Effects of Therapeutic Touch on Pain, Function and Well Being in Persons with Osteo-Arthritis of the Knee: A Pilot Study
A Smith, S Kimmel, S Milz

Citation

Abstract
Objective:
To determine the effects of therapeutic touch treatments on pain, level of function, and quality of life in people with osteoarthritis of the knee.
Methods:
Persons with osteoarthritis of the knee were enrolled in a single-blinded study and randomized into a control group receiving usual treatment and a treatment group to receive two therapeutic touch treatments a week for eight weeks. Subjects were evaluated at baseline, eight weeks and 12 weeks for pain, function, and quality of life using the Medical Outcomes Study (MOS) Short Form (SF36), the Western Ontario and McMaster Universities Index (WOMAC) and the Knee Society Score (KSS).
Results:Of the 60 subjects enrolled, 48 completed the study. A significant improvement in pain was found between groups in the SF36 between baseline and 8 weeks (p = 0.009). The differences in total physical function between baseline and 8 weeks (p = 0.006) and between baseline and 12 weeks (p = 0.001) were statistically significant in the WOMAC. Pain scores at 8 and 12 weeks improved significantly (p=0.010) in the treatment group compared to the control group in the KSS subscales.
Conclusion:Findings in this study indicate that therapeutic touch applied twice a week for eight weeks decreases pain and stiffness of osteoarthritis in the knee. Therapeutic touch does not appear to affect range of motion or stability of the knee as indicated by the examination results of the KSS.

INTRODUCTION
Osteoarthritis (OA) is a leading cause of chronic disability that increases with age and affects more than 21 million Americans (1). This disease produces pain that impairs physical and psychological function and affects quality of life. No cure is available and the therapy typically prescribed has the potential for significant toxicity (2). OA is also estimated to cost $86 billion annually (3). In addition to prevalence and cost, concerns about the adverse effects of nonsteroidal anti-inflammatory drugs (NSAIDS) have led many patients with OA to look for complementary modalities to relieve symptoms and improve function with lower cost and fewer side effects (4).

OA is a disease often seen in older individuals. More than 80% of people over age 75 have clinical OA, and more than 80% over age 50 have radiologic evidence of OA (5). OA is primarily a disease of the cartilage that progressively produces a local response in the tissue, a mechanical change in the articulation of the joint, and failure of function. OA is associated with inflammation and can result from excessive or repetitive motion of the normal joint. Cartilage in the joint is damaged becoming thinner as it develops fissures or large clefts, and proteoglycan synthesis decreases (2). The inflammatory process and joint damage leads to further decrease in load-bearing capacity leading to further destructive processes in the joint. Joints commonly involved in OA are the fingers, hips, knees, and spine. This study focused on the knee because of the higher prevalence of symptomatic knee OA (6, 7), and the authors considered knee joints more accessible for clinical exam and quantitative measures of treatment response.

Therapeutic Touch (TT), developed by Kreiger and Kunz (8), is a complementary modality recognized by the National Institutes of Health and categorized as a manual healing
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method (9). TT is supported by Rogers’ holistic nursing theory (10, 11) which states that all persons are highly complex fields of various forms of life energy. The system is open so the fields of energy are in constant interaction and exchange with surrounding energy fields thereby changing each other. In TT, the practitioner moves energy through his or her hands to the patient thus restoring balance and increasing the person’s capacity to heal (12-15). TT facilitates pattern change and, when dealing with people with chronic pain, time is needed to “overcome” the person’s long held belief that change is not possible (16). Therefore, a number of treatments over time are necessary to be effective in restoring balance and changing patterns of chronic pain thus decreasing perception of pain and improving function. Treatment in this study was standardized applying the standard Kreiger-Kunz method as established by Nurse Healers-Professional Associates International (17).

The purpose of the current study was to determine the effect of twice weekly therapeutic touch treatments on pain, level of functioning, and quality of life (general well-being and mood) over the course of eight weeks. The current study tested the hypotheses that a treatment protocol of TT would: 1) decrease pain scores, 2) improve quality of life, and 3) improve level of function in persons with OA of the knee.

