Appendices

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Appendix A

Philosophical context of clinical epidemiology design in this thesis

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Philosophical context of clinical epidemiology design in this thesis

Research questions included in this thesis

1. What is the effect of relaxation techniques for treating perimenopausal and postmenopausal symptoms?
2. What is the effect of applied relaxation (AR) technique for treating perimenopausal and postmenopausal symptoms when compared with its modified version and how do they compare?
3. What is the effect of Modified relaxation (MR) technique for treating hypertension in postmenopausal women when compared with controls who do not practice MR?

Research titles for publication

Study I

Relaxation for perimenopausal and postmenopausal symptoms.

Study II

Effectiveness of a modified version of the applied relaxation technique in treatment of perimenopausal and postmenopausal symptoms.

Study III

Modified relaxation technique for treating hypertension in Thai postmenopausal women.

1. Theoretical design

1.1 A systematic review of interventions

The first research question is under a philosophical context of a systematic review and meta-analysis of interventions. The purpose is to collate all empirical evidence that fits pre-specified eligibility criteria in order to answer a specific research question. Systematic methods are used to select research articles with a view to minimize bias by providing more reliable findings from which conclusions can be drawn and decisions can be made.[1, 2] The key characteristics of a systematic review are:

- pre-defined clearly stated eligibility criteria for included studies;
- an explicit, reproducible methodology;
- searching strategies attempt to identify all studies that would meet the eligibility criteria;
- validity of the findings of the included studies are assessed for the risk of bias; and
- synthesis and presentation of the characteristics and findings of the included studies.

The intervention effect estimate is calculated as a weighted average of the intervention effects estimated in the individual studies. A weighted average is defined as:

$$\text{weighted average} = \frac{\text{sum of (estimate x weight)}}{\text{sum of weight}} = \frac{\sum y_1 w_1}{\sum w_1}$$

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1.1.1 Relaxation for perimenopausal and postmenopausal symptoms

This study is a systematic review for intervention research. The objective was to determine the effectiveness of relaxation techniques as a treatment for vasomotor symptoms and sleep disturbances in perimenopausal and postmenopausal symptoms. The outcomes of this study were the frequency and intensity of hot flushes, night sweats, and sleep disturbances. There were 4 studies met inclusion criteria

1.2 A randomized clinical controlled trial

A randomized controlled trial (RCT) is a quantitative cohort study; comparative, controlled experiments in which investigators study two or more interventions in a group of individuals who receive them in random order. An RCT is one of the simplest and most powerful tools in clinical research to determine the effect of an exposure on outcome(s).[3, 4] Usually the occurrence relation or causal effect of the RCT study is

Outcome (y) = f(cause x I confounders)

The second and the third studies in this thesis were under a philosophical context of an RCT research. An RCT research is an experimental comparison study in which participants are allocated to treatment/intervention or control/placebo groups, using a random mechanism. An RCT, with its unbiased distribution of confounders, blinding, and randomization, is the best method to study the effect of an intervention because it facilitates statistical analysis. The objective of an RCT research is to determine the exposure(s) on the outcome(s).

The aim of the first RCT was to compare Apply Relaxation (AP) technique with its modified version (MR) in the treatment of menopausal symptoms (hot flushes, night sweats, and sleep disturbances). This design was an equivalence clinical trial. The aim of the second RCT was to compare the effect of MR with controls (who received only health education) on blood pressure control in postmenopausal women with mild hypertension.

1.2.1 Effectiveness of a modified version of the applied relaxation technique in treatment of perimenopausal and postmenopausal symptoms

The theoretical design of this study was under a philosophical context of a randomized controlled trial, as described above. Outcomes of this study were the frequency and intensity of three menopausal symptoms, i.e., hot flashes, night sweat, and sleep disturbances. An occurrence relation can be summarized as

Symptom severity = f(intervention I confounders)

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The participants of this study consisted of 71 (36 women in the AR group and 35 women in the AR group, respectively) menopausal women.

1.2.2 Modified relaxation technique for treating hypertension in Thai postmenopausal women

The theoretical design of this study was under a philosophical context of a randomized controlled trial, as described above. Outcomes of this study were the changes in systolic and diastolic blood pressure. An occurrence relation can be summarized below.

Blood pressure = f(intervention I confounders)

The participants of this study consisted of 432 (215women in the MR group and 217 women in the control group, respectively) Thai postmenopausal women with mild hypertension.

2. Data collection design

2.1 Study setting and period

The systematic review conducted a search of primary articles from all over the world. Searches of the following electronic bibliographic databases were performed to identify randomized controlled trials (RCTs): Cochrane Menstrual Disorders and Subfertility Group Specialized trials register; Cochrane Library (CENTRAL) (Wiley Internet interface), MEDLINE (Ovid), EMBASE (Ovid), PsycINFO (Ovid), Science Citation Index and Social Science Citation Index (Web of Science), CINAHL (Ovid). Hand searches of relevant journals and published conference abstracts were performed; LILACS, Clinical Study Results, PubMed, and OpenSIGLE for grey literature reports in Europe, using the same search terms. Searches included dates up to January 21st, 2013.

Two randomized controlled trials in this thesis were conducted at the Menopausal Clinic, Mahasarakham Provincial Hospital. These studies were carried out between July 2011 and May 2012.

Study design

Study I

The data collection and design of the first study was a systematic review and meta-analysis of interventions. Articles were included if they compared any type of relaxation interventions with no treatment or other treatments (except hormones) for vasomotor symptoms in symptomatic perimenopausal/postmenopausal women. RCTs and crossover randomized controlled trials were included if there was an assessment of vasomotor symptoms, night sweats and sleep disturbances. Participants included perimenopausal and postmenopausal women, either natural or surgically-induced menopause, regardless of ethnicity. Studies were excluded if participants received hormone therapy three months or more before randomization. We included all studies irrespective of the presence of other

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menopausal signs and symptoms before randomization.

The outcomes were the frequency and intensity of hot flashes, night sweats, and sleep disturbance. Information on attrition rate, adverse effects, and quality of life assessment using a valid questionnaire were also included.

Study II

The data collection and design for this randomized controlled trial was a prospective interventional study, as described in the theoretical design. The study compared modified relaxation (MR) with applied relaxation (AR) over a 12-week period on the frequency and intensity of three menopausal symptoms (hot flashes, night sweats, and sleep disturbances) in perimenopausal and postmenopausal women.

The inclusion criteria were women, aged 45–65 years, with irregular menstruation within the previous 12 months or those with either surgical or spontaneous menopause.

The exclusion criteria were women who received any hormone therapy in the 3 months before the study, and those who had uncontrolled hypertension (>95 mmHg diastolic pressure) or used sedatives, tranquilizers, or antidepressant medication on a daily basis.

Women visiting the clinic were questioned about their experiences of hot flashes, night sweats, or sleep disturbances. Potential participants underwent a medical examination by an attending gynecologist at the menopause clinic. Participants rated their symptoms subjectively using a severity rating scale, and those with a global severity score $\geq$5 were invited to participate in the study.

Participants, who were allocated to AR group, received 12 sessions of weekly training. In the MR group, they received one session of modified relaxation training, lasting 60 minutes. Both groups were asked to practice relaxation techniques at home for 15-20 minutes daily. The physical therapist contacted participants by telephone weekly to answer any relevant questions and to encourage daily practice.

The outcomes were determined at 4, 8, and 12 weeks after the start of the intervention, by measuring changes in the frequency and severity of hot flashes, night sweats, and sleep disturbances from baselines.

Study III

The data collection and design of study III was a prospective interventional study, as described in the theoretical design. The study compared the efficacy MR technique with lifestyle education in controlling blood pressure in Thai postmenopausal women with mild hypertension over a 16-week period.

The inclusion criteria were postmenopausal women, aged 45–65 years, who had mild hypertension (HT), defined as a systolic blood pressure (SBP) of 140–159 mmHg or a diastolic blood pressure (DBP) of 90–99 mmHg.

The exclusion criteria were women using antihypertensive medications, sedatives, tranquilizers, or antidepressants during the previous 2 months before the study, and those with language or geographic barrier.

Participants in the MR group received health education and a single 60-minute training session on breathing control, muscle stretching and releasing control, and how to focus

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attention on certain part or whole body. Participants were encouraged to practice MR at home for 15–20 minutes daily for at least 5 days a week. The control group received 30 minutes of health education and educational leaflets from a research nurse. The education covered diet, exercise, and smoking/alcohol cessation.

Both groups received phone calls from their physical therapist at 2, 4, 6, 8, 10, 12, and 14 weeks after the intervention to answer any relevant questions and to encourage continued home practice. Participants visited the menopausal clinic at 4, 8, 12, and 16 weeks to have their blood pressure measured, using the same digital sphygmomanometer and procedure.

The primary and secondary outcomes were the changes in systolic and diastolic blood pressure, respectively.

3. Data analysis design

3.1 A systematic review of intervention

Study I

This study is a systematic review and meta-analysis of intervention to determine the effectiveness of relaxation techniques as a treatment for vasomotor symptom, night sweats and sleep disturbances in perimenopausal and postmenopausal women. The pool analysis was performed as followed

Step 1: Developed a plan for systematic review by defining clear clinical questions and goals, study population, inclusion and exclusion criteria, key literature search terms and explored the literature, and reviewed the grading system for the systematic review.

Step 2: Literature search using the key words defined in the development plan. A literature search was conducted using numerous electronic library databases.

Step 3: Selecting articles that met inclusion criteria. Two independent reviewers assessed abstracts and categorized them for inclusion/exclusion from the review.

Step 4: Assessment of bias risk in included studies

Step 5: Two independent reviewers extracted and stored data in standardized worksheets.

Step 5: Created tables of evidence to facilitate analysis and grading of the evidence.

Step 6: Assessed treatment effect for dichotomous outcomes. The number of events in the control and intervention groups of included studies was used to calculate Peto odds ratios. For continuous outcomes, the mean difference between the control and intervention groups was calculated, if outcomes were measured in the same way across different trials.

Step 7: Assessed heterogeneity among the trials in each analysis, using the I^2statistic.

Step 8: Assessed reporting biases by ensuring a comprehensive search for eligible studies and by checking for duplication of publication.

Step 9: Data synthesis using a fixed-effect model, inverse variance meta-analysis to combine data where trials examined the same intervention and their populations and methods were judged to be sufficiently similar.

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3.2 A randomized controlled trial

Study II

The severity of menopausal symptoms was measured using a global rating scale, which represented a sum of severity scores of hot flashes, night sweats, and sleep disturbances. The severity of each symptom was subjectively rated using a five-point Likert scale, from 0 ("not at all") to 4 ("extremely"). The global rating scale scored from 0 to 12.The number of hot flashes and night sweat was measured as frequency per 24 hours, and sleep disturbances as the number of episodes per week.

The analysis was conducted on an "intention-to-treat" basis, with all participants included. Descriptive statistics were used to summarize baseline demographics and clinical characteristics of participants. Chi-square ($\chi 2$) and Student's *t*-tests were used to compare dichotomous and continuous outcomes between the two groups, respectively. The Wilcoxon rank-sum test was used to assess differences in rating scale variables. A *P*-value of <0.05 (two-tailed) was set to indicate statistical significance.

Study III

The mean differences in systolic and diastolic blood pressure from baselines between the two groups throughout the study period were calculated and compared, using multilevel mixed-effect modeling for repeated measures, adjusting for treatment time, and baseline values as covariates. This assumed there was a therapeutic effect for treatment and time, but that it varied between individuals. Analysis was done on the basis of intention-to-treat. Missing data were assumed to occur at random, and a last observation carried forward (LOCF) method was used to estimate individual missing values.

Differences between groups were compared using chi-square, Mann–Whitney *U* (*Z*), and Student's *t* tests for data that were dichotomous, ordinal, and scale data, as appropriate. A significant difference was set at *P*<0.05 (two-tailed).

