

## 18. Symptoms and Signs

### Reference

Nakakita M, Takenoue K. Relaxing effects of back massage on relaxation in normal postpartum mothers\*. *Nihon Josan Gakkaishi (Journal of Japan Academy of Midwifery)* 2009; 22(3): 362 (in Japanese). Ichushi Web ID 2009204026

#### 1. Objectives

To evaluate the effects of back massage for relaxation in postpartum mothers.

#### 2. Design

Quasi-randomized controlled trial (quasi-RCT).

#### 3. Setting

Obstetrics and gynecology clinics (number of clinics not indicated), Japan.

#### 4. Participants

Forty-five puerperants at the third day after normal delivery.

#### 5. Intervention

Arm 1: a 20-minute massage using back oil (odorless) (n=22).

Arm 2: control (20-minute supine rest) (n=23).

No significant between-group differences in patient background including age, childbirth delivery time, blood loss, multiparous condition, episiotomy history, and baby's birth weight. Perineal tears were frequent in the control group with statistical significance.

#### 6. Main outcome measures

Heart rate and its frequency components analyzed as relaxation indicators.

#### 7. Main results

Treatment significantly decreased heart rate in both groups. Variability in frequency varied but did not change significantly.

#### 8. Conclusions

Considering heart rate and frequency components as relaxation indicators, back massage had no effect on postpartum mothers.

#### 9. Safety assessment in the article

Not mentioned.

#### 10. Abstractor's comments

Maintaining good physical and mental health in postpartum mothers is necessary for building good maternal bonds with the child, so evaluation of health maintenance strategies is extremely important. The relaxation indicator used in this study (heart rate or autonomic nervous function) can be affected by a range of factors, so the trial environment must be carefully managed. In future evaluations, it would be preferable to use subjective sensations, brain waves, and other outcome measures as relaxation indicators.

#### 11. Abstractor and date

Tokutake T, 19 December 2010, 28 February 2011.

## 18. Symptoms and Signs

### Reference

Kimura M, Watanabe E, Watanabe S, et al. Psychosomatic effects of aromatherapeutic hand and foot massage on healthy women using two kinds of essential oils\*. *Josei Shinshin Igaku (Journal of Japanese Society of Psychosomatic Obstetrics and Gynecology)* 2009; 14(1): 62. Ichushi Web ID 2009228467

#### 1. Objectives

To evaluate the efficacy of aromatherapeutic hand and foot massage (AM) using two kinds of essential oils.

#### 2. Design

Crossover randomized controlled trial (RCT - cross over).

#### 3. Setting

Not described, Japan.

#### 4. Participants

Sixteen healthy women.

#### 5. Intervention

Arm 1: massage with lavender and geranium (LA/GE) oils (n=16).

Arm 2: massage with peppermint and lemongrass (PE/LE) oils (n=16).

Arm 3: massage with carrier oil only (control) (n=16).

#### 6. Main outcome measures

Heart rate variation, electroencephalogram (EEG), salivary cortisol (CS) level, salivary IgA level, scores on psychological questionnaire (Profile of Mood States [POMS]/Mini Mental State [MMS] Examination).

#### 7. Main results

The heart rate variation high frequency (HF) value increased after AM with LA/GE, while the LF/HF values increased after AM with PE/LE. The EEG power percentage increased the most after AM with PE/LE. CS concentration decreased greatly after AM with LA/GE and after AM with PE/LE. Salivary IgA increased the most after AM with PE/LE. Although the scores for negative emotions in the psychological questionnaire increased after AM with LA/GE, scores for positive emotions increased after AM with PE/LE. Fatigue decreased the most after AM with PE/LE, while relaxation increased.

#### 8. Conclusions

A short period of aromatherapeutic hand and foot massage not only has psychological effects, it changes physiological indicators and, depending on the type of essential oil used, achieves various psychosomatic effects.

#### 9. Safety assessment in the article

Not mentioned.

#### 10. Abstractor's comments

Previous research has indicated that massage using essential oils has certain psychological and physiological effects: the significance of this study is that it used RCT methods and various stress markers to investigate the distinctive effects of particular oils. However, the design of this study employs the cross over method, and considering salivary indicator stimulus-response time,<sup>1</sup> it would appear that setting the interval between AM applications to 10 minutes was too short for an assessment of the differences between the effects of LA/GE and PE/LE. In addition to the lack of safety evaluation of the oils, neither the number of subjects in the control group nor the trial procedure was specified. The psychological and physiological effects of the AM massage itself, not just the essential oils, are considerable. Further evaluation using a design that takes those points into account would increase its scientific value.

<sup>1</sup> Kirschbaum C, Hellhammer DH. Salivary cortisol in psychobiological research: an overview. *Neuropsychobiology* 1989; 22: 150–69.

#### 11. Abstractor and date

Fujii R, 21 December 2010, 28 February 2011.

