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Mixed Methods Research

Topical Ginger Treatment With a Compress or Patch for Osteoarthritis Symptoms

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Aim: This article is a report of a study evaluating changes in health status before and after topical ginger treatment for adults with moderate to severe osteoarthritis. **Method:** In 2011, 20 adults with chronic osteoarthritis were randomly assigned to one of two groups for 7 consecutive days of topical ginger treatment by trained nurses: Group 1 received a manually prepared ginger compress and Group 2 a standardized ginger patch. Participants had the option to continue self-treatment using the ginger patch for a further 24 weeks. A brief arthritis health questionnaire was completed weekly for 3 weeks and 4 weekly for 24 weeks. **Results:** The mean scores for Group 1 and Group 2 show a notable decline following 1-week topical ginger treatment; scores in pain, fatigue, global effect, and functional status reduced by 48%, 49%, 40%, and 31%, respectively, whereas health satisfaction improved from 80% dissatisfied to 70% satisfied. Scores for all participants in all five domains progressively reduced over the following 24 weeks of self-treatment. **Conclusion:** Topical ginger treatment has the potential to relieve symptoms, improve the overall health, and increase independence of people with chronic osteoarthritis.

Keywords: *older adults; alternative therapies; chronic pain; herbal remedies; chronic conditions*

Osteoarthritis (OA) is a chronic degenerative disease of the articular cartilage primarily affecting the hips, knees, and hands that subsequently accounts for the majority of joint replacements and musculoskeletal pain and disability in Western society (Zhang, Moskowitz, et al., 2008). OA is most prevalent in those over 65 years, especially females, and accounts for more problems while climbing stairs and walking as well as lost efficacy at work than any other disease (Bijlsma, Berenbaum, & Lafeber, 2011). The chronic pain and disability caused by OA often leads to compounding health issues, such as chronic tiredness, inability to cope with life, anxiety, and depression that need to be considered in the overall management (Lane et al., 2011). Research shows that people with OA choose to use more complementary alternative medicines than for any other chronic health condition (Henderson, 2004; Lapane, Sands, Yang, McAlindon, & Eaton, 2012), and there is a preference for topical applications (Callahan et al., 2009; Herman, Craig, & Caspi, 2005). Ginger has been identified as hav-

ing a role as an antiarthritic agent through its antithrombotic and anti-inflammatory effects (Ali, Blunden, Tanira, & Nemmar, 2008; Terry, Posadzki, Watson, & Ernst, 2011), and there is limited research showing beneficial effects from topical ginger applications in OA (Therkleson, 2010a).

The purpose of this study is to advance research on the association between topical ginger treatment using either a traditional manually prepared ginger compress or a standardized ginger patch and the relief of OA symptoms. Although internal ginger

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extract has been found effective in managing subjective experiences of pain and functional impairment in OA (Fajardo & Di Cesare, 2005; Terry et al., 2011), the high doses required often cause gastrointestinal disturbances (Marcus & Suarez-Almazor, 2001; Wigler, Grotto, Caspi, & Yaron, 2003). Topical ginger avoids these potential negative effects, and when applied over the mid-lumbar region, qualitative studies suggest a positive effect on mobility, mood, energy levels, and overall sense of well-being (Therkleson, 2010b; Therkleson & Sherwood, 2004). Topical ginger applied as ginger compresses to the kidney region is part of the practice of anthroposophic nursing for patients with chronic inflammatory conditions such as arthritis. In 1923, anthroposophic nursing was founded in the Ita Wegman Clinic in Arlesheim, Switzerland, and today there are more than 25 specialist hospitals and clinics throughout Europe, with nursing practice summarized in Fingado (2011, 2012). Anthroposophic nurses are registered practicing nurses, who have completed postgraduate education to advance their understanding of the anthroposophical perspective in health and illness as introduced in Steiner and Wegman (1925/1967). Since 1996 in New Zealand, there have been courses educating registered practicing nurses in anthroposophic nursing theory and practice (Therkleson, 2007).

This study is the first known quantitative study of topical ginger treatments for people with OA. In early 2013, a database search for "topical ginger" was done on a wide range of sources: Pub Med Central, Elsevier-Science Direct, Medline, Cumulative Index to Nursing and Allied Health Literature (CINHL), Web of Science, and Blackwell Synergy. Ginger patches were developed to enhance the reliability of results and to ensure that replication was possible in the home, with the minimum of effort from participants.