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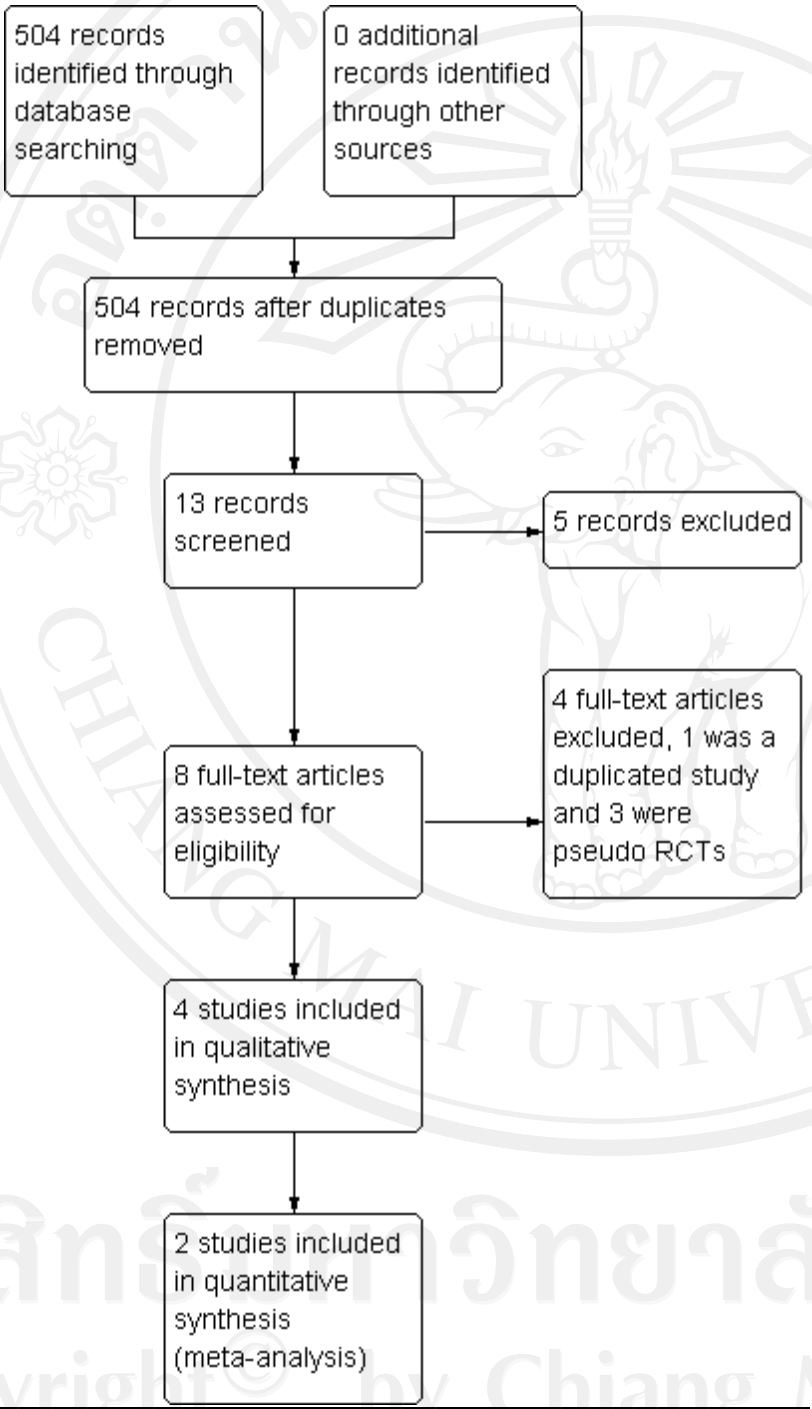
2.4 Study flow

Study I



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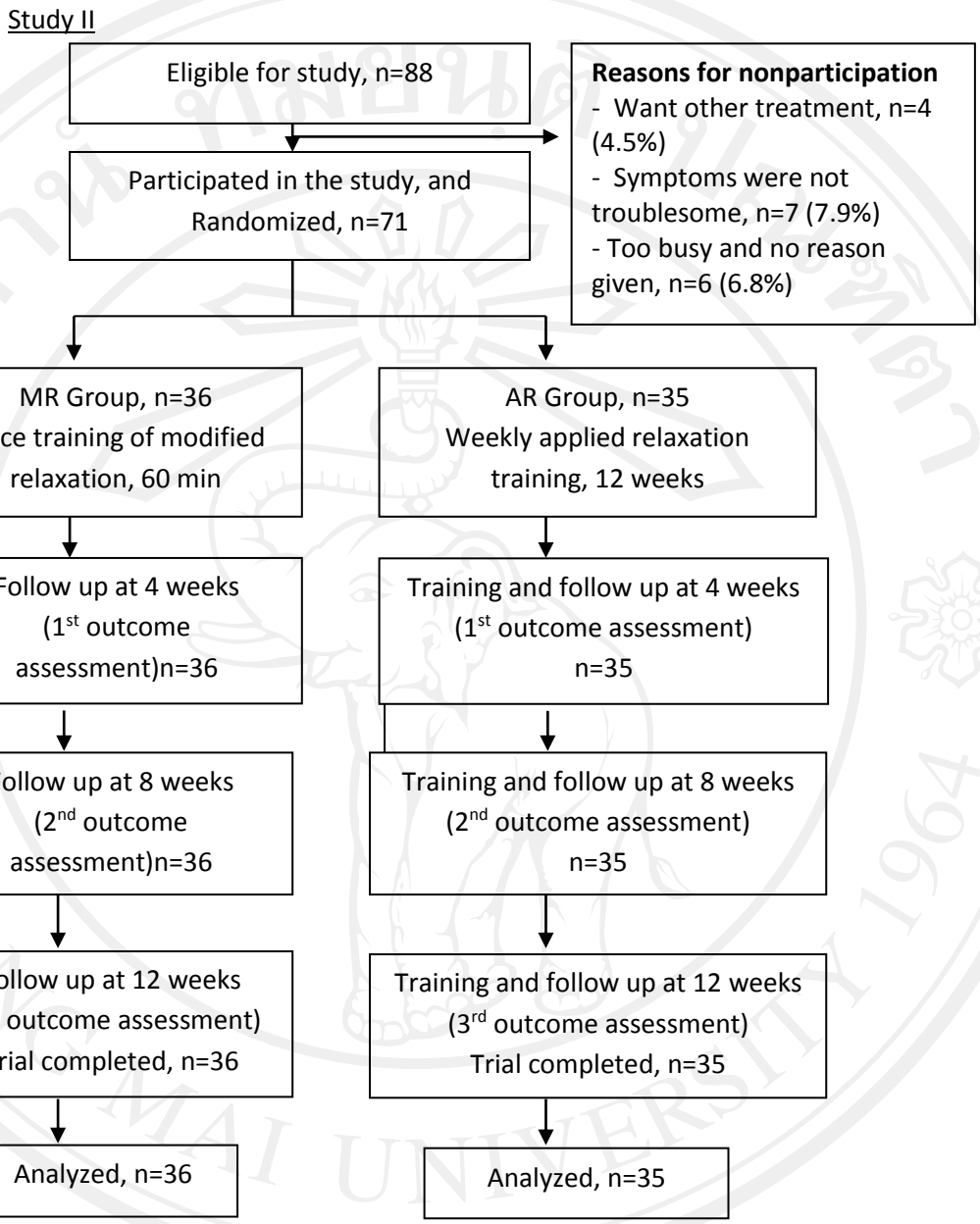

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References

1. Antman EM, Lau J, Kupelnick B, Mosteller F, Chalmers TC. A comparison of results of meta-analyses of randomized control trials and recommendations of clinical experts: Treatments for myocardial infarction. JAMA 1992;268:240-48.
2. Oxman AD, Guyatt GH. The science of reviewing research. Annals of the New York Academy of Sciences 1993;703:125-33.
3. Patumanond J. Clinical Epidemiology:Theoretical Concepts. 1st ed. Bangkok, Thailand: Amarin Printing & Publishing Public Company Limited 2011.
4. Patumanond J. Clinical Epidemiology:Integrated Concepts. 1st ed. Bangkok, Thailand: Amarin Printing & Publishing Public Company Limited; 2011.

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Appendix B

Saensak S, Vutyavanich T, Somboonporn W, Srisurapanont M. Relaxation for perimenopausal and postmenopausal symptoms. Cochrane Database of Systematic Reviews 2013, Issue 7. Art. No.: CD008582. DOI: 10.1002/14651858.CD008582.pub2.

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Relaxation for perimenopausal and postmenopausal symptoms (Review)

Saensak S, Vutyavanich T, Somboonporn W, Srisurapanont M

This is a reprint of a Cochrane review, prepared and maintained by The Cochrane Collaboration and published in *The Cochrane Library* 2014, Issue 7

http://www.thecochranelibrary.com

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[Intervention Review]

Relaxation for perimenopausal and postmenopausal symptoms

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ABSTRACT

Background

Since the time of publication of the Women's Health Initiative (WHI) study, menopausal symptom management has become more complex because of increased awareness of the risks associated with hormone replacement therapy (HRT). Currently, a wide range of management options is available. Some women take prescription drugs, and others use self care strategies, including lifestyle modifications, over-the-counter preparations and complementary and alternative therapies, such as herbal preparations, exercise programmes and relaxation techniques. Relaxation techniques consist of a group of behavioural interventions. They are considered relatively harmless, but their effectiveness in treating vasomotor symptoms and sleep disturbances remains debatable.

Objectives

To determine the effectiveness of relaxation techniques as treatment for vasomotor symptoms and associated sleep disturbances in perimenopausal and postmenopausal women.

Search methods

Searches of the following electronic bibliographic databases were performed in February 2014 to identify randomised controlled trials (RCTs): the Cochrane Menstrual Disorders and Subfertility Group Specialised Trials Register; the Cochrane Central Register of Controlled Trials (CENTRAL), MEDLINE, EMBASE, AMED, PsycINFO, Social Science Citation Index and CINAHL. Handsearches of trial registers, relevant journals and published conference abstracts were also performed.

Selection criteria

RCTs were included if they compared any type of relaxation intervention with no treatment or other treatments (except hormones) for vasomotor symptoms in symptomatic perimenopausal/postmenopausal women.

Data collection and analysis

Two review authors selected studies, assessed quality and extracted data. Included studies were combined, if appropriate, by using a random-effects model to calculate pooled mean differences and 95% confidence intervals.

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Main results

Four studies were eligible for inclusion (281 participants): Two studies compared relaxation with electroacupuncture or superficial needling, one study compared relaxation with paced respiration or placebo control (α-wave electroencephalographic biofeedback) and one study compared relaxation with no treatment.

No evidence was found of a difference between relaxation and acupuncture or superficial needle insertion in the number of hot flushes per 24 hours (mean difference (MD) 0.05, 95% confidence interval (CI) -1.33 to 1.43, two studies, 72 participants, I^2 = 0%; very low-quality evidence). Nor did any evidence suggest a difference between the two interventions in hot flush severity, measured using the Kupperman Index (MD -1.32, 95% CI -5.06 to 2.43, two studies, 72 participants, I^2 = 0%; very low-quality evidence).

The other two studies found no clear evidence of a difference in hot flush frequency between relaxation and paced respiration, placebo or no treatment. The data for these comparisons were unsuitable for analysis.

None of these studies reported night sweats, sleep disturbances associated with night sweats or adverse effects as an outcome.

The main limitations of identified evidence were lack of data, imprecision and failure to report study methods in adequate detail.

Authors' conclusions

Evidence is insufficient to show the effectiveness of relaxation techniques as treatment for menopausal vasomotor symptoms, or to determine whether this treatment is more effective than no treatment, placebo, acupuncture, superficial needle insertion or paced respiration.

PLAIN LANGUAGE SUMMARY

Relaxation for perimenopausal and postmenopausal symptoms

Review question: We wanted to discover whether relaxation techniques were better or worse than other interventions, such as acupuncture, in the management of menopausal symptoms. We reviewed the evidence on the effects of these techniques on hot flushes, night sweats and sleep disturbances in menopausal women.

Background: Management of menopausal symptoms, such as hot flushes, depressed mood or sleep disturbances, has become more complicated because of increased awareness of the risks associated with hormone replacement therapy (HRT). Options include prescription drugs and self care strategies such as relaxation techniques. Relaxation techniques are thought to be relatively harmless, but their effectiveness in treating hot flushes and sleep disturbances remains unclear.

Study characteristics: We found four randomised controlled studies, with 281 participants. Relaxation was compared with electroacupuncture, superficial needling, paced respiration, placebo and no treatment. The age range of participants was 30 to 77 years. These trials were conducted in Sweden, the UK and the USA. No study was funded by an agency with commercial interest in the results of the study. The evidence is current to February 2014.