## 18. Symptoms and Signs

### Reference

Sato K, Ebata Y, Sayama S. A study of the relaxation effect of back massage in puerperants. *Bosei Eisei (Japanese Journal of Maternal Health)*. 2008; 49(3): 169 (in Japanese). Ichushi Web ID 2009035542

#### 1. Objectives

To evaluate the effects of back massage on relaxation in puerperant women.

#### 2. Design

Quasi-randomized controlled trial (Quasi-RCT).

#### 3. Setting

Obstetrics clinic, Japan.

#### 4. Participants

Fifty puerperant women on the first postpartum day (n=50, ages not described).

#### 5. Intervention

Arm 1: Jojoba oil massage group (10 minutes, n=25).

Arm 2: Control group (10 minutes of rest lying down, n=25).

#### 6. Main outcome measures

Blood pressure, pulse, salivary amylase activity, State-Trait Anxiety Inventory (STAI).

#### 7. Main results

- 1) There was a significant between-group difference in STAI state anxiety score but not in blood pressure, pulse, salivary amylase activity, or STAI trait anxiety score.
- 2) Salivary amylase activity decreased in both groups.

#### 8. Conclusions

Back oil massage decreases STAI state anxiety in puerperant women one day after delivery.

#### 9. Safety assessment in the article

Not mentioned.

#### 10. Abstractor's comments

The subject of this study is extraordinarily important. Yet, given that the authors indicate why puerperant women one day after delivery need relaxation and what relaxation methods are commonly used, they should have compared the target therapy to the commonly used methods and a control. Since the recruitment of 50 participants is a positive aspect of the study, this sample size could have been utilized in the study design. Since the study is an RCT, data from both groups should have been presented. The back oil massage techniques used in the study should be described. Furthermore, while the authors conclude that massage decreased state anxiety, the premises underlying the relation between relaxation and anxiety should be stated.

#### 11. Abstractor and date

Tokutake T, 9 December 2011.

## 18. Symptoms and Signs

### Reference

Furuya E, Kaneko Y, Uehara A, et al. The effects of press tack needle treatment and massage on elbow flexion and extension repetitions\*. *Zen Nihon Shinkyu Gakkai Zasshi (Journal of the Japan Society of Acupuncture and Moxibustion)* 2008; 58(3): 487 (in Japanese). Ichushi Web ID 2008280629

#### 1. Objectives

To evaluate the efficacy of press tack needle treatment and massage on elbow flexor low-load isotonic repetitions.

#### 2. Design

Crossover randomized controlled trial (RCT-cross over).

#### 3. Setting

Not described, Japan.

#### 4. Participants

Fifty healthy adult males.

#### 5. Intervention

Arm 1: press tack needle treatment (number of subjects not indicated).

Arm 2: sham treatment group (number of subjects not indicated).

Arm 3: massage treatment (number of subjects not indicated).

Arm 4: control (number of subjects not indicated).

#### 6. Main outcome measures

Maximal strength, number of repetitions, Visual Analog Scale (VAS) score for pain intensity.

#### 7. Main results

There was no significant difference in maximal strength among groups. The number of exercise 2 elbow flexion and extension repetitions was significantly higher in arm 1 than arm 2 ( $103.2 \pm 48.2$  vs  $80.9 \pm 34.9$ ;  $P < 0.01$ ). The numbers were similar in arm 3 ( $75.5 \pm 31.0$ ) and arm 4 ( $71.8 \pm 41.6$ ). There was no significant difference in VAS score between arm 1 and arm 2. It was significantly decreased ( $P < 0.01$ ) in arm 1 compared to arm 4.

#### 8. Conclusions

Press tack needle treatment facilitates performance of higher numbers of exercise repetitions, suggesting its potential in muscle training and rehabilitation.

#### 9. Safety assessment in the article

Not mentioned.

#### 10. Abstractor's comments

This study is interesting as it suggests that the use of neck and shoulder press tack needles increase exercise endurance and that brachial biceps massage reduces pain during elbow flexion and extension. This trial appears to have compared and verified the effectiveness of press tack needles in Arms 1 and 2, and the effectiveness of massage in Arms 3 and 4 by cross-over experiments; however, a clear description of the study design including the numbers of subjects in the intervention groups and the control group is needed. This may, however, be a limitation of structured abstracts. The effect of massage on endurance capacity was not ascertained in this trial, and thus remains an issue for future studies. More specifically, employing petrissage with gripping—which should have a greater effect on muscle circulation—as an intervention rather than minimal pressure effleurage, may have allowed for more accurate verification of the effects of massage. I hope that a future study focuses on massage, including the ideal interventions and stimuli.

#### 11. Abstractor and date

Fujii R, 21 December 2010, 28 February 2011.