Method and Materials

Aim

The aim of this study is twofold: (a) to evaluate a standardized ginger patch alongside that of a traditional manually prepared ginger compress over 7 consecutive days in a clinic by using a simple, brief arthritis questionnaire and (2) to evaluate the use of

the ginger patch at home for over 24 weeks using a simple, brief arthritis questionnaire.

The secondary aims are to

- Evaluate and compare changes in participant perception of pain intensity, chronic fatigue, global effect of OA, mobility, and overall satisfaction with health
- Evaluate participant changes in the use of pain medication and/or pain management
- Evaluate the safety of the application of both the ginger patch and ginger compress through participant and nurse written reports

Design

Part 1. In 2011, a 3-week, open-label, two-group study using three brief self-report questionnaires (SRQ) was used to evaluate participants' perceived response to topical ginger treatments. Throughout the 3 weeks, participants maintained their normal established OA management procedures. Routine analgesic medication was noted in a daily diary alongside a daily pain questionnaire.

Twenty volunteer adults with OA were randomly assigned to either Group 1 (compress) or Group 2 (patch). Randomization was sequential in time as participants were recruited at the first interview. This is a two-group design with a 1:1 allocation to each of the two interventions; Group 1 had 10 receiving a manually prepared ginger compress, and Group 2 had 10 receiving the standardized ginger patch. To ensure equal numbers in each group, a restricted randomized scheme was used, with a block size of 4 (Machin & Fayers, 2010).

The intervention was 7 consecutive days of topical ginger treatments, given at four medical clinics by anthroposophic nurses. Topical ginger treatment was the same for all participants and involved lying on the back in a quiet, warm space, with a pre-warmed ginger patch/compress applied to the mid-lumbar region for 30 minutes, followed by a rest of 20 minutes. The compress and standardized patch each had the equivalent of 1 g dry ground organic *Zingiber officinale* rhizome (ginger) from the same certified batch. The compress was prepared prior to use by dissolving 10 g of ground ginger in 100 mL hot water, soaking a cloth in the mixture and squeezing firmly. The patches were prepared exclusively for the study: each comprising a piece of crepe paper

and extract with 1 g ginger and purified water. The same procedure and protocol for topical ginger compress treatments used in a previous qualitative study for 10 people with OA was followed (Therkleson, 2010b). Before and after each treatment, nurses monitored participants' basic physiological measures of temperature, pulse, respiration, blood pressure, and body weight and the observed and reported effects of the intervention. Although there are no known risks or side effects to ginger therapy, this was an added precaution. The brief Modified Health Assessment Questionnaire (MHAQ) was completed weekly for the first 3 weeks: 1 week before treatment, 12 hours after treatment, and 1 week after treatment.

Part 2. Following the initial 3 weeks, all participants were offered the option to continue self-treatment at home using the ginger patch only as required for a further 24 weeks. The ginger patch was used by all participants for self-treatments because it is simple to apply, as well as convenient and reliable. The ginger compress is awkward and difficult to prepare in a consistent and reliable manner by patients. Participants were educated in the use of the ginger patch, with adequate supplies of patches available from the clinics. The MHAQ was completed four times a week for 24 weeks either in person or by telephone, depending on participant availability.

This study has appropriate state ethical approval in New Zealand. All participants gave their informed, signed consent to be part of the study, and all identification is anonymous.

Sample

The sample comprised 20 consenting Caucasian adults diagnosed with chronic symptomatic OA in any site for at least 1 year. Advertisements went to community groups and medical centers in two New Zealand cities. OA was confirmed by Kellgren and Lawrence X-ray Grades 2 and 3; health assessment was based on clinical diagnosis and completion of the short arthritis assessment scale (SAS; Wolfe, Michaud, Kahler, & Omar, 2004). The SAS asks four simple questions relating to pain, functional status, and global effect of OA in the previous week, each on a 10-point Likert-type scale, with 0 for no problem and 10 for very severe problem. No participant was accepted with a pain score less than 5/10

or a total score less than 18/40. The health assessment excluded those with a joint replacement of the affected joint, rheumatoid arthritis, fibromyalgia, cancer, and other serious health conditions; those who were not naive to the therapy; and those having corticosteroids and/or anticoagulants in the past 12 weeks. This same selection method proved effective in a previous ginger compress qualitative study (Therkleson, 2010a).