Key results: Evidence is insufficient to show the effectiveness of relaxation techniques as treatment for menopausal vasomotor symptoms, or to determine whether this treatment is more effective than no treatment, placebo, acupuncture, superficial needle insertion or paced respiration. No evidence indicates that relaxation reduces the number of hot flushes per 24 hours or their severity. None of the studies reported night sweats, sleep disturbances associated with night sweats or adverse effects as an outcome.

Quality of the evidence: The quality of the evidence was very low. The main limitations of identified evidence included lack of data, imprecision and failure to report study methods in adequate detail.

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SUMMARY OF FINDINGS FOR THE MAIN COMPARISON *[Explanation]*

Relaxation compared with acupuncture for hot flushes

Population: perimenopausal and postmenopausal women with vasomotor symptoms
Intervention: relaxation
Comparison: acupuncture or superficial needling

Outcomes	Illustrative comparative risks* (95% CI) Relaxation versus acupuncture or superficial needling	Relative effect (95% CI)	No. of participants (studies)	Quality of the evidence (GRADE)	Comments
Change in number of hot flushes/24 h (follow-up: 12 weeks)	Mean frequency of hot flushes per 24 hours in the relaxation group was 0.05 lower	1.33 to 1.43	72 (2)	⊕◯◯◯ very low quality[1,2]	
Improvement in severity of hot flushes (follow-up: 12 weeks)	Mean hot flush severity score in relaxation group was 1.32 points lower on a 1 to 16 scale	-5.06 to 2.43	72 (2)	⊕◯◯◯ very low quality[1,2]	
Adverse effects	This outcome was not reported				

*The basis for the **assumed risk is** the median control group risk across studies. The **corresponding risk** (and its 95% confidence interval) is based on the assumed risk in the comparison group and the **relative effect** of the intervention (and its 95% CI).
CI: Confidence interval.

GRADE Working Group grades of evidence.
High quality: Further research is very unlikely to change our confidence in the estimate of effect.
Moderate quality: Further research is likely to have an important impact on our confidence in the estimate of effect and may change the estimate.
Low quality: Further research is very likely to have an important impact on our confidence in the estimate of effect and is likely to change the estimate.
Very low quality: We are very uncertain about the estimate.

[1]Very serious imprecision: small sample size, confidence intervals compatible with substantial benefit from either intervention or with no effect.
[2]Studies did not report adequate details about methods used.

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BACKGROUND

Description of the condition

Reduced oestrogen levels during the menopause contribute to menopausal symptoms (NIH 2005). The major systems affected are the endocrine, reproductive and central nervous systems (WHO 1996; STRAW 2000). It is estimated that 85% of menopausal women report at least one symptom, such as hot flushes, depressed mood or sleep disturbances (McKinlay 1992). The prevalence of menopausal symptoms varies widely and may be influenced by a range of factors, including climate, diet, lifestyle, women's roles and attitudes regarding the end of reproductive life and aging (McKinlay 1992; Freeman 2007). Many women seek treatment for vasomotor symptoms (hot flushes, night sweats) and sleep disturbances (McKinlay 1992; Fauci 1997; Guthrie 2003; McMillan 2004). Severe types of hot flushes commonly cause sleep disruption (Speroff 2000) and are strongly or moderately linked to the menopause (NIH 2005). Peak prevalence of hot flushes occurs during the late menopausal transition (the so-called late perimenopause in several studies) and during early post menopause (Mathews 1990; Holte 1992; Kaufert 1992; Dennerstein 2000; Freeman 2001; Gold 2004; Williams 2008). According to Straw et al, perimenopause is defined as about or around menopause (STRAW 2000). The prevalence of vasomotor symptoms has been reported to be as high as 79% in perimenopausal women and 65% in postmenopausal women. Women with daily vasomotor symptoms had an average of 2.5 very mild, 2.5 mild, 2.6 moderate, 2.5 severe and 1.4 very severe episodes of daytime hot flushes in a typical day. Women with night sweats had an average of 2.4 moderate, 3.2 severe and 2.7 very severe episodes of night sweats in a typical night (Williams 2008).

Several studies have shown that elevated sympathetic activation, acting through central alpha$_2$-adrenergic receptors, contributes to the initiation of hot flushes (Bruck 1980; Freedman 2005). Hot flushes are triggered by small elevations in core body temperature (Bruck 1980; Freedman 2005), and clonidine was found to consistently and significantly reduce flush frequency (Freedman 2005). Moreover, one study showed that injection of yohimbine, an alpha$_2$-adrenergic antagonist that raises the levels of brain norepinephrine, provoked hot flushes in symptomatic women; injection of clonidine, an alpha$_2$-adrenergic agonist that reduces brain norepinephrine, ameliorated them (Goldberg 1994). These data suggest that elevated sympathetic activation, acting through central alpha$_2$-receptors, plays a role in the initiation of hot flushes. A steep decline in oestrogen levels during the menopause is probably involved because oestrogens can modulate the receptors (El-Mas 2004). It is generally believed that hot flushes produce arousals and awakenings from sleep. Many epidemiological studies have confirmed the presence of sleep disturbances during the menopausal transition (Speroff 2000; Barton 2001; Celik 2002; Celentano 2003; Freedman 2004).

Description of the intervention

A variety of treatments for menopausal symptoms have been studied in randomised controlled trials (RCTs) (ERTA 2005; NIH 2005). Oestrogen plus progestin is the standard treatment, and oestrogen alone is used if the woman has had a previous hysterectomy. Such therapies, commonly known as hormone replacement therapy (HRT), were widely prescribed for menopausal women for many years. After publication of the Women's Health Initiative (WHI) study, a marked global decline in the use of HRT occurred, probably as the result of increased awareness of associated risks (NAMS 2004). Combined, continuous HRT significantly increased the risk of venous thromboembolism or a coronary event (after one year's use), stroke and gallbladder disease (after three years' use) and breast cancer (after five years' use) (Marjoribanks 2012). Long-term oestrogens-only HRT also significantly increased the risk of stroke and gallbladder disease (Marjoribanks 2012). Therefore, decisions on how to treat menopausal symptoms require a balance between possible risks and benefits (NIH 2005; Mosconi 2009). Progestin only shows mixed results for the amelioration of vasomotor symptoms (Hickey 2005). A few trials reported no significant difference between testosterone plus oestrogens and oestrogen alone in the treatment of severe hot flushes, vaginal dryness or sleep problems (ERTA 2005). Alternative treatments that have been investigated include antidepressants, isoflavone and other phyto-oestrogens, botanicals, acupuncture and behavioural interventions (ERTA 2005; NIH 2005). Relaxation techniques, a behavioural intervention, appear to reduce sympathetic activity (Hjemdahl 1989; Lee 1989) while lowering blood pressure. This effect may be explained by reduced plasma norepinephrine levels (Hjemdahl 1989).

Cognitive techniques (Payne 2005) include (1) self awareness, a process of awareness of the real self apart from the body, tribulations, emotions and excitement. This technique begins with cessation of body movement and control of the limbs, speech and sense organs; (2) imagery, the creation of a mental picture of a safe, peaceful, restful, beautiful and happy place or event; (3) goal-directed visualisation, the discovery of one's emotional and spiritual balance to fulfil goals; (4) autogenic training, involving the production of a profound state of physical relaxation, bodily health and mental peace by creating a feeling of warmth and heaviness throughout the body; and (5) meditation, a process selected to calm down a busy mind. Relaxation techniques (Payne 2005) include (1) Jacobson progressive relaxation, which requires an understanding of neural physiology to calm down the mind and nervous system; (2) a modified version of Jacobson progressive relaxation, known as Bernstein and Borkovec's version, which involves the number and duration of training sessions, the duration of muscle tension and release and the use of suggestion to facilitate relaxation; (3) Everly and Rosenfeld's passive relaxation, which focuses on muscle relaxation; (4) Madder release, which employs mainly physical exercise to relax both the mind and the body; (5) Ost's applied relaxation, which involves the use of rapid

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relaxation whenever symptoms appear (Ost 1987); (6) Poppen's behavioural relaxation training, which stresses the use of different self control techniques appropriate for each environmental stress; (7) the Mitchell method, which involves a physiological technique of relieving stress-induced muscle tension by relaxing the whole or a part of the body; (8) the Alexander technique, which helps a person discover a new balance in the body by re-educating the mind and body to release unnecessary tension; and (9) Benson's relaxation response, which involves repetition of a word, sound, prayer or muscular activity to oppose the fight-or-flight response. Refocusing on repetition when other thoughts intrude is a determining factor that influences cognitive behaviour.

This review concentrated on the use of relaxation techniques for the treatment of menopausal symptoms. These relaxation techniques were based on physiological principles of somatic or cognitive relaxation, or both. Two well-known somatic relaxation techniques for vasomotor symptoms are paced respiration (slow, controlled diaphragmatic breathing) and muscle relaxation. The most common forms of muscle relaxation are progressive muscle relaxation and passive muscle relaxation (Benson 2000).

How the intervention might work

It has been suggested that relaxation techniques effectively reduce muscle sympathetic activity and venous norepinephrine concentrations, leading to lower blood pressure (Hjemdahl 1989; Lee 1989). Paced respiration and muscle relaxation reduce the frequency and intensity of hot flushes through a similar mechanism (Germaine 1984; Freedman 2005; Nedstrand 2005), thus minimising discomfort (NAMS 2004) and sleep disturbances. Many clinical trials have suggested that paced respiration, applied relaxation and progressive relaxation are beneficial in treating menopausal symptoms (Germaine 1984; Freedman 1992; Hunter 1996; Irvin 1996; Wijma 1997; NAMS 2004; Freedman 2005; Nedstrand 2005). However, no systematic review with meta-analysis has been conducted on this topic.

Why it is important to do this review

Since the time of publication of the WHI study, menopausal symptom management has become more complex because of increased awareness of the risks associated with HRT (NAMS 2004). Since 1992, women have used a wide range of alternative options. Some take prescription drugs, and others use self care strategies, such as lifestyle modifications, over-the-counter preparations, complementary and alternative therapies including herbal preparations and exercise programmes (McKinlay 1992; Bair 2002). Relaxation is an alternative method of treating vasomotor symptoms, but its effectiveness remains debatable. In this review, we aim to ascertain the effectiveness of relaxation techniques in treating hot flushes, night sweats and sleep disturbances compared with no treatment or other treatments, except hormonal therapy.

OBJECTIVES

To determine the effectiveness of relaxation techniques as treatment for vasomotor symptoms and associated sleep disturbances in perimenopausal and postmenopausal women.

METHODS

Criteria for considering studies for this review

Types of studies

Randomised controlled trials (RCTs) and cross-over RCTs that included assessment of vasomotor symptoms and sleep disturbances. In the case of cross-over trials, we planned to use only pre-cross-over data. Quasi- or pseudo-RCTs were excluded from the review.

Types of participants

Perimenopausal and postmenopausal women and women during or after natural or surgically induced menopause, regardless of ethnicity. They were not to have received any HRT for a minimum of three months before randomisation. We included all studies irrespective of the presence of other menopausal signs and symptoms before randomisation.

Types of interventions

Trials were included if they compared any type of relaxation intervention with no treatment or other treatments, except hormonal therapy. Any dosage or duration of relaxation intervention was included. No restriction was placed on who delivered the intervention (medical doctors, primary health practitioners, physical therapists, health promotion agencies or researchers). Interventions not involving any type of relaxation were excluded. Studies in which both arms received hormonal treatment were eligible.

Types of outcome measures

Primary outcomes

Primary outcomes

Frequency and intensity of:

1. hot flushes;
2. night sweats; and

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3. sleep disturbance in association with night sweats.
Outcomes were required to be measured and scored by validated questionnaires.

Secondary outcomes

4. Attrition rate.
5. Adverse effects.
6. Quality of life assessment using a valid questionnaire.

Search methods for identification of studies

We searched for all published and unpublished RCTs of relaxation for perimenopausal and postmenopausal symptoms, without language restriction and in consultation with the Menstrual Disorders and Subfertility Group (MDSG) Trials Search Co-ordinator. The study flow diagram is summarised in Figure 1.