## 18. Symptoms and Signs

### Reference

Ogai R, Matsumoto T, Kosaka M. Petrissage massage applied during resting period between two successive bouts of intense leg exercise improves performance during second bout. *Nihon Undo Seirigaku Zasshi (Journal of Exercise and Sports Physiology)* 2009; 16(1): 1–7 (in Japanese with English abstract). Ichushi Web ID 2009259007

#### 1. Objectives

To compare petrissage massage applied immediately after the first exercise bout and immediately before the second bout as a means of recovering from fatigue between two successive bouts of exercise.

#### 2. Design

Crossover randomized controlled trial (RCTcross over).

#### 3. Setting

Females from a university physical education department, who exercise regularly, Japan.

#### 4. Participants

Eleven healthy females.

#### 5. Intervention

Arm 1: massage group (immediately after exercise, n=11).

Arm 2: massage group (immediately before exercise, n=11).

Arm 3: control group (resting seated, n=11).

#### 6. Main outcome measures

Mechanical power output, lower-limb fatigue, muscle stiffness.

#### 7. Main results

Mechanical power output increased significantly under Arm 1 and Arm 2 conditions ( $P < 0.05$ ). VAS scores increased for lower-limb fatigue with the first exercise bout, but at 15 minutes after massage in Arm 1, it decreased significantly in comparison to other conditions. Muscle stiffness increased after the first exercise bout, but 15 minutes after exercise it decreased significantly in Arm 1 only ( $P < 0.05$ ), and at 30 minutes after exercise, it decreased significantly with Arm 1 and Arm 2 in comparison to the control group ( $P < 0.05$ ).

#### 8. Conclusions

Petrissage massage improved exercise performance, muscle stiffness, and lower-limb fatigue, but its timing does not affect subsequent exercise performance.

#### 9. Safety assessment in the article

Not mentioned.

#### 10. Abstractor's comments

The material on petrissage massage is detailed and describes the involvement of expert practitioners. Use of a control group (rest) helped confirm that the effects were due to petrissage massage. While objective outcome indicators including blood lactate and muscle stiffness were measured, it appears that changes in muscle stiffness are linked to lower-limb fatigue, yet the changes in blood lactate level are difficult to explain. Some consideration has been given to psychological factors, but there is no data, so no conclusions can be made. If psychological factors are included in a future study, the protocols would need to incorporate objective data, and markers such as psychological parameters (subjective) and stress.

#### 11. Abstractor and date

Tsukayama H, 27 December 2010, 18 March 2011.

## 18. Symptoms and Signs

### Reference

Nishida T, Tachiyama R, Ping PY, et al. Effects of back massage for pain caused by prolonged lying in prone position. *Nihon Kango Gakkai Ronbunshu Kango Sogo (Japanese Nursing Association Articles – General Nursing)*. 2006; 37: 182–4 (in Japanese). Ichushi Web ID 2007145532

#### 1. Objectives

To evaluate the effectiveness of massage for mid and low back pain caused by prolonged lying in the prone position.

#### 2. Design

Crossover randomized controlled trial (RCT–cross over).

#### 3. Setting

Nursing laboratory at a university (university name not specified), Japan.

#### 4. Participants

Nine average adult females during the low temperature phase of the menstrual cycle (age range: 21–23 years).

#### 5. Intervention

The trial was run in a laboratory with the temperature at  $27.2\pm 0.9^{\circ}\text{C}$  and humidity at  $58.2\pm 5.6\%$ . After lying in the prone position for 20 minutes, participants received massage of the low back, mid back, neck, and shoulders for 5 minutes, and were then instructed to stay in the prone position for a further 60 minutes. Participants in the control group stayed in the prone position for 85 minutes.

Arm 1: Massage group (number of participants not specified).

Arm 2: Control group (no treatment, number of participants not specified).

#### 6. Main outcome measures

Electrocardiogram (heart rate variability), brain waves, and visual analogue scale (VAS) scores for comfort, pain intensity, and low/mid back pain intensity.

#### 7. Main results

1) Brain waves: the amount of  $\alpha_1$  and  $\alpha_2$  waves, which increase with relaxation, was significantly greater at the time of massage and 30 minutes after massage compared to the control group. However, no significant difference was found in the amount of  $\delta$  or  $\theta$  waves, which increase with drowsiness, or  $\beta_1$  or  $\beta_2$  waves, which increase when alert.

2) Heart rate variability: low frequency (LF), high frequency (HF), and LF/HF, which reflect sympathetic and parasympathetic activity, showed no significant difference.

3) Subjective evaluation: Comparing scores before and after lying in the prone position, comfort showed a significant increase in the massage group compared to the control group, while low/mid back pain intensity decreased significantly in the massage group.

#### 8. Conclusions

Low/mid back massage is an effective intervention for relieving pain and for relaxing patients who lie in the prone position for prolonged periods.