SUBJECTS AND METHODS

This study was a randomized, single blinded pilot study of the effects of TT compared to standard treatment. The study physician, who was blinded to group assignment, evaluated subjects including a clinical exam of the knee. If both knees were affected, the one designated by the subject as the worse knee was examined. Artificial knees were excluded. Each subject was also administered the survey instruments at baseline, at 8 to10 weeks, and at follow up at 12 to 16 weeks. The treatment group received two TT sessions per week for eight weeks completing at least ten treatments. The control group and the treatment group both continued usual care provided by their continuity physician. The study was approved by the Institutional Review Board of the affiliated institution.

The sample consisted of sixty subjects recruited from a family medicine center, general internal medicine practices, and other practice settings. Inclusion criteria consisted of subjects diagnosed with (or exhibiting signs and symptoms of) OA of at least one knee joint, able to read and speak English and agreement to participate by signing informed consent. Both genders over 50 years old were included. Subjects with a diagnosis of connective tissue disorder and those with bilateral total joint replacement of the knee were excluded. Subjects with dementia, severe psychotic illnesses, or with a known systemic illness producing joint symptoms were excluded. The current study was a pilot study for the researchers, who plan a larger study in the future in an attempt to differentiate between smaller changes.

After obtaining informed consent, subjects were randomized into the treatment or control group. The study physician who conducted the clinical exams was unaware of group assignment. Treatments were conducted by Registered Nurses trained and experienced in TT and were completed in separate locations from exams.

Pain is subjective and personal and is defined as an
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unpleasant sensory and emotional experience associated with actual or potential tissue damage, or described in terms of such damage (23). In this study, pain was subjectively measured by the paper and pencil survey pain sections of the Knee Society Score (KSS) (Knee Society Clinical Rating System) (24) and the Western Ontario and McMaster Universities Osteoarthritis Index (WOMAC) (25-28). The KSS consists of points given for pain, range of motion, and stability in both the coronal and sagittal planes, with deductions for fixed deformity, and extensor lag. The KSS function score consists of points given for the ability to walk on level surfaces and the ability to ascend and descend stairs, with deductions for the use of external supporting devices. In the current study, knee range of motion and stability were assessed using the objective clinical exam portion of the KSS by the same physician for every subject.

The Western Ontario and McMaster Universities (WOMAC) Osteoarthritis Index (25-28) is a disease-specific, self-administered, health status measure. This measure probes clinically-important symptoms in the areas of pain, stiffness and physical function in patients with OA of the hip and/or knee. The index consists of 24 questions (5 pain, 2 stiffness and 17 physical function) and can be completed in less than 5 minutes. The WOMAC (24, 25) is a valid, reliable and sensitive instrument for the detection of clinically important changes in health status following a variety of interventions. WOMAC results are reported as a normalized score. Individual question responses are assigned a score of between 0 (extreme) and 4 (none). Individual question scores are then summed to form a raw score ranging from 0 (worst) to 96 (best). Finally, raw scores are normalized by multiplying each score by 100/96 producing a reported WOMAC Score of between 0 (worst) to 100 (best).

Quality of life was operationally defined as those factors contributing to health and the meaningfulness of life that impact on people’s happiness. Perception of interpersonal distress, negative affect, and depressive symptoms are associated with increased disease activity and the person’s ability to adapt (29, 30). Quality of life was measured by the subjective self-administered SF 36 (31-34) survey. The SF 36 health survey measures eight domains and provides a psychometrically based physical component summary and a mental component summary. Scores are calibrated 1-100 with higher scores indicating lower quality of life. The SF36 is well validated and is a reliable instrument often used to measure quality of life. The KSS pain and function scores have been found to have moderate to strong correlations with corresponding domains of the WOMAC and SF36 (35).

DATA ANALYSIS

Initial analysis was performed to determine if the treatment group differed from the control group. Descriptive statistics were used to describe the sample. T-tests were used for differences in continuous variables, and Chi-square analysis was used for differences in categorical variables. All data analysis was conducted using SPSS, version 15.0 (SPSS, Inc., Chicago, Illinois.)

Repeated measures analysis of variance (RANOVA) was then used to determine if any of the SF36, WOMAC, or KSS scores varied over time. The interaction between time (baseline, 8 weeks, and 12 weeks) and group (treatment, control) was evaluated to determine if the two groups changed over time differently. Contrast comparisons were then made between the baseline measurement and the 8 week measurement and between the baseline measurement and the 12 week measurement.