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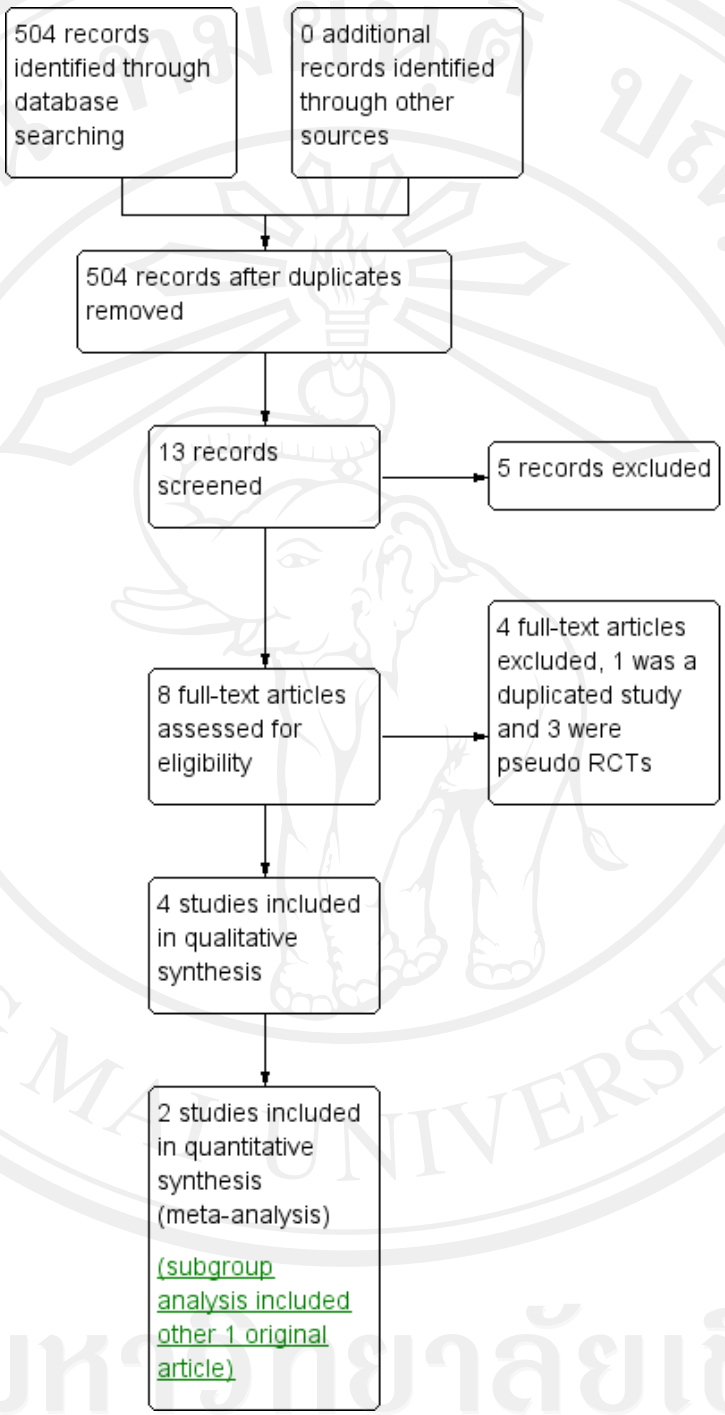
Figure 1. Study flow diagram.



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Electronic searches

Searches were based on text words and index terms (Appendix 1). Searches of the following electronic bibliographic databases were performed to identify RCTs: the Cochrane Menstrual Disorders and Subfertility Group Specialised Trials Register, the Cochrane Central Register of Controlled Trials (CENTRAL, part of *The Cochrane Library*) (Wiley Internet interface) (Appendix 2), MEDLINE (Ovid) (Appendix 3), EMBASE (Ovid) (Appendix 4), the Allied and Complementary Medicine Database (AMED) (Appendix 5) and PsycINFO (Ovid) (Appendix 6). Information about ongoing trials and recently completed studies was obtained by searching the National Research Register (NRR), Current Controlled Trials and ClinicalTrials.gov. The last search date was 19 February 2014.

Searching other resources

Handsearches of relevant journals and published conference abstracts were performed; the authors also searched the Latin American and Caribbean Health Science Information Database (LILACS), PubMed and the Open System for Information on Grey Literature in Europe (OpenSIGLE), using the same search terms. Relevant review articles were searched and experts were contacted for information on additional trials. Published reviews of relaxation interventions and menopausal symptoms were used as sources of studies. Reference lists of identified studies were checked for additional citations.

Data collection and analysis

Data collection and analysis were conducted in accordance with the *Cochrane Handbook for Systematic Reviews of Interventions* (Higgins 2011).

Selection of studies

Two review authors (SS and WS) independently selected reports potentially fulfilling the inclusion criteria of this review based on the titles and abstracts. Disagreements were resolved through discussion. Authors of the original reports were contacted to obtain further details if the articles contained insufficient information. A reminder was sent if no response was received after three weeks.

Data extraction and management

Two review authors (SS and WS) independently extracted data by using a data extraction form designed by the review authors. When disagreements were not resolved by consensus, other review authors (TV and MS) were consulted to resolve the discrepancies. Trial ID and names and contact details of authors of the full articles were recorded. In addition, the date and method of query to the study authors (e.g. by phone) and their responses were recorded. This process was undertaken for all trials, regardless of their inclusion or exclusion from the review. For each included trial, information was collected regarding the location of the trial, the quality of the trial and the risk of bias, participant characteristics (age range, eligibility criteria, menopausal status, natural vs surgically induced menopause), baseline characteristics of treatment groups, the nature of the interventions (types of therapies, mode of administration, doses administered and duration of treatment) and data related to outcomes, for example, body mass index, well-being score, menopausal symptoms and hormonal profiles. Information on reported benefits and adverse effects (if available) was also collected. Data were checked for accuracy and were entered into the Review Manager software (RevMan 2012).

Assessment of risk of bias in included studies

Two review authors (SS and WS) independently used the Cochrane risk of bias assessment tool to evaluate sequence generation; allocation concealment; blinding of participants, providers and outcome assessors; completeness of outcome data; selective outcome reporting; and other sources of bias. Disagreements were resolved through discussion or by consultation with a third review author (TV). The conclusions were summarised in a risk of bias table (Figure 2; Figure 3).

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Figure 2. Methodological quality summary: review authors' judgements about each methodological quality item for each included study.

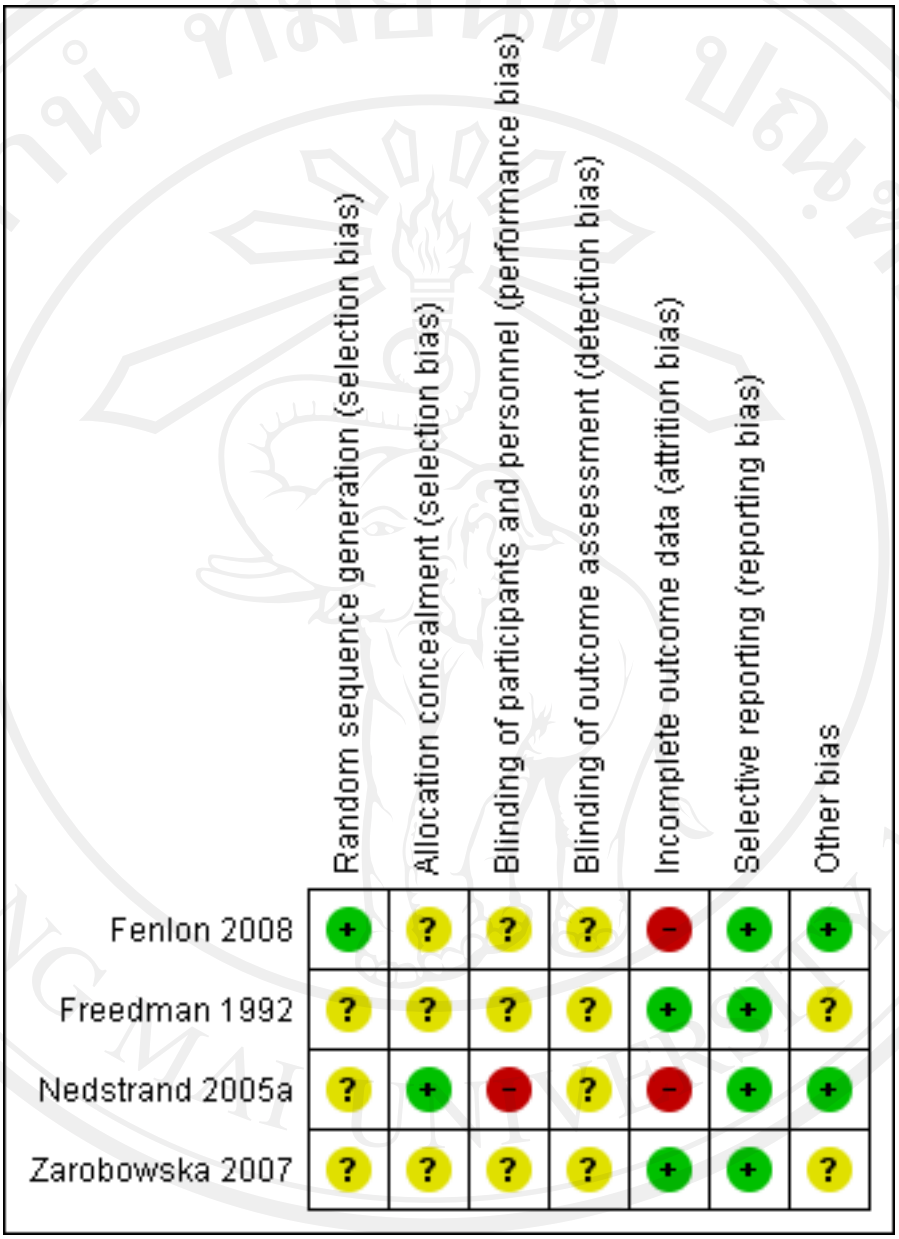

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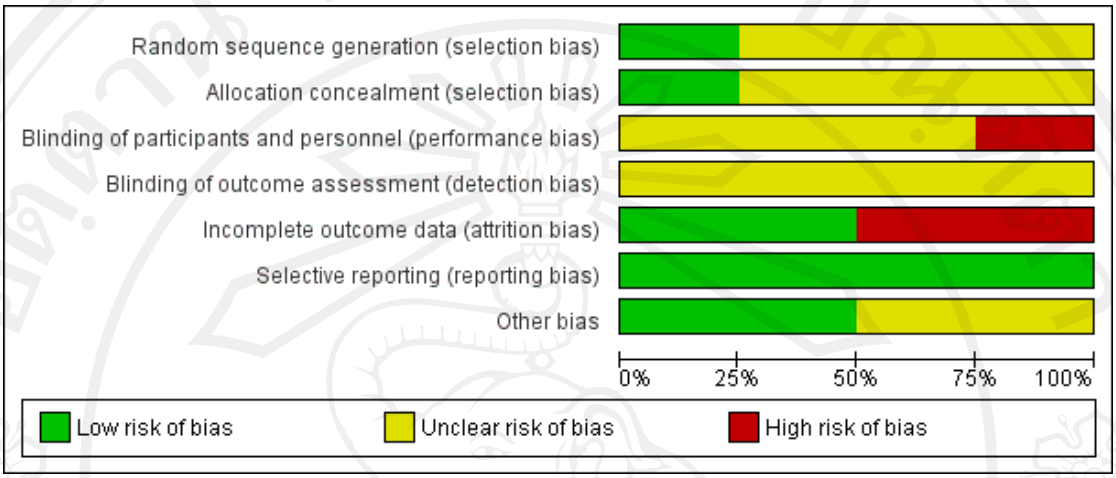
Figure 3. Methodological quality graph: review authors' judgements about each methodological quality item presented as percentages across all included studies.



Measures of treatment effect

For dichotomous outcomes, the numbers of events in control and intervention groups of included studies were used to calculate Peto odds ratios. For continuous outcomes, the mean difference (MD) between control and intervention groups was calculated, if outcomes were measured in the same way across different trials. We planned to use standardised mean difference (SMD) if the outcomes were reported on different scales. Confidence intervals (CIs; 95%) were presented for all outcomes and comparisons.