#### 9. Safety assessment in the article

Not mentioned.

#### 10. Abstractor's comments

The study objectively demonstrates that massage effectively reduces pain intensity and relieves low/mid back pain caused by prolonged lying in the prone position. Hopefully it will be integrated into the care of patients forced to lie in the prone position for long periods, for example, after retinal detachment surgery. The study is of great interest to those seeking to improve the quality of nursing care. The integrity of the design is high: the low/mid back pain model, the massage treatment, and the outcome evaluation methods are well devised. The study cannot, however, be rated as a high quality randomized controlled trial, because of the small sample size, the failure to specify the numbers of subjects in the massage or control groups and failure to specify the method of allocation. In addition, no change was observed in heart rate variability, which correlates with brain wave findings ( $\alpha$  wave increase), suggesting that issues remain around the parameter settings for capturing parasympathetic activity. Yet, the study has great significance in that its support of the effectiveness of massage is based on brain wave findings as well as subjective evaluation. Hopefully the authors will verify their results through clinical practice and will further deepen and develop their study into research which can build up qualitative evidence of patient satisfaction.

#### 11. Abstractor and date

Fujii R, 3 December 2011.

## 18. Symptoms and Signs

### Reference

Nagata H, Tanaka E, Takefu M, et al. Effects of Lower Limb and Dorsolumbar Massages on Edema in Postpartum Women, *Biomedical Soft Computing and Human Sciences* 2009; 14(1): 109–15. Ichushi Web ID 2010097338

#### 1. Objectives

To compare the effects of dorsolumbar and lower-limb massage on edema in postpartum women.

#### 2. Design

Crossover randomized controlled trial (RCT-cross over).

#### 3. Setting

Obstetrics clinics in Kumamoto City, Japan.

#### 4. Participants

Women who had given birth 2–5 days previously.

#### 5. Intervention

Arm 1: lower limb massage (n=9).

Arm 2: dorsolumbar massage (n=10).

#### 6. Main outcome measures

Circumference (lower limb, big toe), cutaneous blood flow (tibialis anterior muscle), lower limb volume.

#### 7. Main results

Both groups showed reduction in the lower limb volume as well as the circumference of the lower leg and big toe, and an increase in the cutaneous blood flow in the tibialis anterior muscle.

#### 8. Conclusions

Lower limb and dorsolumbar massage with elevation of the lower limbs both reduce lower limb edema.

#### 9. Safety assessment in the article

Not mentioned.

#### 10. Abstractor's comments

The evaluation used objective measures, which compensates for the weakness in the study design that the patients were not masked to the group or treatment assignment. Regrettably, the evaluator was also not masked to the group or treatment assignment, which would have given the data even greater reliability. In both groups, lower limb edema was effectively reduced. However, both groups also employed 30-minute lower limb elevation, so it is difficult to determine whether the improvement was due to the massage or the lower limb elevation. Overcoming these difficulties and masking the evaluator could be expected to achieve results of even higher reliability.

#### 11. Abstractor and date

Tsukayama H, 27 December 2010, 18 March 2011.

## 21. Others

### Reference

Tonegawa Y, Uchizaka S, Takemura E, et al. Changes in leg skin temperature after foot bath — Comparison of the effects of massage and no massage\*. *Nagano Sekijūji Byōin Ishi (Medical Journal of Nagano Red Cross Hospital)*. 2004; 17: 116–8 (in Japanese). Ichushi Web ID 2004208587

#### 1. Objectives

To evaluate heat retention effectiveness of massage immediately after foot bath.

#### 2. Design

Randomized controlled trial (RCT).

#### 3. Setting

Nagano Red Cross Hospital, Japan.

#### 4. Participants

Six healthy adults (age range: 20 to 21 years, mean age not described).

#### 5. Intervention

Arm 1: Massage group. Combination of massage and footbath (n=3, mean age not specified).

Arm 2: No-massage group. Footbath alone (n=3, mean age not specified).

#### 6. Main outcome measures

Skin temperature measured by infrared thermography.

#### 7. Main results

1) All skin temperature measurements (up to 5 hours after treatment) at the toes (third toe) and anterior surface of the leg were elevated by foot baths in both groups. Third-toe skin temperatures (°C) at rest and at 5 hours after treatment were 18.4 and 21.1, 18.1 and 24.3, and 19.7 and 28.3, respectively, in the three Arm 1 participants and 22.0 and 24.2, 20.3 and 24.1, and 20.8 and 22.6, respectively, in the three Arm 2 participants. Similarly, the anterior leg surface temperatures (°C) were 28.6 and 32.5, 27.2 and 30.7, and 28.6 and 32.2 in Arm 1 and 31.4 and 33.1, 30.8 and 32.8, and 31.0 and 32.1 in Arm 2. The sample size was too small for statistical analysis.

2) A stronger heat-retention tendency was found in Arm 1 than Arm 2.

