completed in each group at the beginning and end of the study. The analysis indicated that the improvement of the pain situation was more pronounced in the intervention group compared with the control group (Pillai's trace = .593, $F_{(1,27)} = 39.40$, $p < .001$, $\eta_p^2 = .593$), which explained 59% of the variance. The Therapeutic Touch intervention resulted in lower scores on the QBPDS, which indicated an improvement of the experienced back pain (Fig. 3).

Effect of Therapeutic Touch in Relieving Back Pain

Table 1 outlines the NPRS baseline measurement before the Therapeutic Touch treatment. The difference in the mean baseline measurement was not significant between the intervention and control group ($t_{(27)} = .197$, $p = .85$).

A reduction of the NPRS mean score can be identified in the intervention group from the first to the fourth day. The pain score before the treatment averaged 4.33 points (SD $\pm$ 2.09) on the first day, 3.6 points (SD $\pm$.98) on the second day, 2.73 points (SD $\pm$.79) on the third day, and 2.47 points (SD $\pm$ 1.12) on the fourth day. The long-term effect of Therapeutic Touch was highly significant and indicated a major effect (Pillai's trace = .641, $F_{(3,12)} = 7.1$, $p = .005$, $\eta_p^2 = .641$). Over time, the NPRS values were reduced before treatment (Fig. 4).

The direct before and after effect of Therapeutic Touch was highly significant and indicated a major effect on all 4 treatment days ($\eta_p^2 = 2.19$ to 3.40) (Table 2).

The difference of the NPRS between the endpoints of the intervention and control group indicated a highly significant result ($t_{(27)} = 6.28$, $p < .001$) and major effect ($d = 2.33$).

Table 1
Numeric Pain Rating Scale Baseline Measurement before Treatment

NPRS	Intervention Group	Control Group
Mean	4.33	4.21
Median	4	4
SD	2.10	.89
Maximum	8	6
Minimum	0	3
95% CI	3.17; 5.49	3.70; 4.73

NPRS = Numeric Pain Rating Scale; SD = standard deviation; CI = confidence interval.

Discussion

Back pain can have a variety of causes (Airaksinen et al., 2006) and may persist for a long time, usually more than 3 months. Most of the time, pain is managed with pharmacologic interventions, but those interventions may cause adverse effects (Decker, Wardell, & Cron, 2012). The nonpharmacologic intervention Therapeutic Touch may offer back pain patients an alternative method and gives support not only on a physical level but also may positively influence psychological factors that contribute to the development and chronification of back pain (Aghabati et al., 2010; Kunz, 2004). The present pilot study found the beneficial effect of Therapeutic Touch in reducing back pain in neurologic patients over a 4-day period. No other study was identified that evaluated the effect of Therapeutic Touch on back pain. A similar study by Decker et al. (2012) evaluated Healing Touch, a similar energy healing modality, in non-community-dwelling older adults ($N = 20$) with persistent pain. The study reported statistically nonsignificant improvements in pain and activities of daily living. However, the quality of life decreased in the intervention group receiving Healing Touch treatment (Decker et al., 2012). Those statistically nonsignificant results are not in agreement with present study's results, which present a reduction of the QBPDS score from 72.53 (SD $\pm$ 14.10) to