Not all of the subjects enrolled completed the study. Of the 60 subjects beginning the program, 12 completed only the baseline measurements and could not be included in the analysis. Of the 48 subjects included in the repeated measures analysis, 13 had some missing information. Initial analysis using SPSS eliminated any subjects without scores at all three reporting times. The number of missing subjects varied for each instrument and for each measurement within each instrument. For the SF36 scores, 3-5 subjects were eliminated. For the WOMAC scores, 6-13 subjects were eliminated. For the KSS scores, 3-6 subjects were eliminated.

RESULTS

DEMOGRAPHICS

Descriptive data for the demographic variables of age, height, weight, time with osteoarthritis, body mass index (BMI), gender, ethnicity, and marital status can be found in Table 1. The results of the independent samples t-tests indicate no difference between the treatment group and the control group in terms of age, height, weight, time with OA, and body mass index (BMI). Additionally, no differences existed between the treatment group and control group in terms of gender, ethnicity, and marital status.
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Table 1 – Demographics by Group

<table>
<thead>
<tr>
<th></th>
<th>Control Group</th>
<th>Treatment Group</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age</td>
<td>28</td>
<td>32</td>
</tr>
<tr>
<td>Height</td>
<td>25</td>
<td>25</td>
</tr>
<tr>
<td>Weight</td>
<td>25</td>
<td>25</td>
</tr>
<tr>
<td>SF-36</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Females</td>
<td>22</td>
<td>21</td>
</tr>
<tr>
<td>Males</td>
<td>6</td>
<td>10</td>
</tr>
<tr>
<td>Ethnicity</td>
<td>28</td>
<td>31</td>
</tr>
<tr>
<td>White, non-Hispanic</td>
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<td>20</td>
</tr>
<tr>
<td>Hispanic</td>
<td>1</td>
<td>3</td>
</tr>
<tr>
<td>African-American</td>
<td>2</td>
<td>6</td>
</tr>
<tr>
<td>Marital status</td>
<td></td>
<td></td>
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<tr>
<td>Single</td>
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<td>4</td>
</tr>
<tr>
<td>Married</td>
<td>18</td>
<td>18</td>
</tr>
<tr>
<td>Widowed</td>
<td>4</td>
<td>12</td>
</tr>
<tr>
<td>Divorced</td>
<td>1</td>
<td>5</td>
</tr>
<tr>
<td>Other</td>
<td>2</td>
<td>0</td>
</tr>
</tbody>
</table>

Independent sample t-tests indicated that the means for the treatment group and for the control group did not differ at baseline for any of the SF36 subscales. A summary of SF36 scores is depicted in Table 2. The results of the repeated measures analysis of variance on the SF36 subscale indicated that over time, the change in physical function differed between the treatment group and the control group (p = 0.007). Bodily pain appeared to change over time (p = 0.035), but became a non-statistically significant change when the alpha was adjusted using the Bonferroni method. Figure 1 depicts the changes over time for bodily pain. Higher scores indicate decreased pain. In Figure 1, the difference in change for bodily pain between baseline and 8 weeks is statistically significant (p = 0.009), whereas the difference in change between baseline and 12 weeks is not statistically significant (p = 0.122).
Figure 3
FIGURE 1 – Change in SF36 Bodily Pain Score Over Time for the Treatment and Control Groups

WOMAC

Independent sample t-tests indicated that the baseline means for the treatment group and for the control group did not differ with statistical significance for any of the WOMAC subscales. A summary of WOMAC scores is depicted in Table 3. The results of the repeated measures analysis of variance on the WOMAC subscales indicated that over time, physical function, total stiffness, and total physical function changed differently between the treatment and control group. Figure 2 depicts the changes over time for total physical function. Lower scores indicate improvement in function. In Figure 2, the difference in change for total physical function between baseline and 8 weeks (p = 0.006) and between baseline and 12 weeks (p = 0.001) are both significant.