Unit of analysis issues

The analysis was conducted "per woman randomised."

Dealing with missing data

For included studies, levels of attrition were noted. The impact of including studies with high levels of missing data in the overall assessment of treatment effect was explored by using sensitivity analysis. For all outcomes, analyses were carried out, as far as possible, on an intention-to-treat basis, that is, we were attempting to include in the analyses all participants randomly assigned to each group. The denominators for each outcome in each trial represented the number randomly assigned minus any participants whose outcomes were known to be missing.

Assessment of heterogeneity

We considered whether the clinical and methodological characteristics of the included studies were sufficiently similar for meta-analysis to provide a clinically meaningful summary. We used the I^2 statistic to measure heterogeneity among the trials in each analysis. If we identified substantial heterogeneity, that is, above 50%, we planned to explore it by performing a prespecified subgroup analysis.

Assessment of reporting biases

In view of the difficulty of detecting and correcting for publication bias and other reporting biases, the review authors aimed to minimise their potential impact by ensuring a comprehensive search for eligible studies and by staying alert for duplication of data. If 10 or more studies were included in an analysis, we planned to use a funnel plot to explore the possibility of small-study effects (i.e. a tendency for estimates of the intervention effect to be more beneficial in smaller studies).

Data synthesis

We carried out statistical analysis using Review Manager software (RevMan 2012). We used a fi xed-effect model inverse variance meta-analysis to combine data when trials examined the same in-

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tervention and their populations and methods were judged sufficiently similar. In the event of substantial clinical, methodological or statistical heterogeneity, we did not combine study results by means of metaanalysis but instead summarised them in narrative form.

This review will be updated every two years or whenever new RCTs are published.

Subgroup analysis and investigation of heterogeneity

If sufficient studies were available, we planned to conduct the following subgroup analyses for the primary outcomes.

1. Perimenopause or postmenopause.
2. Type of relaxation technique.
3. Severity of symptoms at baseline.
4. Studies with hormonal treatment as a co-intervention versus those without.

Sensitivity analysis

We planned to perform sensitivity analyses to explore the influence of various factors on effect size by (1) repeating the analysis while excluding unpublished studies; (2) repeating the analysis while taking account of study quality, in particular, studies with adequate treatment concealment and double-blinding; (3) repeating the analysis by excluding very long or large studies to establish how much they dominate the results; and (4) repeating the analysis by excluding studies using the filter of language of publication, source of funding (industry vs other) or country.

However, too few studies were identified to allow meaningful sensitivity analysis.

RESULTS

Description of studies

See Characteristics of included studies and Characteristics of excluded studies.

Results of the search

A total of 504 potentially relevant references were identified and screened (Figure 1). In all, 491 references were excluded on the basis of titles and abstracts. Only 13 references were retrieved for more detailed evaluation. Five were considered not suitable for inclusion in the review, as they were commentaries, observational studies or reviews. After risk of bias assessment was performed, three more publications were excluded, as they were pseudo-RCTs.

Included studies

Study design

Four studies met the eligibility criteria (Freedman 1992; Nedstrand 2005a; Zarobowska 2007; Fenlon 2008). Two trials were done in Sweden (Nedstrand 2005a; Zarobowska 2007), one in the UK (Fenlon 2008) and one in the USA (Freedman 1992). All included trials were RCTs. One trial (Zarobowska 2007) had two RCTs performed in parallel. Intention-to-treat analysis was clearly specified in only two trials (Freedman 1992; Fenlon 2008). Two studies stated that power calculations were used to statistically estimate the sample size (Nedstrand 2005a; Fenlon 2008).

Participants

The four studies in this review randomly assigned 281 menopausal women. The age range of participants was 30 to 77 years. Three trials (Freedman 1992; Nedstrand 2005a; Fenlon 2008) reported comparable demographic characteristics of study groups at baseline. This information was unclear in one trial (Zarobowska 2007). Three trials recruited women whose last menstrual bleeding had taken place six or more months ago (Nedstrand 2005a; Zarobowska 2007; Fenlon 2008). Only one trial (Freedman 1992) included women who had amenorrhoea for one year or longer. Two trials (Nedstrand 2005a; Zarobowska 2007) confirmed menopausal status by serum follicle-stimulating hormone and oestradiol levels. Two studies (Nedstrand 2005a; Fenlon 2008) recruited postmenopausal women with primary breast cancer who were suffering from hot flushes. Two trials (Zarobowska 2007; Fenlon 2008) recruited only women with natural menopause. One trial (Zarobowska 2007) excluded women with severe metabolic, thromboembolic or endocrine diseases; women with uncontrolled hypertension (> 95 mmHg diastolic blood pressure) and those who used sedatives, tranquillisers and antidepressants on a daily basis. Two trials (Freedman 1992; Fenlon 2008) excluded women who had stopped hormone treatment within the previous six months.

Intervention

One RCT compared applied relaxation with electroacupuncture (Nedstrand 2005a). One trial (Zarobowska 2007) compared applied relaxation with superficial needle insertion, electroacupuncture or oral oestrogen. In this meta-analysis, participants in the superficial needle insertion and electroacupuncture groups were combined as the "acupuncture group (n=30) and compared with those in the applied relaxation group (n=15)."

One trial (Freedman 1992) compared participants given paced respiration or muscle relaxation with controls, who received only α-wave electroencephalographic biofeedback. One trial (Fenlon 2008) compared relaxation techniques (deep-breathing techniques, muscle relaxation and guided imagery) with no treatment. We excluded one RCT, which compared the effects of transdermal oestrogen and placebo. In another RCT, women were randomly assigned to receive oral oestrogens, applied relaxation, electroacupuncture and superficial needle insertion. We included only data from the two groups of women who received applied relaxation or electroacupuncture.

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The duration of intervention was 12 weeks in three trials (Nedstrand 2005a; Zarobowska 2007; Fenlon 2008) and four weeks in one trial (Freedman 1992). The number and time of follow-up evaluation varied considerably, at one week (Zarobowska 2007), four weeks (Freedman 1992; Nedstrand 2005a; Zarobowska 2007), seven weeks (Fenlon 2008), eight weeks (Nedstrand 2005a), 12 weeks (Nedstrand 2005a; Zarobowska 2007), three months (Nedstrand 2005a; Fenlon 2008) and six months after treatment (Nedstrand 2005a). One RCT compared applied relaxation with electroacupuncture (Nedstrand 2005a).

Outcomes

All studies used self report to assess vasomotor symptoms. Three trials (Freedman 1992; Nedstrand 2005a; Zarobowska 2007) recorded the number of hot flushes per 24 hours. Two trials (Nedstrand 2005a; Fenlon 2008) used the Kupperman Index score of climacteric symptoms. No study reported night sweats or sleep disturbances as an outcome.

No studies reported data on adverse effects or quality of life.

Two trials (Nedstrand 2005a; Zarobowska 2007) compared relaxation techniques with acupuncture and reported outcomes as continuous data that could be combined in the meta-analysis. Data from the final follow-up visit were pooled, regardless of the time since baseline.

The other two trials (Freedman 1992; Fenlon 2008) compared participants who received relaxation interventions versus controls given paced respiration (Freedman 1992), placebo (α-wave electroencephalographic biofeedback) (Freedman 1992) or no treatment (Fenlon 2008), but outcomes were reported as mean or median, which could not be analysed because the data had a wide standard deviation (Freedman 1992) and no data on standard deviation were provided (Fenlon 2008).

Excluded studies

Two reports were not RCTs (Irvin 1996; IhnSook 2004). One trial (Nedstrand 2005b) compared a relaxation intervention with hormonal treatment.

Risk of bias in included studies

For details, please refer to the methodological quality summary (Figure 2; Figure 3).

Allocation

Random sequence generation

One study (Fenlon 2008) was rated as having low risk of bias in this domain, and three (Freedman 1992; Nedstrand 2005a; Zarobowska 2007) as having unclear risk.

Allocation concealment

Two studies (Nedstrand 2005a; Fenlon 2008) were rated as having low risk of bias in this domain, and two (Freedman 1992; Zarobowska 2007) as having unclear risk.

Blinding

Blinding of participants and personnel

One study (Nedstrand 2005a) was rated as having high risk in this domain, and three (Freedman 1992; Zarobowska 2007; Fenlon 2008) as having unclear risk.

Blinding of outcome assessment

All four studies (Freedman 1992; Nedstrand 2005a; Zarobowska 2007; Fenlon 2008) were rated as having unclear risk of bias in this domain. All four trials (Freedman 1992; Nedstrand 2005a; Zarobowska 2007; Fenlon 2008) were unblinded.

Incomplete outcome data

Two studies were rated as having low risk of attrition bias (Freedman 1992; Zarobowska 2007), and two studies having high risk of attrition bias (Nedstrand 2005a; Fenlon 2008).

Selective reporting

All included trials (Freedman 1992; Nedstrand 2005a; Zarobowska 2007; Fenlon 2008) were judged to be at low risk of selective outcome reporting.

Other potential sources of bias

Two studies (Zarobowska 2007; Fenlon 2008) were rated as low risk and two (Freedman 1992; Nedstrand 2005a) as unclear risk. We found no potential sources of within-study bias in any of the four studies.

Effects of interventions

See: **Summary of findings for the main comparison**

The nature of the included studies meant that data from only two studies could be pooled (Nedstrand 2005a; Zarobowska 2007). A total of 72 participants were included in the meta-analysis.

1 Relaxation versus acupuncture

Two studies made this comparison (Nedstrand 2005a; Zarobowska 2007). One of these studies (Zarobowska 2007) included an arm receiving electroacupuncture and an arm receiving superficial needle insertion. For our primary analysis, participants in the superficial needle insertion and electroacupuncture groups were combined as the "acupuncture group (n=30). The effect was examined in a sensitivity analysis."

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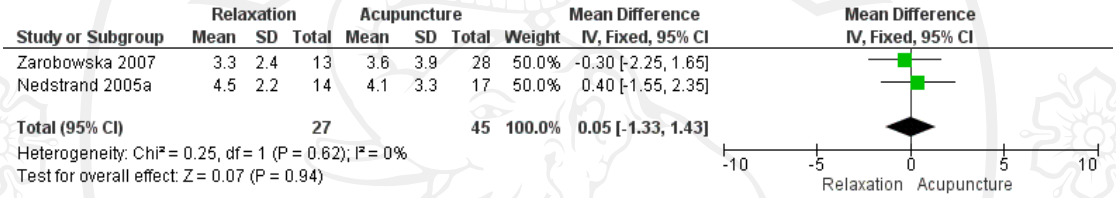
Primary outcomes

1.1 Hot flushes

Changes in the number of hot flushes per 24 hours

No evidence was found of a difference between relaxation and acupuncture or superficial needle insertion in the change in number of hot flushes per 24 hours (MD 0.05, 95% CI -1.33 to 1.43, two studies, 72 women, I^2 = 0%) (Figure 4).

Figure 4. Forest plot of comparison: 1 Relaxation versus acupuncture, outcome: 1.1 Change in number of hot flushes/24 h.

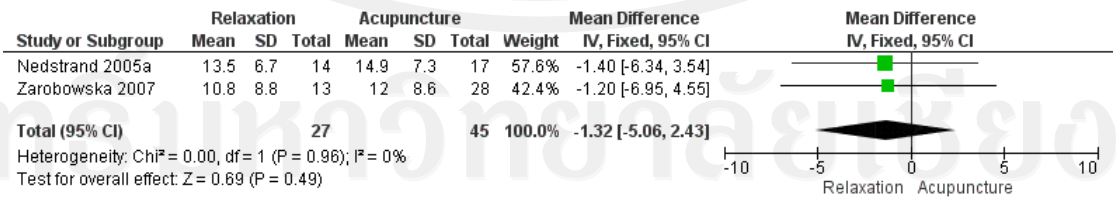


When we excluded from the analysis the group given only superficial needle insertion, no difference between groups was noted (MD 0.16, 95% CI -1.35 to 1.68, two studies, 59 participants, I^2 = 0%).

Improvement in the severity of hot flushes

No evidence showed a difference between the two groups in hot flush severity, measured using the Kupperman Index (MD -1.32, 95% CI -5.06 to 2.43, two studies, 72 women, I^2 = 0%) (Figure 5).