Data Collection

This study uses three brief SRQ that have been found reliable and valid in rheumatology: (a) SAS, (b) modified MHAQ, and (c) daily pain questionnaire for 21 days.

The SAS (Wolfe, Michaud, Kahler, et al., 2004) was used solely to confirm selection of participants. The SAS is designed specifically to assess OA symptoms quickly and effectively in the clinical and research setting (Wolfe, Michaud, Kahler, et al., 2004).

The MHAQ was completed 7 days before topical ginger treatments, within 12 hours after the treatments, 7 days later, and 4 weekly for 24 weeks. The MHAQ was prepared by the National Data Bank for Rheumatic Diseases to be used as a simple, brief questionnaire in the clinical and research setting. It was effective in the prospective Arthritis Outcomes Study led by Wolfe, Pincus, Thompson, and Doyle (2003). The MHAQ is one page long and asks 14 simple questions relating to the past week: (a) 3 independent questions on pain, fatigue, and global effect each recorded on a 10-cm visual analog scale (VAS); (b) 10 questions on functional status recorded on the Health Assessment Questionnaire-II (HAQ-II; Wolfe, Michaud, & Pincus, 2004); and (c) one question on health satisfaction recorded on a categorical scale. The HAQ-II has 10 items and was developed as a brief and simplified version of the original HAQ (Bruce & Fries, 2003a, 2003b) disability index used in rheumatology.

The daily pain scale was completed for 21 consecutive days (7 days before therapy, 7 days during therapy, and 7 days after therapy) on a 10-cm VAS, with 0 for no problem and 10 for very severe problem. The 10-cm VAS is recognized in rheumatology as the most robust quantitative pain measure (Sokka, 2003; Tuulikki, 2003). Changes in pain relief medication were also recorded daily below the scale. The additional data relating to medication provide

increased understanding of the changes in OA status before and after topical ginger therapy.

Participant total mean scores are given for the three questions on a VAS and the HAQ-II, with proportions for the one categorical variable. MHAQ total scoring was out of 3, with each of the questions on the 10-cm VAS and the 10 questions on the HAQ-II totaling 3. The 21-day pain scale was scored from 0 to 3, with 0 being no problem and 3 being a severe problem. The HAQ-II has 10 items with each scored from 0 to 3: 0 to 1 is mild to moderate disability, 1 to 2 is moderate to severe disability, and 2 to 3 is severe to very severe disability. The total HAQ-II score is divided by 10, resulting in 3 being the highest score possible in functional status. By maintaining consistency in the scoring of each question, it was possible to compare the final scores of the groups.

Results

The sample size is small limiting formal statistical testing; nonetheless means, standard deviation (*SD*), standard error bars, and % differences are given. Excel software was used to analyze the data.

The sample comprised 20 consenting Caucasian adults with varying characteristics and OA status at baseline. Participants, mean age 64 years, 80% female, had a mean pain score at baseline of 6.8, with 10 being the most extreme pain; mean pain score for Group 1 was 6/10 and for Group 2 7/10. Most participants had OA of the hips and/or knees (17/20, 85%), whereas the remainder in the hands, shoulder, cervical, and lumbar regions for a mean of 8 years, *SD* of 6. Sixteen participants were from participating medical practices and 4 from the community. The SAS was quick and simple to complete, easily scored and effective in confirming selection. Total SAS scores ranged from 36/40 to 18/40, with a mean score of 26/40 and *SD* of 4.5; mean of Group 1 was 6/10 and Group 2 was 7/10.

The MHAQ was well received by participants; it was brief and easily completed. The 21-day pain VAS gave added confidence in scoring pain on the MHAQ.

Part 1: The mean MHAQ scores for Groups 1 and 2 show a notable decline after topical ginger treatment; Group 1 was 1.75/3 at baseline and 1.15/3 one week after therapy,

whereas Group 2 was 1.85/3 at baseline and 0.95/3 one week after therapy (see Figure 1).

Part 2: Following the week of topical ginger compress treatments in the clinics, Group 1 is identified as Group 1a and is now using only ginger patches as is Group 2. Figure 1 shows the mean MHAQ scores, excluding health satisfaction status for Groups 1a and 2, 4 weekly for 24 weeks on a line plot with error bars.