Figure 4
TABLE 3 – Interaction between Time Period (Baseline, 8 weeks, 12 weeks) and Group (Control vs Treatment) for WOMAC Scores

<table>
<thead>
<tr>
<th></th>
<th>Baseline</th>
<th>8 Weeks</th>
<th>12 Weeks</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Treat</td>
<td>Control</td>
<td>Treat</td>
</tr>
<tr>
<td><strong>P</strong> pain</td>
<td>6.57</td>
<td>6.88</td>
<td>4.65</td>
</tr>
<tr>
<td>(3.20)</td>
<td>(4.45)</td>
<td>(3.28)</td>
<td>(3.97)</td>
</tr>
<tr>
<td><strong>S</strong> stiffness</td>
<td>3.33</td>
<td>4.11</td>
<td>2.35</td>
</tr>
<tr>
<td>(1.80)</td>
<td>(1.50)</td>
<td>(1.58)</td>
<td>(2.09)</td>
</tr>
<tr>
<td><strong>PF</strong> physical function</td>
<td>23.05</td>
<td>30.00</td>
<td>15.90</td>
</tr>
<tr>
<td><strong>TP</strong> total pain</td>
<td>6.07</td>
<td>6.87</td>
<td>4.74</td>
</tr>
<tr>
<td>(3.90)</td>
<td>(4.67)</td>
<td>(3.51)</td>
<td>(3.70)</td>
</tr>
<tr>
<td><strong>TS</strong> total stiffness</td>
<td>3.88</td>
<td>3.10</td>
<td>2.50</td>
</tr>
<tr>
<td>(2.07)</td>
<td>(1.60)</td>
<td>(1.57)</td>
<td>(2.06)</td>
</tr>
<tr>
<td><strong>TPF</strong> total physical function</td>
<td>24.25</td>
<td>28.85</td>
<td>15.25</td>
</tr>
</tbody>
</table>

*p* values statistically significant at *p* = 0.008 (Bonferroni adjusted).

Figure 5
FIGURE 2 – Change in WOMAC Total Physical Function Scores Over Time for the Treatment and Control Groups

KNEE SOCIETY SCORE

Independent sample t-tests indicated that the means for the treatment group and for the control group did not differ at baseline for any of the KSS subscales. A summary of KSS
scores is depicted in Table 4. The results of the repeated measures analysis of variance on the KSS subscales indicated that over time, pain and total knee scores changed between the treatment and control groups.

**Figure 6**

TABLE 4 – Interaction Between Time Period (Baseline, 8 weeks, 12 weeks) and Group (Control vs Treatment) for KSS Scores

<table>
<thead>
<tr>
<th>Time Period</th>
<th>Control</th>
<th>Treatment</th>
</tr>
</thead>
<tbody>
<tr>
<td>Baseline</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Mean (sd)</td>
<td>Mean (sd)</td>
<td></td>
</tr>
<tr>
<td>Pain</td>
<td>36.50</td>
<td>26.25</td>
</tr>
<tr>
<td>ROM</td>
<td>22.82</td>
<td>23.10</td>
</tr>
<tr>
<td>TF</td>
<td>64.41</td>
<td>68.30</td>
</tr>
<tr>
<td>TK</td>
<td>57.34</td>
<td>61.82</td>
</tr>
<tr>
<td>S</td>
<td>20.08</td>
<td>17.00</td>
</tr>
</tbody>
</table>

*p = 0.001 (Bonferroni adjusted)*

**DISCUSSION**

The current study tested the hypotheses that a treatment protocol of TT would: 1) decrease pain scores, 2) improve quality of life, and 3) improve level of function in persons with OA of the knee. The study provides evidence that TT is effective in relieving pain and stiffness, and in improving function and quality of life in persons with self-described OA of the knee. No evidence existed that TT influenced range of motion or stability of the knee upon clinical examination using the KSS. However, when TT was applied in vitro to fibroblasts, tendon cells, and bone cells in a study by Gronowicz, et al (36), the treatments produced significant increase in proliferation of tenocytes, fibroblasts, and osteoblasts. Further research using frequent treatments with TT over longer periods of time may result in some improvement in range of motion and stability.