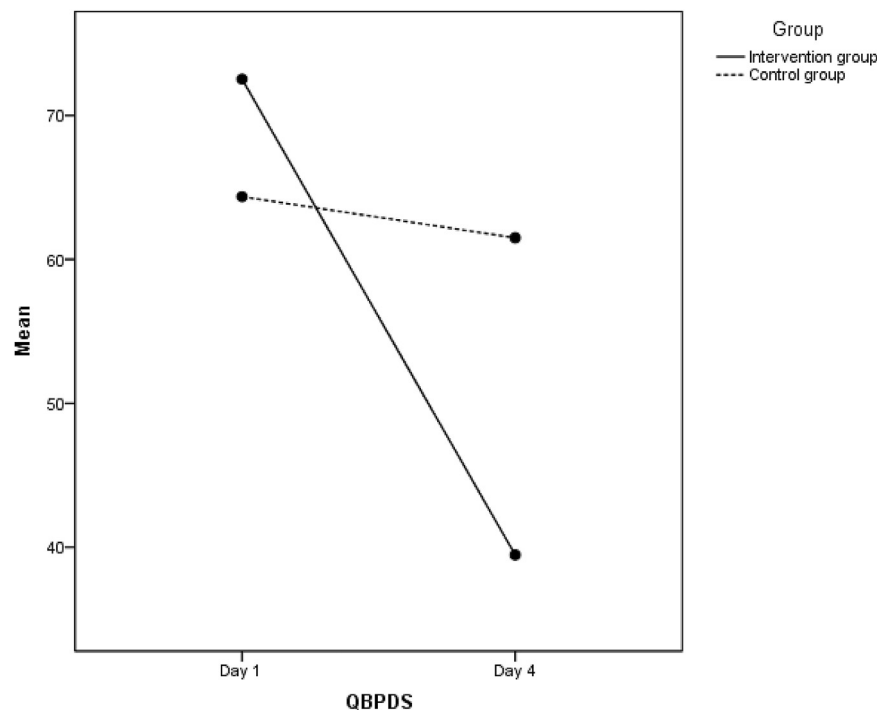


Figure 3. Quebec Back Pain Disability Scale mean values over a period of 4 days.

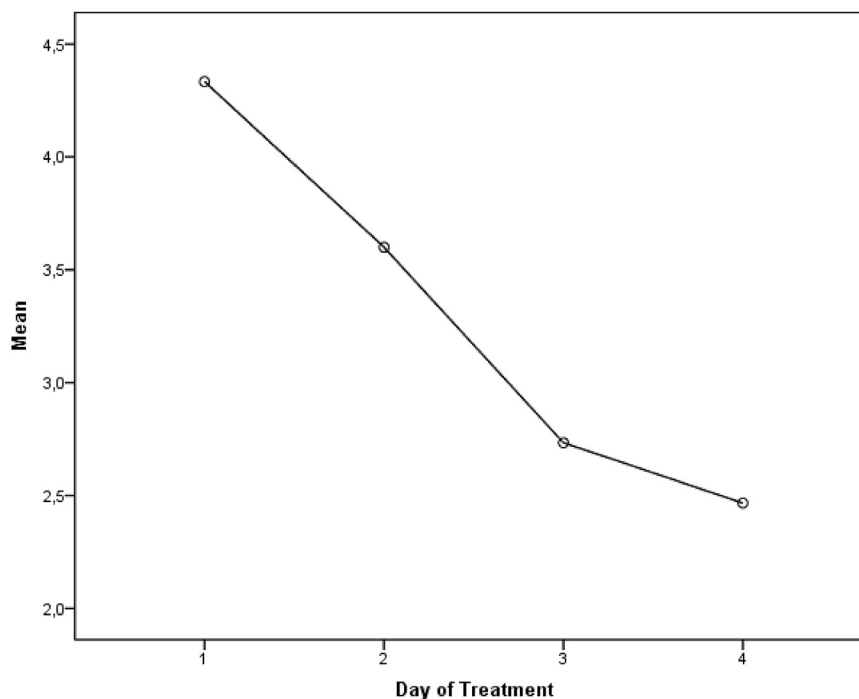


Figure 4. NPRS mean values over a period of days.

39.47 (SD $\pm$ 8.77) points in the intervention group, indicating an improvement in the activities of daily living. In the control group the mean QBPDS score barely changed between the baseline and endpoint measurement. The results are also supported by Lin and Taylor (1998), who reported a significant before and after effect of Therapeutic Touch treatment on pain in elderly patients ($n = 95$). Midilli and Eser (2015) reported significant differences ($p < .001$) in pain intensity measured on a 0–10 scale in post–cesarean delivery patients ($n = 45$) receiving Reiki intervention, another biofield therapy (Henneghan & Schnyer, 2015). This corresponds to a 2.54 point reduction on the numeric scale compared with the control group, with a 0.37 point reduction over 4 days. In the present study a 1.86 point reduction could be achieved on the NPRS before the Therapeutic Touch treatment in the intervention group over 4 days. The endpoint NPRS measurement between the intervention and control group resulted in a reduction of pain intensity ($p < .001$) and indicated a major effect ($d = 2.33$) between the two groups. Other studies also support the pain-relieving effect of Therapeutic Touch in cancer patients (Cook, Guerrerio, & Slater, 2004; Post-