The mean MHAQ scores indicate a positive response after 1 week treatment on the VAS in pain, fatigue, and global effect, with percentage responses of 48%, 49%, and 40%, respectively, and on the HAQ-II for functional status 31%. Tubach et al. (2005) state that a meaningful clinical improvement in knee and hip OA for pain on the 10-cm VAS is 40.8% to 32% and global effect on the 10-cm VAS 39% to 32%, whereas functional status on Western Ontario and McMaster Universities Osteoarthritis Index function is 26% to 21%. Figures 2 to 5 show box plots for Group 1/1a and Group 2 with standard error bars for each of the four domains of the MHAQ—pain, fatigue, functional status, and global effect—over the 27-week study. At baseline, the median in all four domains varied from 2.4 to 1.2/3, and after 27 weeks, it was below 0.4/3 in all domains.

The final question for health satisfaction status on a categorical scale indicates a positive shift, with 80% dissatisfied 7 days before therapy, 70% satisfied 7 days after therapy, and 82% satisfied 24 weeks after self-treatment (see Table 1).

During the initial 3-week study, the daily mean pain scores compared favorably with the weekly MHAQ mean pain scores, with a *SD* of 0.01. The baseline mean pain score for all participants was 2.2/3, then 7 days after therapy the mean was 0.95/3. All participants in the sample registered a reduction in pain no matter what happened (medication taken, activity level, and degree of severity of symptoms). Medication for pain relief decreased during the study. At commencement, 6 participants took no pain relief, and 14 took conventional analgesics as required. After 7 days of ginger therapy, 5 of the 14 participants continued their usual medication regime, whereas 9 stopped all forms of analgesia; then 4 weeks later, 11 participants reported requiring no further pain relief as previously required. After 4 weeks, 78% of those previously taking analgesia were no longer requiring this additional support.

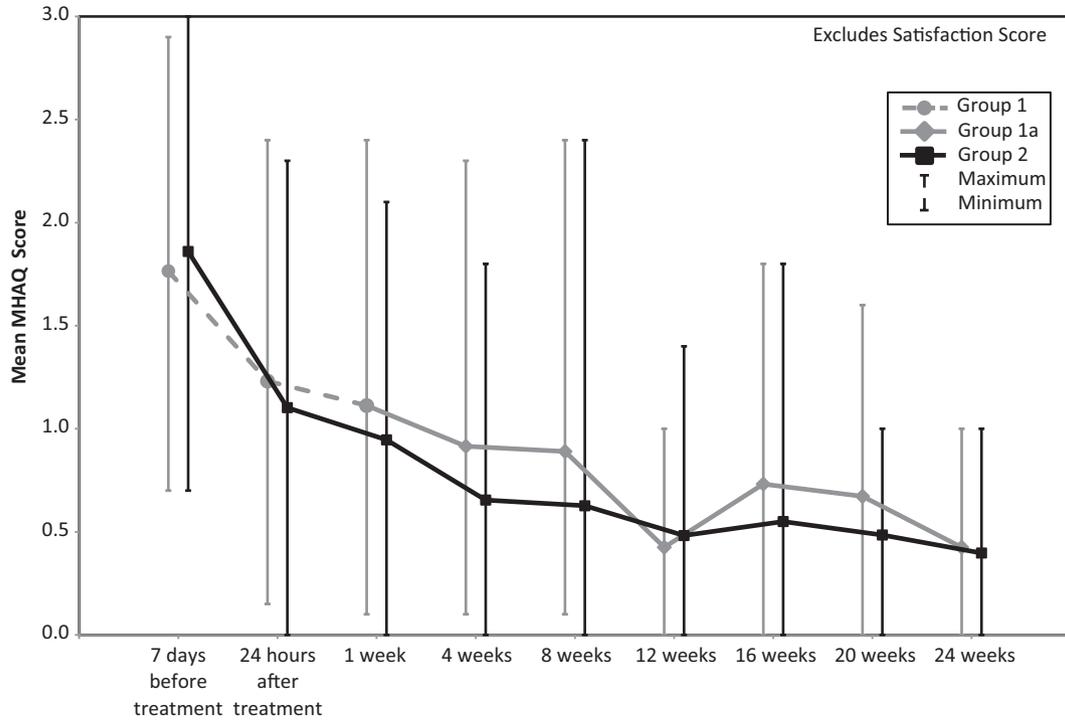


Figure 1. Mean MHAQ Scores for Groups 1/1a and 2
 Note: MHAQ = Modified Health Assessment Questionnaire.