#### 8. Conclusions

Massaging the feet for 10 minutes after a foot bath tends to improve heat retention.

#### 9. Safety assessment in the article

Not mentioned.

#### 10. Abstractor's comments

This study investigates the heat retention effects of combining foot bath with massage, and is commendable for having investigated the effects up to 5 hours after a foot bath. However, sample size (only three participants per group) is insufficient for definite outcomes. In addition, the authors should have had the no-massage group keep their legs horizontal for 10 minutes, to control for the effect of treatment in the horizontal in the massage group. Furthermore, simultaneous measurement of skin blood flow and temperature at nearby sites would have increased the reliability of the study.

#### 11. Abstractor and date

Ogata A, 12 December 2011



## 21. Others

### Reference

Ichida K, Ye H, Ogura Y, et al. A comparison of full-body Anma and local Anma — Using skin temperature and deep temperature as indicators\*. *Nihon Shugi Ryoho Gakkai Zasshi (The Journal of Japanese Association of Manual Therapy)*. 2004; 15(1): 13–7 (in Japanese). Ichushi Web ID 2006259812

#### 1. Objectives

To evaluate the effects of full-body massage and unilateral upper-limb Anma on peripheral circulation.

#### 2. Design

Crossover randomized controlled trial (RCT – cross over).

#### 3. Setting

Acupuncture and Physical Therapy Teacher Training School, University of Tsukuba, Ibaraki, Japan.

#### 4. Participants

Thirteen healthy adult males (mean age: 29.4±5.7 years).

#### 5. Intervention

Anma included effleurage, petrissage, and pressure in the prone position.

Arm 1: Full-body Anma group (20 minutes, excluding upper limb on one side, n=13).

Arm 2: Unilateral upper limb Anma group (20 minutes, n=13).

Arm 3: Control group (resting in the prone position, 20 minutes, n=13)

#### 6. Main outcome measures

Hand skin temperature and deep temperature, blood pressure, heart rate.

#### 7. Main results

Skin temperature increased in both hands with full-body Anma and in only the hand on the side treated with unilateral upper-limb Anma. There were no significant changes in hand deep temperature, blood pressure, or heart rate.

#### 8. Conclusions

Full-body Anma increases skin temperature in both hands, but unilateral upper-limb Anma increases skin temperature in only the hand on the treated side.

#### 9. Safety assessment in the article

Not mentioned.

#### 10. Abstractor's comments

This is an interesting trial that compared the effectiveness of full-body and local Anma. However, the study failed to pay sufficient attention to reproducibility: the Anma techniques are described only as effleurage, petrissage, and pressure. While temperature data are used as an indicator of peripheral circulation, room temperature settings or records are not mentioned. The authors attribute the change in skin temperature to an effect on sympathetic nerve function, but they also have good grounds for attributing the lack of any significant difference in blood pressure or heart rate to data collection timing, something that should also be considered in terms of design.

#### 11. Abstractor and date

Fujii R, 9 December 2011.

## 21. Others

### Reference

Wada T, Usuda Y, Fukushima M, et al. Does sole pressure stimulation increase low back skin temperature? Comparison of the effects of sole stimulation with low back stimulation on low back skin temperature\*. *Nihon Shugi Ryoho Gakkai Zasshi (The Journal of Japanese Association of Manual Therapy)*. 2004; 15(1): 18–22 (in Japanese). Ichushi Web ID 2006259813

#### 1. Objectives

To compare and verify low back skin temperature responses to pressure stimulation at the sole and low back.

#### 2. Design

Crossover randomized controlled trial (RCT–cross over).

#### 3. Setting

Not described, Japan.

#### 4. Participants

Sixteen healthy adult males (mean age 29.9±5.4 years).

#### 5. Intervention

Arm 1: Sole stimulation group (n=16, mean age not specified).

Arm 2: Low back stimulation group (n=16, mean age not specified).

#### 6. Main outcome measures

Infrared thermography, thermocouple.

#### 7. Main results

Right sole stimulation significantly increased skin temperatures of the low back (areas A, B, C;  $P<0.05$ , or  $P<0.01$ , or  $P<0.001$ ), buttocks, popliteal area, and sole (left/right) ( $P<0.01$  or  $P<0.001$ , or  $P<0.001$ ). Low back (medial edges of L5 erector spinae muscles) stimulation significantly increased skin temperatures of the low back (areas A, B, C, D, E;  $P<0.05$ , or  $P<0.01$ , or  $P<0.001$ ), buttocks, popliteal area, and sole (left/right;  $P<0.01$ , or  $P<0.001$ ).

The effect of sole stimulation differed from that of low back stimulation in only two parts of the body: skin temperature in the low back (area E) was significantly increased by low back stimulation, while skin temperature of the left sole (treatment side) was significantly increased by sole stimulation. There was no significant difference in effects on skin temperatures of other parts of the body.