Figure 5. Forest plot of comparison: 1 Relaxation versus acupuncture, outcome: 1.2 Change in severity of hot flushes (Kupperman score).



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When we excluded from analysis the group given only superficial needle insertion, no difference between groups was noted (MD -0.64, 95% CI -4.30 to 3.0, two studies, 59 participants, I^2 = 0%).

1.2 Night sweats

This outcome was not reported.

1.3 Sleep disturbance

This outcome was not reported

Secondary outcomes

1.4 Attrition rate

Nedstrand 2005a reported that five of 19 in the relaxation group and two of 19 in the acupuncture group had dropped out at 12 weeks post treatment.
Zarobowska 2007 reported that two of 15 in the relaxation group and two of 30 in the acupuncture plus superficial needle insertion group had dropped out at 12 weeks post treatment.

1.5 Adverse effects

This outcome was not reported

1.6 Quality of life

This outcome was not reported

2 Relaxation versus paced respiration

One study made this comparison (Freedman 1992).

Primary outcomes

2.1 Hot flushes

Change in hot flush frequency per 24 hours
A significant decrease in hot flush frequency was reported in the paced respiration group (P value < 0.02) but not in the muscle relaxation group. However, no significant differences between the two interventions were reported. Pretest and post-test, mean numbers of hot flushes per 24 hours were as follows: muscle relaxation group: pretest 14.2 (standard deviation (SD) 9.8), post-test 13.6 (SD 10.6); paced respiration group: pretest 15.7 (SD 8.1), post-test 9.6 (SD 6.2).
Our other outcomes of interest were not reported in this study.

3 Relaxation versus no treatment or placebo

Two studies made this comparison (Freedman 1992; Fenlon 2008). Data were reported as medians in one (Fenlon 2008) and as means with very large standard deviations in the other (Freedman 1992), so they were unsuitable for analysis.

Primary outcomes

3.1 Hot flushes

Changes in the number of hot flushes per week

One study (Fenlon 2008) reported no evidence of a difference between relaxation and no-treatment groups at three-month follow-up (median difference five flushes per week, P value 0.06).
The other study (Freedman 1992) reported no evidence of a difference between pretreatment and post-treatment frequency of hot flushes during 24 hours' ambulatory monitoring after the muscle relaxation technique had been used (mean ± SD: 14.2 ± 9.8, 13.6 ± 10.6).
Our other outcomes of interest were not reported in these studies.

Other analyses

No statistical heterogeneity was detected. Too few studies were identified to allow meaningful sensitivity analysis or to assess for publication bias. We will carry out these analyses in future updates if more studies become available.

DISCUSSION

Summary of main results

Evidence is insufficient to show the effectiveness of relaxation techniques as treatment for menopausal vasomotor symptoms, or to reveal whether this treatment is more effective than no treatment, placebo, acupuncture, superficial needle insertion or paced respiration.

Overall completeness and applicability of evidence

Too few data were available for review authors to evaluate the effectiveness of relaxation techniques for vasomotor symptoms. No data on night sweats and sleep disturbances were reported. Although several trials included quality of life as an outcome, investigators typically used invalid measures. The percentage of dropouts in the relaxation group was higher than that in the acupuncture or superficial needle insertion group, but the reasons for this loss to follow-up were unclear. Adverse events and tolerability of relaxation interventions were not reported. It is important to know the benefits and harms of a relaxation intervention before it can be recommended as a treatment option for menopausal symptoms.

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Quality of the evidence

The quality of the evidence was very low. The main limitations of the evidence were lack of data, imprecision and failure to report study methods in adequate detail. No studies reported adverse events, night sweats or sleep disturbances associated with night sweats, and two studies did not provide data that were suitable for analysis.

Potential biases in the review process

Every effort was made to identify all relevant studies. However, additional trials in other database sources may not have been accessible through our search. Our decision to combine the two control groups (electroacupuncture and superficial needling) in one study (Zarobowska 2007) could have influenced our results, but a sensitivity analysis including only the electroacupuncture group did not influence our findings.

Agreements and disagreements with other studies or reviews

With the limited evidence obtained, this review reported no differences or changes in the number and severity of hot flushes per 24 hours between participants given relaxation therapy and those treated with acupuncture or superficial needle insertion. The results were consistent with those of other RCTs (Freedman 1992; Fenlon 2008).

AUTHORS' CONCLUSIONS

Implications for practice

Few RCTs were available that had assessed the effectiveness of relaxation intervention for the management of menopausal vasomotor symptoms. We found insufficient evidence to evaluate the effects of a relaxation intervention in comparison with acupuncture or superficial needle insertion in reducing vasomotor symptoms. The quality of the evidence was very low. However, relaxation techniques require long and continuous practice to achieve the treatment effect, and participant compliance can be a problem.

Implications for research

Good-quality RCTs of an adequate sample size that compare relaxation intervention with placebo or other types of interventions are urgently needed. Studies should evaluate not only the effect of the intervention on the frequency and intensity of vasomotor symptoms, but also the impact of treatment on women's daily life and compliance with treatment.

ACKNOWLEDGEMENTS

We would like to thank the Thai Cochrane Network and the Australasian Cochrane Centre for providing excellent training in writing protocols and other related processes for developing a Cochrane review. We appreciated the kind help of referees who were involved in the review. Last but not least, we would like to thank the Clinical Epidemiology PhD Programme administrative staff and faculty, especially Professor Dr Jayanton Patumanond and Associate Professor Chamaiporn Tawichasri, for their kind support and advice.

REFERENCES

References to studies included in this review

Fenlon 2008 ***{published data only}***
Fenlon D, Corner J, Haviland JS. A randomized controlled trial of relaxation training to reduce hot flashes in women with primary breast cancer. *Journal of Pain and Symptom Management* 2008;**35**(4):397–405.

Freedman 1992 ***{published data only}***
Freedman R, Woodward S. Behavioral treatment of menopausal hot flushes: evaluation by ambulatory monitoring. *American Journal of Obstetrics and Gynecology* 1992;**167**:436–9.

Nedstrand 2005a ***{published data only}***
Nedstrand E, Wijma K, Wyon Y, Hammar M. Vasomotor symptoms decrease in women with breast cancer randomised to treatment with applied relaxation or electro-acupuncture: a preliminary study. *Climaceric* 2005;**8**:243–50.

Zarobowska 2007 ***{published data only}***
Wyon Y, Wijma K, Nedstrand E, Hammar M. A comparison of acupuncture and oral estradiol treatment of vasomotor symptoms in postmenopausal women. *Climacteric* 2004;**7**: 153-64.
Zaborowska E, Brynhildsen J, Danberg S, Fredriksson M, Lindh-Astrand L, Nedstrand E, et al.Effects of acupuncture, applied relaxation, estrogens and placebo on hot flushes in postmenopausal women: an analysis of two prospective, parallel, randomised studies. *Climacteric 2007* 2007;**10**(1): 38–45.

References to studies excluded from this review

IhnSook 2004 ***{published data only}***
Ihn-Sook J. Effect of progressive muscle relaxation using biofeedback on perceived stress, stress response, immune response and climacteric symptoms of middle-aged women. *Daehan Ganho Haghoeji* 2004;**34**(2):213–24.

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Irvin 1996 *{published data only}*
Irvin JH, Domar AD, Clark C, Zuttermeister PC, Friedman R. The effects of relaxation response training on menopausal symptoms. *Journal of Psychosomatic in Obstetrics and Gynecology* 1996;**17**:202–7.

Nedstrand 2005b *{published data only}*
Nedstrand E, Wijma K, Wyon Y, Hammar M. Applied relaxation and oral estradiol treatment of vasomotor symptoms in postmenopausal women. *Maturitas* 2005;**51**: 154-62.

Additional references

Bair 2002
Bair YA, Gold EB, Greendale GA, Sternfeld B, Adler SR, Azari R, et al.Ethnic differences in use of complementary and alternative medicine at midlife: longitudinal results from SWAN participants. *American Journal of Public Health* 2002;**92**(11):1832–40.

Barton 2001
Barton D, Loprinzi C, Wahner-Roedler D. Hot flashes: aetiology and management. *Drugs & Aging* 2001;**18**(8): 597–606.

Benson 2000
Benson H, Klipper MZ. *The Relaxation Response*. New York: HarperCollins Publishers, November 2000.

Bruck 1980
Bruck K, Hinckel P. Thermoregulatory noradrenergic and serotonergic pathways to hypothalamic units. *Journal of Physiology* 1980;**304**:193–202.

Celentano 2003
Celentano E, Galasso R, Berrino F. Correlates of age at natural menopause in the cohorts of EPIC-Italy. *Tumori* 2003;**89**(6):608–14.

Celik 2002
Celik H, Ayar A, Tug N, Cikim G, Kilic N, Parmaksiz C. Effects of tibolone on plasma homocysteine levels in postmenopausal women. *Fertility and Sterility* 2002;**78**(2): 247–50.

Dennerstein 2000
Dennerstein L, Dudley EC, Hopper JL, Guthrie JR, Burger HG. A prospective population-based study of menopausal symptoms. *Obstetrics and Gynecology* 2000;**96**:351–8.

El-Mas 2004
El-Mas MM, Abdel-Rahman AA. Differential modulation by oestrogen of 2-adrenergic and I1-imidazoline receptor-mediated hypotension in female rats. *Journal of Applied Physiology* 2004;**97**:1237–44.

ERTA 2005
Evidence Report/Technology Assessment. Menopause-Related Symptoms. *Management of Evidence Report/ Technology Assessment Number 120.* AHRQ Publication No. 05-E016-2, March 2005.

Fauci 1997
Fauci AS, Braunwald E, Isselbacker KJ. *Harrison's Principles of Internal Medicine*. 14th Edition. New York: McGraw-Hill, 1997.

Freedman 2004
Freedman RR, Roehrs TA. Lack of sleep disturbance from menopausal hot flashes. *Fertility and Sterility* 2004;**82**(1): 138–44.

Freedman 2005
Freedman EW, Sammel MD, Lin H, Gracia CR, Kapoor S, Ferdousi T. The role of anxiety and hormonal changes in menopausal hot flashes. *Menopause* 2005;**12**:258–66.

Freeman 2001
Freeman RR. Physiology of hot flashes. *American Journal of Human Biology* 2001;**13**:453–64.

Freeman 2007
Freeman EW, Sammel MD, Lin H, Gracia CR, Pien GW, Nelson DB, et al.Symptoms associated with menopausal transition and reproductive hormones in midlife women. *Obstetrics and Gynecology* 2007;**110**:230–40.

Germaine 1984
Germaine LM, Freedman RR. Behavioral treatment of menopausal hot flashes: evaluation by objective methods. *Journal of Consulting and Clinical Psychology* 1984;**52**: 1072–9.

Gold 2004
Gold EB, Block G, Crawford S, Lachance L, FitzGerald G, Miracle H, et al.Lifestyle and demographic factors in relation to vasomotor symptoms: baseline results from the Study of Women's Health Across the Nation. *American Journal of Epidemiology* 2004;**159**:1189-99.

Goldberg 1994
Goldberg RM, Loprinzi CL, O'Fallon JR, Veeder MH, Miser AW, Mailliard JA, et al.Transdermal clonidine for ameliorating tamoxifen-induced hot flashes. *Journal of Clinical Oncology* 1994;**12**:155–8.

Guthrie 2003
Guthrie JR, Dennerstein L, Taffe JR, Donnelly V. Health care-seeking for menopausal problems. *Climacteric* 2003 Jun;**6**(2):112–7.

Hickey 2005
Hickey M, Davis SR, Sturdee DW. Treatment of menopausal symptoms: what shall we do now?. *Lancet* 2005;**366**(9483): 409–21.

Higgins 2011
Higgins JPT, Green S (editors). *Cochrane Handbook for Systematic Reviews of Intervention version 5.1.0 [updated March 2011]*. The Cochrane Collaboration, 2011. www.cochrane–handbook.org.

Hjemdahl 1989
Hjemdahl P, Fagius J, Freyschusss U. Muscle sympathetic activity and norepinephrine release during mental challenge in humans. *American Journal of Physiology* 1989;**257**:341–7.