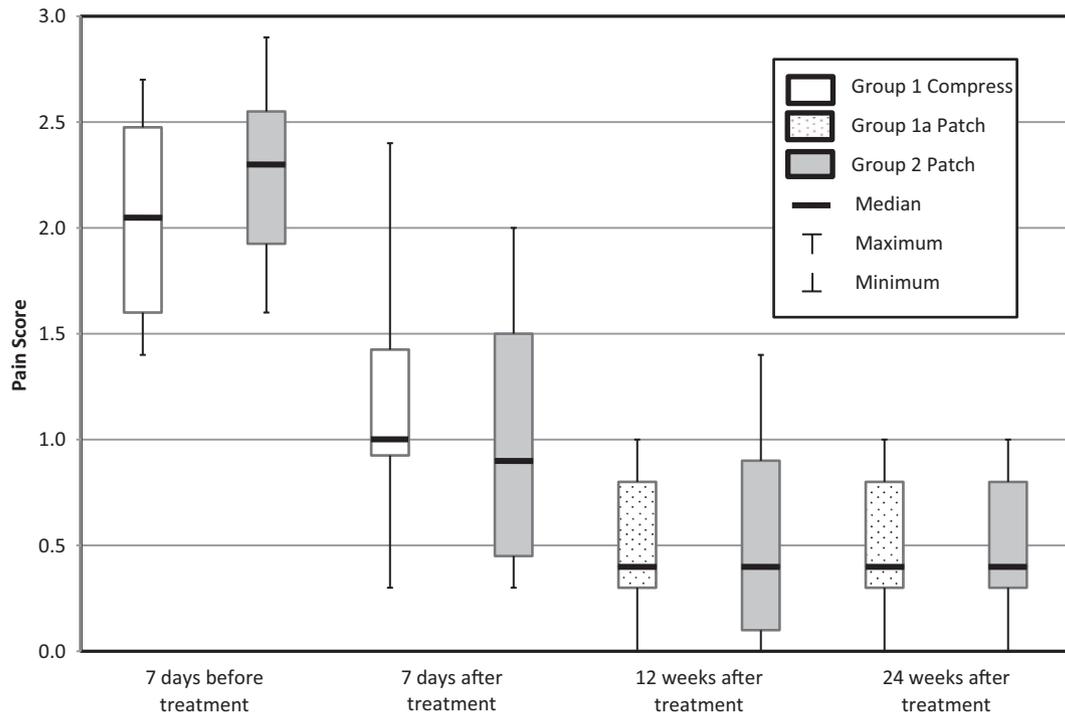


Figure 2. MHAQ Mean Pain Scores for Groups 1/1a and 2
 Note: MHAQ = Modified Health Assessment Questionnaire.