#### 8. Conclusions

Pressure stimulation to the sole and low back increases skin temperature in the low back and leg, not only in the stimulated areas, suggesting that another factor besides the spine has that effect.

#### 9. Safety assessment in the article

Not mentioned.

#### 10. Abstractor's comments

While this trial was conducted according to a systematic protocol, skin temperature increases were observed from the low back to the sole after pressure stimulation at the low back and sole, which suggests the possibility that a systemic response was triggered, and therefore there is a need to measure upper body skin temperature. In addition, outcome measures including autonomic indicators, such as blood flow should be added, if the authors are to observe the specific effects of low back and sole stimulation.

#### 11. Abstractor and date

Ogata A, 17 December 2011.

## 21. Others

### Reference

Ueda N, Maruta T, Uno I. Trial of aromatherapy for dialysis patients – A strategy for discomfort\*. *Yodogawa Christian Byoin Gakujutsu Zasshi (Y.C.H. Medical Bulletin)* 2004; 17–9 (in Japanese). Ichushi Web ID 2005292837

#### 1. Objectives

To evaluate the efficacy of aromatherapy for treating discomfort due to dialysis.

#### 2. Design

Crossover randomized controlled trial (RCT–cross over).

#### 3. Setting

Kidney clinic (Yodogawa Christian Hospital), Japan.

#### 4. Participants

Forty-three patients undergoing dialysis three times per week at a kidney clinic.

#### 5. Intervention

Arm 1: Aromatherapy oil group (7 males, 8 females, mean age 62, dialysis 21 months, n=15).

Arm 2: Olive oil group (8 males, 5 females, mean age 64, dialysis 16 months, n=13).

Arm 3: Control (no treatment) group (no oil; 9 males, 6 females, mean age 65, dialysis 17 months, n=15).

Approximately eight minutes of massage, mainly of the lower limbs, three times per week for one week.

#### 6. Main outcome measures

Questionnaire, 4-point scale discomfort assessment.

#### 7. Main results

(1) Limb itchiness ( $P=0.001$ ), puncture site itchiness ( $P=0.012$ ), and soreness due to restricted movement during dialysis ( $P=0.000$ ) improved in Arm 1 after massage. Lower limb coldness ( $P=0.041$ ) and soreness due to restricted movement during dialysis ( $P=0.002$ ) decreased in Arm 2.

(2) There was no significant change in any measure in Arm 3.

(3) Total score for discomfort in Arm 1 was significantly different ( $P<0.05$ ) after treatment from that in Arm 2 and Arm 3.

#### 8. Conclusions

Aromatherapy oil massage relieves discomfort in dialysis patients.

#### 9. Safety assessment in the article

Not mentioned.

#### 10. Abstractor's comments

Assessment of discomfort in dialysis patients has important clinical implications. There is a need to evaluate the efficacy of aromatherapy massage for relief of discomfort. The trial is commendable for systematically comparing the aromatherapy oil group, the oil group to an olive oil group and control group. However, the authors do not mention whether the same masseur was used, so that point is unclear. The authors need to investigate the influence of communication during massage and the use of aromatherapy oil alone.

#### 11. Abstractor and date

Ogata A, 24 December 2010, 18 March 2011.

# Appendix 6

**Evidence Reports of  
Korean Medicine Treatment 2010:  
132 Randomized Controlled Trials  
(EKOM 2010)**

**The Special Committee for EBM  
The Korean Oriental Medical Society (KOMS)**

**25 December 2011**

## Executive Summary

The Korean Oriental Medical Society (KOMS) launched the Special Committee for EBM in March 2010 as a way to establish the foundations for evidence-based Korean Medicine.

This publication is intended to present the English structured abstracts of 132 of randomized controlled trials (RCTs) of Korean Medicine treatment from “Geungeojungsimui Hanuichiryo” (근거중심의 한의치료, Evidence Korean Medicine Treatment, Koonja Publishing Inc., 2011) which contains 306 abstracts of studies including non-RCT design.

[http://www.koonja.co.kr/shop/goods/goods\\_view.php?goodsno=13970](http://www.koonja.co.kr/shop/goods/goods_view.php?goodsno=13970)

The data sources of searches were 1) The Cochrane Library (CENTRAL); 2) Pubmed; 3) the database offered by Korea Institute of Oriental Medicine (KIOM, <http://oasis.kiom.re.kr>); and 4) homepage of 17 academic societies related to Korean Medicine.

Each structured abstract consists of 8 items in accordance with global standards, i.e., objectives; design; setting; participants; intervention; main outcome measures; main results; and conclusion, and 3 additional items, i.e., safety assessment in the article; abstractor’s comments; and abstractor’s name and date.

Structured abstracts were arranged in the order used in the International Statistical Classification of Diseases and Related Health Problems 10th Revision (ICD10).