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Holte 1992
Holte A. Influences of natural menopause on health complaints: a prospective study of healthy Norwegian women. *Maturitas* 1992;**14**:127–41.

Hunter 1996
Hunter M, Liao KL. Evaluation of a four-session cognitive behavioural intervention for menopausal hot flushes. *British Journal of Health Psychology* 1996;**1**:113–25.

Kaufert 1992
Kaufert PA, Gilbert P, Tate R. The Manitoba project: a re-examination of the link between menopause and depression. *Maturitas* 1992;**14**:143–55.

Lee 1989
Lee DD, Kimura S, DeQuattro V, Davison G. Relaxation therapy lowers blood pressure in hypertensive with raised plasma norepinephrine and blunts pressor response to anger. *Clinical and Experimental Hypertension. Part A, Theoretical Practice* 1989;**11 Suppl 1**:191–8.

Marjoribanks 2012
Marjoribanks J, Farquhar C, Roberts H, Lethaby A. Long term hormone therapy for perimenopausal and postmenopausal women. *Cochrane Database of Systematic Reviews* 2012, Issue 7. [DOI: 10.1002/14651858.CD004143.pub4]

Mathews 1990
Mathews KA, Wing RR, Kuller LH, Meilahn EN, Kelsey SF. Influences of natural menopause on psychological characteristics and symptoms of middle-aged healthy women. *Journal of Consulting and Clinical Psychology* 1990;**58**:345–51.

McKinlay 1992
McKinlay SM, Brambilla DJ, Posner J. The normal menopause transition. *Maturitas* 1992;**14**:103–15.

McMillan 2004
McMillan TL, Mark S. Complementary and alternative medicine and physical activity for menopausal symptoms women's health. *Journal of the American Medical Women's Association* 2004;**59**:270–7.

Mosconi 2009
Mosconi P, Donati S, Colombo C, Mele A, Liberati A, Satolli R, Consensus Conference Working Group. Informing women about hormone replacement therapy: the consensus conference statement. *BMC Women's Health* 2009;**9**:14.

NAMS 2004
The North American Menopause Society. Treatment of menopause-associated vasomotor symptoms: position statement of The North American Menopause Society. *Menopause* 2004;**11**:11–33.

Nedstrand 2005
Nedstrand E, Wijma K, Wyon Y, Hamma M. Applied relaxation and oral estradiol treatment of vasomotor symptoms in postmenopausal women. *Maturitas* 2005;**51**:154–62.

NIH 2005
National Institute of Health. NIH State-of-the-Science Conference Statement on Management of Menopause-Related Symptoms. NIH Consensus and State-of-the-Science Statements March 21-23, 2005:5–13.

Ost 1987
Ost LG. Applied relaxation: description of a coping technique and review of controlled studies. *Behaviour Research and Therapy* 1987;**25**(5):397–409.

Payne 2005
Payne RA. *Relaxation Techniques: A Practical Handbook for the Health Care Professional.* Third Edition. China: Elsevier Limited, 2005.

RevMan 2012
The Cochrane Collaboration. Review Manager (RevMan) Version 5.2. Copenhagen: The Nordic Cochrane Centre: The Cochrane Collaboration, 2012.

Speroff 2000
Speroff L, Symons J, Kempfert N, Rowan J. The effect of varying low-dose combinations of norethindrone acetate and ethinyl estradiol on the frequency and intensity of vasomotor symptoms. *Menopause* 2000;**7**(6):383–90.

STRAW 2000
Soules MR, Sherman S, Parrott E, Rebar R, Santoro N, Utian W, et al.Executive summary: Stages of Reproductive Aging Workshop (STRAW), Park City, Utah, July 2001. *Menopause* 2001;**8**:402–7.

WHO 1996
World Health Organization. WHO Scientific Group on Research on the Menopause in the 1990s. WHO Technical Report Series. Geneva, Switzerland: WHO, 1996. *WHO Scientific Group on Research on the Menopause in the 1990s. WHO Technical Report Series*. Geneva, Switzerland: WHO, 1996.

Wijma 1997
Wijma K, Melin A, Nedstrand E, Hammar M. Treatment of menopausal symptoms with applied relaxation: a pilot study. *Journal of Behavior Therapy and Experimental Psychiatry* 1997;**28**:251–64.

Williams 2008
Williams E, Kalilani L, DiBenedetti B, Zhou X, Granger AL, Fehnel SE, et al.Frequency and severity of vasomotor symptoms among perimenopausal and postmenopausal women in the United States. *Climacteric* 2008;**11**(1):32–43.

* *Indicates the major publication for the study*

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CHARACTERISTICS OF STUDIES

Characteristics of included studies *[ordered by study ID]*

Fenlon 2008

Methods	RCT comparing relaxation with no intervention
Participants	This study randomly assigned 150 women to applied relaxation (n = 74) or control (n = 76). At 1 month after completion of the trial, 50 and 54 participants remained in the relaxation and control groups, respectively. At 3 months, 46 and 51 participants remained in these respective groups. However, data were expressed as median and not mean scores as in the other trials (Freedman 1992; Nedstrand 2005a; Zarobowska 2007) . 150 women with natural menopause aged 36 to 77 years. 61 women were in the relaxation group and 64 were in the control group. Post menopause was defined as 6 months without menstruation. Participants had primary breast cancer and were suffering from troublesome hot flushes. Women taking oestrogen, aromatase inhibitors or other hormone therapies, except tamoxifen, were excluded
Interventions	Applied relaxation in the treatment arm. Controls received general discussion on menopause management and advice about lifestyle measures to improve health, such as diet, exercise, vaginal moisturisers and stress reduction
Outcomes	Frequency and severity of hot flushes (reported as median and median difference) Hunter menopause scale to measure distress caused by flashes, quality of life using Functional Assessment of Cancer Therapy with the endocrine subscale (FACT-ES) and anxiety by the Spielberg State/Trait Anxiety Index (STAI) Outcomes were assessed at 1 and 3 months after treatment
Notes	150 randomly assigned; 125 participated at day 0 (start of relaxation treatment)

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	An independent trials office was responsible for randomisation, using a computer-generated randomisation list
Allocation concealment (selection bias)	Unclear risk	The recruiting nurse did not have access to the randomisation list. Allocation was made by a telephone call to an independent trial office
Blinding of participants and personnel (performance bias) All outcomes	Unclear risk	No information given
Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	No information given

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Fenlon 2008 (*Continued*)

Incomplete outcome data (attrition bias) All outcomes	High risk	Of 74, 46 women were randomly assigned/ analysed to the relaxation group, and of 76, 51 women were randomly assigned/analysed to the control group. Reasons given for dropping out were "not like the diary, " flushes stopped, reminder of cancer, illness, no time for relaxation practice, family reasons and no reason given
Selective reporting (reporting bias)	Low risk	Outcomes were prospectively measured, using appropriate measuring instruments. All outcomes were reported
Other bias	Low risk	Appeared to be free from other sources of bias

Freedman 1992

Methods	RCT, 3 parallel groups in equal numbers: paced respiration, muscle relaxation and α-wave biofeedback (control)
Participants	This study randomly assigned 33 participants to muscle relaxation, paced respiration or placebo control (n = 11 per group). 11 participants in paced respiration, in muscle relaxation and in α-wave feedback group. All postmenopausal women experienced at least 5 hot flushes per day and had been amenorrhoeic $\geq$ 1 year
Interventions	Participants in paced respiration group were instructed to breathe 6 to 8 cycles/min and to increase the amplitude of the abdominal tracing. Participants in the muscle relaxation group were initially trained to systematically tense and then relax 16 gross muscle groups. Participants in the α-wave feedback group received visual feedback for the production of 8 to 13 Hz electroencephalographic activity. Training was done in three 10-minute trials, separated by 5-minute rest periods
Outcomes	Hot flush frequency during 24-hour ambulatory monitoring, respiration rate and tidal volume
Notes	Trial received funding from the National Institute on Aging

Risk of bias

Bias	**Authors' judgement**	**Support for judgement**
Random sequence generation (selection bias)	Unclear risk	Method of randomisation not reported
Allocation concealment (selection bias)	Unclear risk	No information on allocation concealment

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Freedman 1992 (*Continued*)

Blinding of participants and personnel (performance bias) All outcomes	Unclear risk	No information on blinding
Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	Insufficient information to permit a judgement of yes or no
Incomplete outcome data (attrition bias) All outcomes	Low risk	11 participants randomly assigned to paced respiration, 11 to muscle relaxation and 11 to α-wave feedback group. All participants were included in the final analysis
Selective reporting (reporting bias)	Low risk	Number of flushes was measured over a 24-hour period, and other outcomes were objectively measured by using appropriate equipment, thus less prone to bias. All outcomes were reported
Other bias	Unclear risk	Duration of the 3 interventions was not specified. Unclear information regarding the exact time when outcome assessment was performed

Nedstrand 2005a

Methods	RCT comparing applied relaxation with electroacupuncture in equal numbers 38 participants were randomly assigned to applied relaxation or electroacupuncture (n = 19 per group). Attrition rate at 12 weeks after treatment was 26.3% (5/19) in the relaxation group and 10.5% (2/19) in the acupuncture group
Participants	Of 19, 14 women were randomly assigned/analysed to the applied relaxation group and of 19, 17 women were randomly assigned/analysed to the electroacupuncture group. All women were naturally or surgically postmenopausal with breast cancer and at least 2 hot flushes/24 h
Interventions	The study group received 12 weekly sessions of applied relaxation, each lasting 60 minutes. The control group received 30 minutes of electroacupuncture treatment twice a week for the first 2 weeks and once a week for 10 weeks Participants were followed at 3 and 6 months after treatment
Outcomes	Changes in number of flushes/24 h and in sum score of Kupperman Index
Notes	Trial received funding from Swedish Foundation for Heath Care Science and Allergy Research, Cancer and Trafikskadades Forbund and Lion Foundation

Risk of bias

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Nedstrand 2005a (*Continued*)

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	No information given
Allocation concealment (selection bias)	Low risk	Labels in sealed, opaque envelopes were used
Blinding of participants and personnel (performance bias) All outcomes	High risk	Possibly an unblinded study, as mentioned in the discussion
Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	Insufficient information to permit a judgement of yes or no
Incomplete outcome data (attrition bias) All outcomes	High risk	Of 19, 14 women were randomly assigned/analysed to the applied relaxation group and of 19, 17 women were randomly assigned/analysed to the electroacupuncture group. In applied relaxation group, 5 participants dropped out during ot before the 12 weeks of treatments with various social or personal reasons. 2 dropped out from the electroacupuncture group (1 moved away and the other dropped out for an unknown reason)
Selective reporting (reporting bias)	Low risk	All outcomes were reported
Other bias	Low risk	Appeared to be free of other sources of bias

Zarobowska 2007

Methods	2 RCTs performed in parallel at the same outpatient clinic. In the first RCT, 60 women were randomly assigned in equal numbers to therapy with applied relaxation, electroacupuncture, superficial needle insertion or oral oestradiol. In the second RCT, 42 women were randomly assigned to transdermal oestrogen therapy or placebo. Only data from the first RCT were included in this meta-analysis, as the second RCT did not meet eligibility criteria
Participants	This study randomly assigned 60 participants to applied relaxation, superficial needle insertion, electroacupuncture or oral oestrogen (n = 15 per group). At 3 months' follow-up, 4 participants were lost (2 in the applied relaxation group, and 2 in the acupuncture group). Only 41 participants completed the study and were included in the analyses. Attrition rate was 13.3% (2/15) in the relaxation group and 6.7% (2/30) in the acupuncture group. 15 participants were randomly assigned to applied relaxation, 15 to electroacupuncture and 15 to superficial needle insertion. Naturally or surgically post-

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	menopausal women with at least 6 months of amenorrhoea. All suffered from hot flushes severe enough that they requested therapy. Women with severe metabolic, thromboembolic or endocrine disease, with uncontrolled hypertension (> 95 mmHg diastolic blood pressure) and who used sedatives, tranquillisers and antidepressants on a daily basis were excluded
Interventions	The relaxation group received weekly training sessions, lasting 60 minutes each, for a 12-week period. The electroacupuncture group received 30 minutes of treatment twice a week for the first 2 weeks and once a week for another 10 weeks. No information was given for the superficial needle insertion group. The hormonal treatment group received 17beta-oestradiol 2 mg for 12 weeks and 10 mg medroxyprogesterone acetate daily for another 2 weeks to shed the endometrium
Outcomes	Mean number of hot flushes/24 h and change in number of hot flushes/24 h Kupperman Index used to assess 11 different menopausal symptoms subjectively
Notes	In this meta-analysis, participants in the superficial needle insertion group and in the electroacupuncture group were combined as the "acupuncture group (n=30) and compared with those in the applied relaxation group (n=15)" Trial received funding from the Swedish Medical Research Council. Study authors stated that parts of the first RCT had been previously published