Findings in this study indicate that TT applied twice a week for eight weeks decreases pain and stiffness of osteoarthritis in the knee. Results of the SF36, the WOMAC, and the KSS demonstrated that the treatment group had a significant reduction in pain and stiffness between the baseline exam and the exam conducted at the end of the eight weeks of treatment as compared to no difference in the control group. The pain and stiffness in the treatment group also continued to be significantly improved from baseline compared to the follow up exam indicating that although lessening, the relief of pain continued to be effective 4 to 6 weeks after the last treatment. The results suggest that TT produces relief of pain and has prolonged effect. Since the pain was beginning to increase according to all of the survey instruments, evidence would suggest the treatments would need to be resumed in order to maintain the energy balance and relief of pain. The results parallel pharmacological treatment that requires maintenance but without the serious side effects of NSAIDs and other pain relief medications.

Subjects responded to questions which asked about their perception of their general health and how their health affected daily activities such as running, lifting, and doing housework. Subjects responded to questions about their vitality such as how much energy they have and their outlook on life. The subscales measuring role due to physical function, role due to emotional function, social functioning and mental health indicated no significant difference in either group. Although not significant, the role emotional scores decreased slightly in the control group and increased slightly in the treatment group. Two to three months may not be a long enough time to make pattern changes affecting role, social functioning, or mental health. Further research is indicated to conduct a long range study on the effects of TT treatments over time.

Another major finding of this study indicates that TT appears to improve functional ability of persons with OA of the knee. The SF36 physical function scores and the WOMAC physical difficulty scores were significantly improved between baseline and week 8 and between baseline and week 12 in the treatment group while no difference existed in the control group. The total KSS approached significance for the difference between baseline and eight weeks, and was significantly different between baseline and twelve weeks in the treatment group. No difference existed in the control group suggesting that more time may have been required for subjects to achieve results.

TT does not appear to affect range of motion or stability of the knee as indicated by the examination results of the KSS.
The examiner measured the actual range of motion of the knee at baseline and again at times two and three and neither group showed change. This result may be expected since the KSS was designed to measure changes that occur after reconstructive surgery. Although TT is expected to balance energy and affect perception of pain, stiffness, well being and function, at this time, TT is not expected to result in structural changes.

Although this study included a control group, a mock TT group was not included. Subjects who entered the study and received treatment may have been more likely to perceive TT as beneficial. However, the persistence of treatment benefits for 4 weeks beyond the actual treatment period may indicate benefit beyond a placebo effect. The dropout rate was similar for both treatment and control groups indicating that subjects were committed to remaining in the study. The diagnosis of OA of the knee was based on patient report, and no radiologic studies were obtained at the beginning or end of the study reflecting “real world” practice since radiological results do not always correlate with patient’s perception of pain or disability (37).

Further research needs to be conducted to examine more long term effects of TT on OA of the knee and in other joints. A limitation of the study included the fact that this study took place over the course of a year during which subjects experienced fluctuations in weather. The authors recommend that future research include a log of the temperature and humidity at the time of each exam and survey to see if these are factors in results. Radiologic studies at baseline and in long term follow up would also be useful although such studies do not always correlate with the severity of patient’s symptoms. Conducting a study using a mock treatment group in addition to a control and active treatment group would better define the influence of any placebo effect. This method was not possible in the current study because of lack of economic and manpower resources.

Another limitation was that no data were collected on what medications the OA subjects were receiving. Though the sample was randomized, this factor could confound the results. In addition, recruitment from various medical groups could introduce different treatment practices.

**CONCLUSION**

TT offers a non-pharmacologic intervention that may be easy to do in the home or community, is cost effective, and may lessen symptoms and improve function (38). Implications of this study indicate that health care providers should consider TT as an adjunct or complementary therapy that can help their OA patients manage pain and improve function. Interested health care providers can pursue education and training in the use of the Krieger-Kunz method of TT so they can administer this therapy in inpatient and outpatient settings.

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Author Information

A. Ann Smith, PhD, PMHCNS, BC
Professor Emerita, College of Nursing, University of Toledo

Sanford R Kimmel, MD, FAAFP, FAAP
Professor of Family Medicine, College of Medicine, University of Toledo

Sheryl A Milz, PhD, CIH
Associate Professor and Interim Chair, Department of Public Health and Preventive Medicine, College of Medicine, University of Toledo