We would appreciate your comments on compilation method, the contents of the structured abstracts, information on references not included in the reports, if any, and other matters.

Please send your comments to the follows:

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kihocho58@gmail.com (Ki-Ho Cho)

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## 1. Project Background

Against its long history and tradition, Korean Medicine faces difficulty in standardizing and evaluating its effectiveness and safety, due to its diverse school of thoughts and their way of diagnosing. Moreover, Korean Medicine as a discipline gets criticized for the lack of scientific evidence.

While in Japan, the Special Committee for Evidence Based Medicine of the Japan Society for Oriental Medicine (JSOM) published its first report “EBM in Kampo 2002, Internal report (*Nihon Toyo Igaku Zasshi (Journal of Japanese Oriental Medicine)* 2002; 53(5), supplement issue) in September 2002,. Since then it has been actively publishing the reports, including the “Evidence Report of Kampo Medicine Treatment: 345 Randomized Controlled Trials” (EKAT 2010, <http://www.jsom.or.jp/medical/ebm/index.html> )

There have been no such activities within Korean Medicine. Thus, in March 2010, the Korean Oriental Medical Society (KOMS) launched the Special Committee for EBM as a way to establish the foundations for evidence-based Korean Medicine.

This is the first attempt in Korea of its kind. Over numerous trial and errors, we have made progress but there still is more up ahead. It is our hope that this effort serves as a stepping stone for further improvement as the committees become more active.



## 2. The Special Committee for EBM, Korean Oriental Medical Society (KOMS)

The Special Committee for EBM was launched in March 2010. A total of 12 members were appointed, i.e., 11 clinicians (Korean Medical Doctor: KMD) and 1 EBM expert, under the headship of its chair, Professor Ki-Ho Cho (Kyung Hee University). Its original purpose was to collect good Korean Medicine clinical papers, analyze and publish “Geungeojungsimui Hanuichiryo” (근거중심의 한의치료, Evidence Report of Korean Medicine Treatment, Koonja Publishing Inc., 2011) which contains 306 abstracts of studies including non-RCT design.

### Chairman

Ki-Ho CHO	KMD, PhD	Internal medicine
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### Vice chairman

Jin-Sung KIM	KMD, PhD	Internal medicine
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### Committee members

Ho-Yeon GO	KMD, PhD	Internal medicine
Jong-In KIM	KMD, PhD	Acupuncture and moxibustion
Ho-Jun KIM	KMD, PhD	Rehabilitation
Hae-Jung NAM	KMD, PhD	Ophthalmology, otolaryngology & dermatology
Myeong -Soo LEE	PhD	Evidence based medicine
Byung-Cheol LEE	KMD, PhD	Internal medicine
Eui- Ju LEE	KMD, PhD	Sasang constitution medicine
Gyu-Tae JANG	KMD, PhD	Pediatrician
Seong-Hun CHO	KMD, PhD	Neuropsychiatry
Jung-Hoon CHO	KMD, PhD	Gynecology

## 3. International activities of the Special Committee for EBM, KOMS

The Special Committee for EBM, Korean Oriental Medicine Society (KOMS) increased academic exchanges with the Special Committee for EBM, Japan Society for Oriental Medicine (JSOM) .

First, Special Committee for EBM, KOMS translated EKAT 2010 compiled by the Special Committee for EBM, JSOM into Korean and published it under the name

“근거중심의 한방처방” (Geungeojungsimui Hanbangcheobang, 拠中心の漢方処方).  
Koonja Publishing Inc., in July 2011.

[http://www.koonja.co.kr/shop/goods/goods\\_view.php?goodsno=13267](http://www.koonja.co.kr/shop/goods/goods_view.php?goodsno=13267)

As second phase, thru the joint efforts between the Special Committee for EBM, KOMS and Dr. Kiichiro Tsutani (Chief Investigator, Projec of Systemaic Review of Efficacy, Safety and Efficiency of Traditional East Asian Medicine, funded by Health and Labour Sciences Research Grants of Japan (fiscal year 2010-2011) and Dr. Koki Tsuruoka (Research Contributor of the same) from Japan, the traing workshop on evidence-based medicine (EBM) was held on 19 July 2010 in Seoul, Republic of Korea. The methods of developing Evidence Repor of Kampo Treatment (EKAT) were introduced and discussions were made. Later, several meetings were held by the Special Committee for EBM, KOMS to develop Korean system. It was decided to develop Evidence Reports of “good” studies of Koream Medicine including both RCTs and non-RCTs, which will lead evidence-based Korean medicine, in Korean and translate RCT parts of it into English. The 132 RCTs were identified and translated as “Evidence Report on Korean Medicine Treatment 2010” (EKOM 2010).