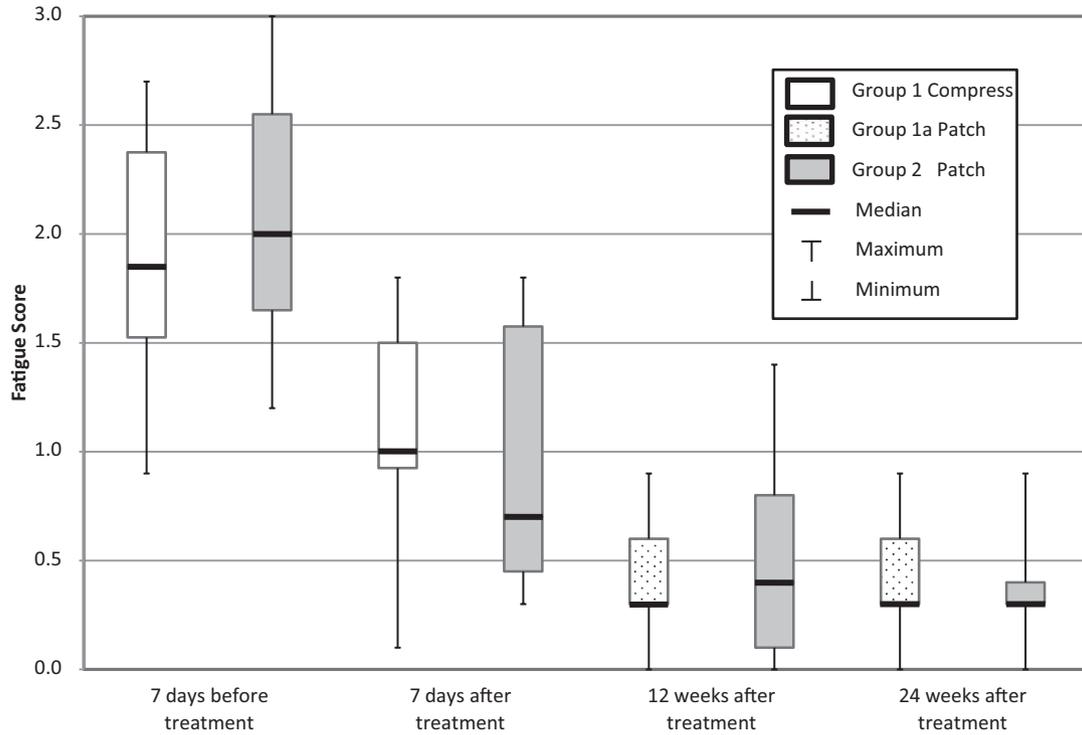


Figure 3. MHAQ Mean Fatigue Scores for Groups 1/1a and 2
Note: MHAQ = Modified Health Assessment Questionnaire.

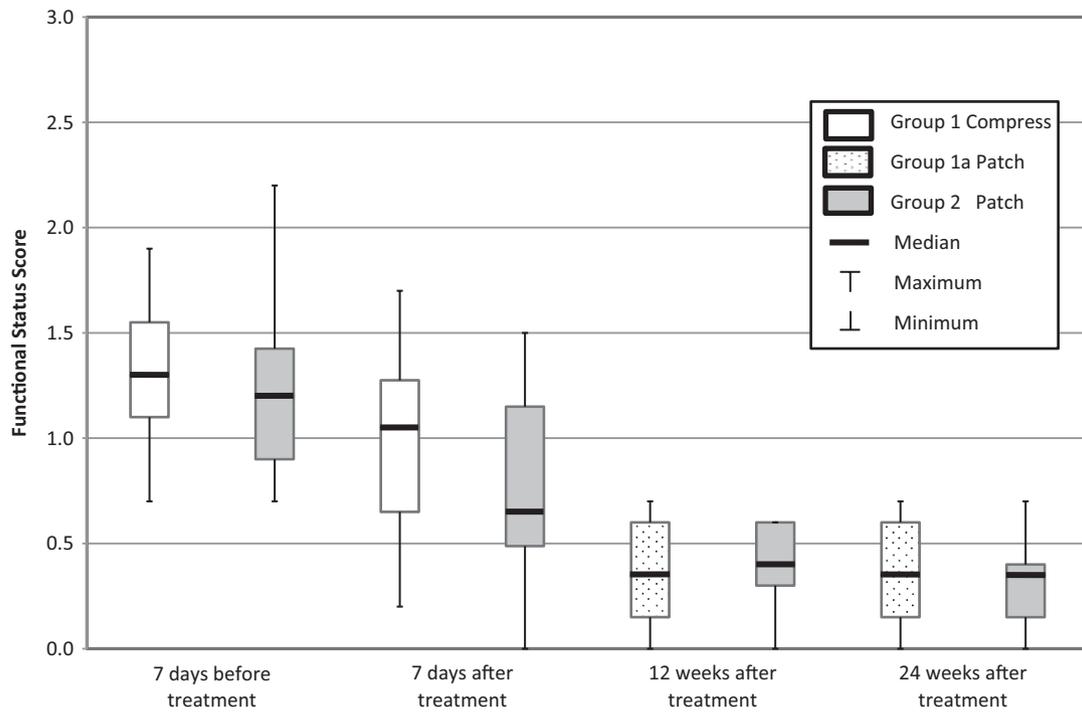


Figure 4. MHAQ Mean Functional Status Scores for Groups 1/1a and 2
Note: MHAQ = Modified Health Assessment Questionnaire.