White et al., 2003). This positive trend toward the effectiveness of Therapeutic Touch has also been reported in palliative and end-of-life care patients (Henneghan & Schnyer, 2015), although precise conclusions on the effectiveness of Therapeutic Touch in reducing pain cannot be drawn. The quality of studies, applied methods, and mixed and small populations samples limit the significance of the compared study results (Henneghan & Schnyer, 2015), as well as the present pilot study results.

Study Limitations

The study results are not representative because of the positive selection process of patients who participated in the investigation. For data privacy reasons, only demographic data on age and sex were collected from the participants. Also, administered pharmacologic interventions could not be documented because of data privacy. Hence the pain-relieving effect of the Therapeutic Touch treatment might be a result of administered drug therapy. The sample size of 30 patients per group was not achieved because of limited time resources in the nursing unit. As a result of unforeseen circumstances in the neurologic study unit, Therapeutic Touch had to take place in the patient's room instead of in an extra room.

As another study limitation, the placebo effect needs to be mentioned. Several factors play an important role in the context of the placebo effect's impact on pain relief, such as patients' expectations for the subsequent treatment or cure, physician-patient interaction, therapeutic environment, and even empathy (Brody & Brody, 2011). Studies that also compared mock Therapeutic Touch for pain relief proved a significant effect that cannot be explained solely by the patient's expectations and thus differentiates Therapeutic Touch from a placebo effect (Aghabati et al., 2010; Gordon, Merenstein, D'Amico, & Hudgens, 1998; Lin & Taylor, 1998). This was also presented by Keller and Bzdek (1986), who reported significant tension headache pain level reduction with Therapeutic Touch compared with a placebo stimulation version of Therapeutic Touch (Keller & Bzdek, 1986). In this present study, however, a

Table 2
Direct Pre- and Post-Test Effect of Therapeutic Touch Treatment in the Intervention Group

Paired Samples	Mean	Mean Difference	SD	<i>p</i>	<i>t</i>	η_p^2
Day 1						
NPRS_B	4.33		2.09			
NPRS_A	1.00	–3.33	1.56	<.001	9.597	2.48
Day 2						
NPRS_B	3.60		.98			
NPRS_A	.47	–3.13	.52			
Day 3						
NPRS_B	2.73		.79	<.001	13.201	3.40
NPRS_A	.20	–2.53	.41			
Day 4						
NPRS_B	2.47		1.12	<.001	8.500	2.19
NPRS_A	.20	–2.27	.56			

Note: NPRS_B score before treatment, NPRS_A after treatment.
 η_p^2 = partial eta²; NPRS = Numeric Pain Rating Scale.

placebo Therapeutic Touch intervention was not possible because the Therapeutic Touch treatments took place during the regular nursing daytime shift. There were no additional time or personnel resources available to train unit nurses on performing a placebo Therapeutic Touch intervention.

Conclusions

This pilot study presents first results on the effectiveness of Therapeutic Touch in reducing back pain in adult neurologic patients. Therapeutic Touch seems to be a noninvasive, cost-effective method to provide more professional patient care. Another aspect of Therapeutic Touch is the presence of a nurse in the patient's room for a longer period. The nurse's daily routine rarely allows enough time for longer conversations with or without patient care. Therefore Therapeutic Touch offers nurses a nonpharmacologic alternative intervention for pain management and support of their patients. Future studies should be conducted with larger sample sizes and should compare Therapeutic Touch to other non-pharmacologic interventions such as massage treatment.

Clinical Implications

Therapeutic Touch has established itself as a patient-demanded CAM modality to complement general nursing interventions. Therapeutic Touch can support conventional pharmacologic methods to reduce the pain experience of affected patients. The implementation of Therapeutic Touch requires time resources for trained, holistic, and empathic nurses to apply this cost-effective and alternative method to elevate back pain symptoms of patients.

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