#### **4. Study collection and search strategy**

##### **(1) Principles for collection of studies**

A certain principles were needed for selecting for “good” studies . Members of the Sepcial Committee deliberated and set the following principles:

First is clinical trial papers on human subjects written by Korean Oriental Medical doctors.

Second is the selction of journals. For domestic journals, we used only journals registered or to-be-registered with Hangugyeongujaedan (한국연구재단, the Korea Research Foundation, <http://www.nrf.re.kr/html/kr/>) for maintaining quality. Both online and manual searches on papers from each journal, from the first issue to present issue, were conducted. As for online search, each society’s homepage and traditional medical information portals (<http://oasis.kiom.re.kr>) were utilized.

For papers in international journals,. PubMed and the Cochrane Library (CENTRAL), were searched. Hand search period was from the first issue of the journal to the March/2010 issue.

##### **(2) Selectin of domestic journals**

A total of 17 domestic Korean Medicine journals which are published by KOMS and by subspecialty societies under KOMS were searched as listed in **Table 1**

**Table 1 Searched domestic academic journals related to Korean Medicine and number of papers**

Domestic Academic Journals related Korean Medicine	Number of Papers
<i>Journal of Korean AM-Meridian &amp; Pointology Society</i> 大韓經絡經穴學會誌	430
<i>Journal of Korean Oriental Association for Study of Obesity</i> 韓方肥滿學會誌	130
<i>Journal of Korean Oriental Medical Ophthalmology &amp; Otolaryngology &amp; Dermatology</i> 大韓韓方眼耳鼻咽喉皮膚科學會誌	705
<i>Journal of Korean Oriental Medicine</i> 大韓韓醫學會誌	2,195
<i>Journal of Korean Oriental Oncology</i> 大韓癌韓醫學會誌	125
<i>Journal of Korean Oriental Pediatrics</i> 大韓韓方小兒科學會誌	558
<i>Journal of Korean Pharmacopuncture Institute</i> 大韓藥鍼學會誌	356
<i>Journal of Oriental Medical Thermology</i> 大韓韓方體熱醫學會誌	46
<i>Journal of Oriental Neuropsychiatry</i> 大韓韓方神經精神科學會誌	503
<i>Journal of Oriental Rehabilitation Medicine</i> 韓方再活醫學科學會誌	640
<i>Journal of Sasang Constitutional Medicine</i> 四象體質醫學會誌	789
<i>Korean Journal of Oriental Internal Medicine</i> 大韓韓方內科學會誌	1,370
<i>Korean Journal of Oriental Physiology and Pathology</i> 大韓東醫生理病理學會誌	1,985
<i>The Journal of Korean Acupuncture &amp; Moxibustion Society</i> 大韓鍼灸學會誌	1,695
<i>The Journal of Oriental Chronic Diseases</i> 大韓韓方成人病學會誌	180
<i>The Journal of Oriental Obstetrics &amp; Gynecology</i> 大韓韓方婦人科學會誌	899
<i>The Korean Journal of Joongpoong</i> 大韓中風學會誌	27

### (3) Search strategy

To reduce error and increase accuracy, we conducted electronic search and manual search. And 12,653 academic papers were scollated electronically and manually from the first issue of journals to March 2010. For electronic search, each society's homepage and traditional medical

information portals, Jeontonguihakjeongbo portal (전통의학정보포털, 傳統醫學情報 portal, <http://oasis.kiom.re.kr>) were mainly utilized.

Both Pubmed and The Cochrane Library CENTRAL) were searched for international journal papers until June 2010. A total of 41 clinical trial papers were found. Search strategy appears in Table 2.

**Table 2 Search strategy in PubMed and the Cochrane library CENTRAL until June 2010**

Search Terms		Result	Result Related to KOM*
PubMed	Korea and Oriental (Limit: clinical trial, human, Complementary medicine)	54	37
	Korea and Oriental (Clinical trial, ) Human (Limit: clinical trial, human)	60	33
	Korea and (Korean medicine or Oriental medicine) (Limit: clinical trial, human)	428	37
The Cochrane Library	Korea and Oriental	37	
Total			41

\* KOM: Korean Oriental Medicine

#### (4) Paper selection process

Quality assessment and paper selection of the domestic 12,653 papers and international 41 papers, total 12697 papers was conducted. Result is showed in Fig. 1

After first screening excluding in vivo, in vitro and literature review, 11,690 studies were excluded and 1,004 clinical study papers were obtained.

As second screening, each members of the Committee selected papers which are reliable, quality and and with practical value, and 666 studies were excluded, then 338 studis obtained.

As third screeing, 32 were identified as dulplaction, etc, and 306 were obtained. Structured abstracts were developed.

Finally, 306 papers were classified into 8 study design categories after much deliberation and discussion among the Committee members. Results are shown in Table 3. Among these, 132 RCTs papers (116 domestic papers and 16 international papers) were selected and translated into the English language.