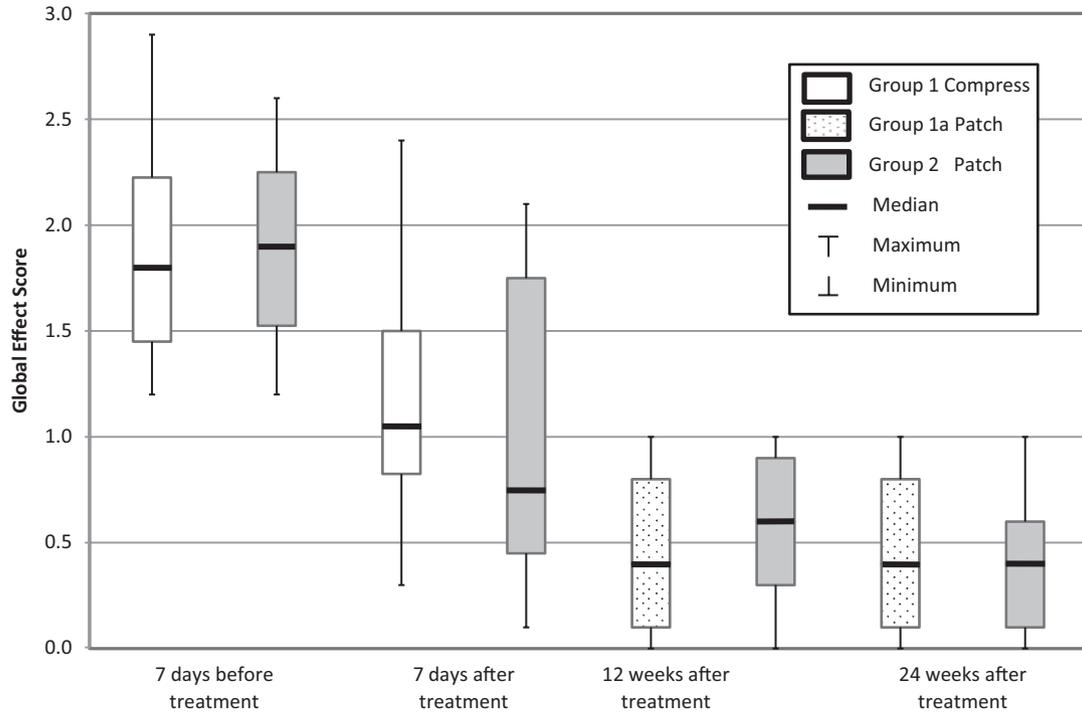


Figure 5. MHAQ Mean Global Effect Scores for Groups 1/1a and 2
 Note: MHAQ = Modified Health Assessment Questionnaire.

Table 1. MHAQ Health Satisfaction, Groups 1/1a and 2

	7 Days Before Therapy	7 Days After Therapy	12 Weeks After Therapy	24 Weeks After Therapy
Very satisfied	0%	20%	26%	39%
Somewhat satisfied	5%	50%	58%	44%
Neither satisfied nor dissatisfied	15%	5%	5%	6%
Somewhat dissatisfied	45%	20%	11%	11%
Very dissatisfied	35%	5%	0%	0%

Note: MHAQ = Modified Health Assessment Questionnaire.

The 20 participants were motivated to be 100% compliant in every aspect of the study, and there were no reported adverse effects from nurses or participants. One participant did not continue self-treatment due to comorbidities that compromised the ability to maintain a balanced perspective, when completing the SRQ.

Limitations

Although this study shows a positive response to topical ginger therapy, the small numbers do not

allow for clinical significance. There are a number of limitations because this is

- A study with no specific hypothesis.
- A small sample based in one culture with treatments given in four selected medical practices. A larger participant sample from a wider pool would avoid biases and support statistically based generalizations.
- A sample with a variation of OA sites. A study centering on a single OA site would provide a more even cohort.

- An open-label, two-group design, with no control for observational biases, natural history, or maturation.
- A treatment that includes rest, warmth, and relationship to the nurse and the researcher.

Discussion

This study extends previous qualitative research on topical ginger treatments that reported the warming and relaxing experience of topical ginger compresses (Therkleson, 2010b; Therkleson & Sherwood, 2004). The same procedure is used as with previous research of the ginger compress, while the manually prepared ginger compress is evaluated alongside a standardized ginger patch by using simple, brief SRQs. Results show the ginger patch worked as well as the compress, irrespective of medication taken, level of activity, and degree of severity of symptoms. Previous research for people with OA has shown the significance of relaxation and warmth physically and emotionally (Baird & Sands, 2006; Cantarini et al., 2007; Chen et al., 2010; Morone & Greco, 2007) and that chronic pain leads to difficulties with cognitive functioning and psychological well-being (Dohrenbusch, Buchanan, Lipka, & Ott, 2008; Mouchnino et al., 2005; Smith & Zautra, 2008). Results from this study are consistent with this research; participants prior to topical ginger treatments suffered extreme chronic pain, fatigue, exhaustion, and dissatisfaction with their health status.

Pain on movement is the primary symptom of OA, and pain is considered the most important category of body functionality in the International Classification of Function, Disability and Health (Stucki et al., 2002). This study showed a significant shift in pain symptoms by using the 10-cm VAS pain scoring daily for 21 days, and the MHAQ 7 days before and 7 days after therapy. Considering that a 30% reduction in pain on a VAS is meaningful, this study's results are notable (Kelly, 2001). Participants reported a reduction in chronic fatigue, dissatisfaction with health status, and overall global effect of OA, as well as pain and functional status. Topical ginger treatments are reportedly effective in managing chronic respiratory and metabolic problems as well as anxiety and depressive disorders (Fingado, 2012) and have no known side effects, which improves its profile over the use of nonsteroidal anti-inflammatory drugs, COX-2 inhibitors, and analgesics for people with OA. Topical ginger

is not found to have the negative effects of internal ginger administration for people with OA (Marcus & Suarez-Almazor, 2001) or the peripheral anesthesia caused by topical capsaicin (Dedov et al., 2002).

Caution must be used in considering these results as chronic pain is the one condition in which a statistically significant effect is observed when a placebo is used for patients with OA. Systematic reviews on the reported placebo effect in randomized control trials for patients with OA found that the placebo is very effective in treating self-report pain, stiffness, and functionality in patients with OA (Zeidler, 2011; Zhang, Robertson, Jones, Dieppe, & Doherty, 2008). Although this is an important factor, it needs to be considered alongside the results of this study, where participants reported a significant reduction in chronic fatigue, dissatisfaction with health status, overall global effect of OA, as well as analgesia, pain, and functional status.

In this study, the topical application of ginger was distal to the OA site, which suggests systemic absorption. The active ingredients of ginger (gingerols and shogaols) have a molecular weight of 150 to 190 Da, a lipophilicity log P range 3.5, and moderate solubility in water and oil, which allows good potential for skin penetration (Jolad et al., 2004; Minghetti et al., 2007). Studies on human skin using ginger extract show evidence of absorption. Ginger extract was absorbed in human epithelial tissue and inhibited COX-2 (Tjendraputra, Tran, Liu-Brennan, Roufogalis, & Duke, 2001), and Mingetti et al. (2007) found that a gingerol extract on a plaster was absorbed transdermally through human epidermis as well as having an effective anti-inflammatory response on mouse skin. Mingetti et al. conclude there would likely be an anti-inflammatory effect with the transdermal delivery of ginger.

Topical ginger treatments offer a novel approach to managing the debilitating symptoms of OA. The mechanism of action is likely a combination of increased warmth and relaxation, systemic absorption of the ginger, and the placebo effect resulting from receiving the intervention along with the opportunity to self-treat in the home.

Conclusion

Topical ginger on the mid-lumbar region is a simple treatment that has the potential to manage the complex range of symptoms experienced by people

with OA. Manually prepared compresses and standardized patches applied for 7 consecutive days decreased symptoms of pain and disability for 20 adults with OA. This positive response continued over the following 24 weeks, with self-treatment. Topical ginger treatments were found to improve the subdimensions of quality of life scores of physical function, pain, and health satisfaction and overall global effect of OA. The noninvasive nature of topical ginger avoids the risks of conventional medication and surgery and has the potential to delay and possibly negate the use of these more invasive treatments. This study advances previous qualitative studies on topical ginger for OA by using brief and simple SRQs. Although a small sample, the positive response warrants further controlled research with a larger and more even cohort.

The domain of topical ginger is those people with OA for whom existing treatments are unsatisfactory due to personal preference, complex comorbidities, and/or existing medication regimes. The wide range of symptoms, ongoing debilitating effect, and absence of a cure means people with OA are often prepared to consider a range of options, including alternative approaches. Topical ginger treatments are a convenient, simple, and economical option that needs to be considered in the care of the aged with OA.

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