Risk of bias

Bias	**Authors' judgement**	**Support for judgement**
Random sequence generation (selection bias)	Unclear risk	Insufficient information to permit a judgement
Allocation concealment (selection bias)	Unclear risk	No information given on allocation concealment
Blinding of participants and personnel (performance bias) All outcomes	Unclear risk	No information given
Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	Insufficient information to permit a judgement
Incomplete outcome data (attrition bias) All outcomes	Low risk	Of 15, 13 women were randomly assigned/analysed to applied relaxation group. Of 15, 15 women were randomly assigned/analysed to electroacupuncture group and fo 15, 13 women were randomly assigned/analysed to superficial needle insertion group. 2 participants dropped out from the applied relaxation group because they considered the training program to be too

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Zarobowska 2007 (*Continued*)

		time-consuming. All women in the electroacupuncture and oral oestradiol group completed 12 weeks of treatment. 2 women were excluded from the superficial needle insertion group because 1 did not start treatment because of severe migraine, and the other was repeatedly absent from therapy
Selective reporting (reporting bias)	Low risk	All outcomes were reported
Other bias	Unclear risk	Insufficient information for evaluation of equality of baseline demographic data Part of the first RCT had been previously published elsewhere. Unclear whether some patients might not be represented in Nedstrand 2005a and Nedstrand 2006

Characteristics of excluded studies *[ordered by study ID]*

Study	Reason for exclusion
IhnSook 2004	Not an RCT
Irvin 1996	Pseudo-RCT
Nedstrand 2005b	Comparison of applied relaxation with oral oestradiol treatment

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DATA AND ANALYSES

Comparison 1. Relaxation versus acupuncture or superficial needle insertion

Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
1 Change in number of hot flushes/24 h	2	72	Mean Difference (IV, Fixed, 95% CI)	0.05 [-1.33, 1.43]
2 Change in severity of hot flushes (Kupperman score)	2	72	Mean Difference (IV, Fixed, 95% CI)	-1.32 [-5.06, 2.43]

Comparison 2. Relaxation versus acupuncture

Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
1 Change in number of hot flushes/24 h	2	59	Mean Difference (IV, Fixed, 95% CI)	0.16 [-1.35, 1.68]
2 Change in severity of hot flushes (Kupperman score)	2	59	Mean Difference (IV, Fixed, 95% CI)	-0.64 [-4.30, 3.03]

Analysis 1.1. Comparison 1 Relaxation versus acupuncture or superficial needle insertion, Outcome 1 Change in number of hot flushes/24 h.

Review: Relaxation for perimenopausal and postmenopausal symptoms

Comparison: 1 Relaxation versus acupuncture or superficial needle insertion

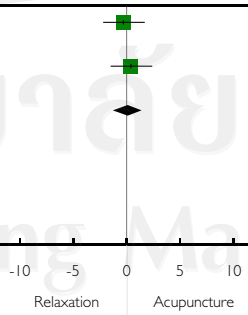
Outcome: 1 Change in number of hot flushes/24 h

Study or subgroup	Relaxation N	Mean(SD)	Acupuncture N	Mean(SD)	Mean Difference IV,Fixed,95% CI	Weight	Mean Difference IV,Fixed,95% CI
Zarobowska 2007	13	3.3 (2.4)	28	3.6 (3.9)		50.0 %	-0.30 [-2.25, 1.65]
Nedstrand 2005a	14	4.5 (2.2)	17	4.1 (3.3)		50.0 %	0.40 [-1.55, 2.35]
Total (95% CI)	**27**		**45**			**100.0 %**	**0.05 [-1.33, 1.43]**

Heterogeneity: Chi^2 = 0.25, df = 1 (P = 0.62); I^2 =0.0%

Test for overall effect: Z = 0.07 (P = 0.94)

Test for subgroup differences: Not applicable



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Analysis 1.2. Comparison 1 Relaxation versus acupuncture or superficial needle insertion, Outcome 2 Change in severity of hot flushes (Kupperman score).

Review: Relaxation for perimenopausal and postmenopausal symptoms

Comparison: 1 Relaxation versus acupuncture or superficial needle insertion

Outcome: 2 Change in severity of hot flushes (Kupperman score)

Study or subgroup	Relaxation N	Relaxation Mean(SD)	Acupuncture N	Acupuncture Mean(SD)	Mean Difference IV,Fixed,95% CI	Weight	Mean Difference IV,Fixed,95% CI
Nedstrand 2005a	14	13.5 (6.7)	17	14.9 (7.3)		57.6 %	-1.40 [-6.34, 3.54]
Zarobowska 2007	13	10.8 (8.8)	28	12 (8.6)		42.4 %	-1.20 [-6.95, 4.55]
Total (95% CI)	**27**		**45**			**100.0 %**	**-1.32 [-5.06, 2.43]**

Heterogeneity: Chi^2 = 0.00, df = 1 (P = 0.96); I^2 =0.0%

Test for overall effect: Z = 0.69 (P = 0.49)

Test for subgroup differences: Not applicable

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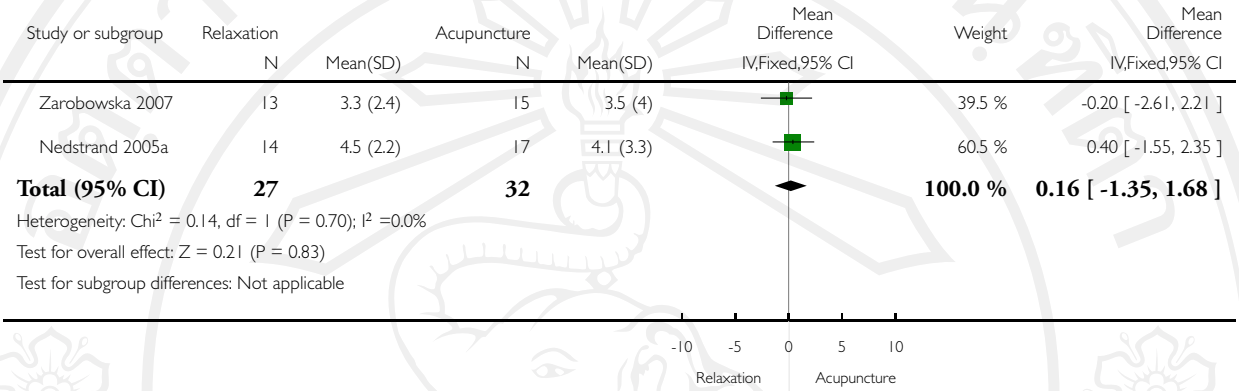
Analysis 2.1. Comparison 2 Relaxation versus acupuncture, Outcome 1 Change in number of hot flushes/24 h.

Review: Relaxation for perimenopausal and postmenopausal symptoms

Comparison: 2 Relaxation versus acupuncture

Outcome: 1 Change in number of hot flushes/24 h

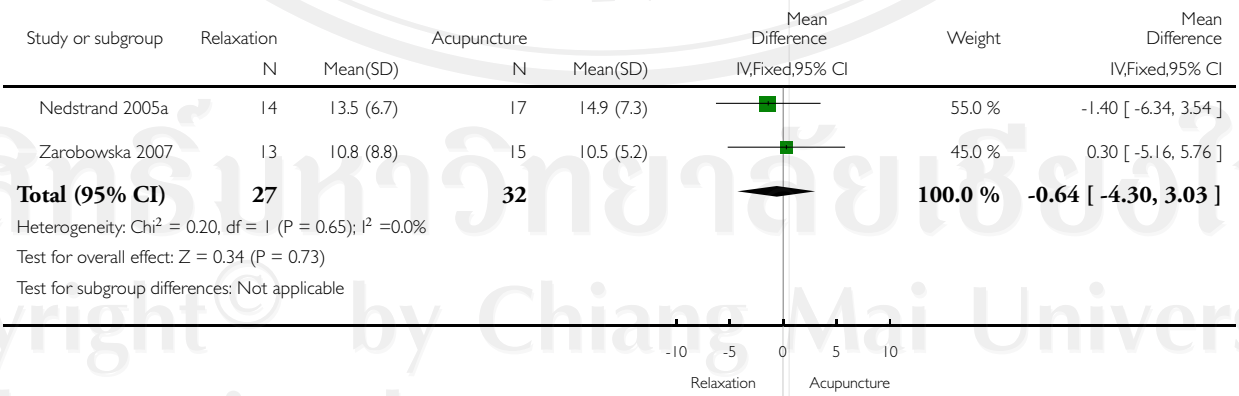


Analysis 2.2. Comparison 2 Relaxation versus acupuncture, Outcome 2 Change in severity of hot flushes (Kupperman score).

Review: Relaxation for perimenopausal and postmenopausal symptoms

Comparison: 2 Relaxation versus acupuncture

Outcome: 2 Change in severity of hot flushes (Kupperman score)



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APPENDICES

Appendix 1. Search string

Keywords CONTAINS “menopausal” or “menopausal symptoms” or “menopausal symmtoms” or “Menopause” or “perimenopausal” or “perimenopause” or “perimenpause” or “hot flashes” or “hot flushes” or “hot flushes frequency” or “hot flushes severity” or “climacteric ” or “climacteric symptoms” or “climacteric symptoms - vasomotor” or “climacteric symtoms” or “climacteric symptoms-psychological” or “climacteric depression” or “nocturnal diaphoresis” or “night sweats” or “night time awakenings” or “sleep disturbances” or Title CONTAINS “menopausal” or “menopausal symptoms” or “menopausal symmtoms” or “Menopause” or “perimenopausal” or “perimenopause” or “hot flashes” or “hot flushes” or “hot flushes frequency” or “hot flushes severity” or “climacteric ” or “climacteric symptoms” or “climacteric symptoms - vasomotor” or “climacteric symptoms-psychological” or “climacteric depression”
AND
Keywords CONTAINS “Relaxation Techniques” or “yoga” or “massage therapy” or “coping strategies” or “*Aromatherapy” or Title CONTAINS “Relaxation Techniques” or “yoga” or “massage therapy” or “coping strategies” or “*Aromatherapy”

Appendix 2. CENTRAL search strategy

Source: CENTRAL
Database: EBM Reviews-Cochrane Central Register of Controlled Trials
Date of search: December 2012
1 exp menopause/ or exp perimenopause/ or exp postmenopause/ (4991)
2 (menopaus$ or perimenopaus$ or postmenopaus$).tw. (9942)
3 exp Climacteric/ (5209)
4 climacter$.tw. (590)
5 vasomotor.tw. (810)
6 hot flash$.tw. (343)
7 hot flush$.tw. (588)
8 night sweat$.tw. (84)
9 nocturnal sweat$.tw. (8)
10 (sleep adj2 disturb$).tw. (1208)
11 or/1-10 (12723)
12 exp Relaxation/ or exp Muscle Relaxation/ or exp Relaxation Therapy/ (3269)
13 aromatherapy/ or breathing exercises/ or meditation/ or exp relaxation therapy/ or exp tai ji/ or exp therapeutic touch/ or exp yoga/ (1923)
14 relax$.tw. (5895)
15 breathing.tw. (4081)
16 meditation.tw. (379)
17 massag$.tw. (1035)
18 yoga.tw. (332)
19 (pac$ adj2 respiration$).tw. (12)
20 (cop$ adj2 technique$).tw. (184)
21 or/12-20 (13578)
22 11 and 21 (210)
23 limit 22 to yr=“2012 -Current” (7)

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Appendix 3. MEDLINE search strategy

Database: Ovid MEDLINE(R) In-Process & Other Non-Indexed Citations, Ovid MEDLINE(R) Daily and Ovid MEDLINE(R)
Searched from 1946 to present

1 exp menopause/ or exp perimenopause/ or exp postmenopause/ (42642)
2 (menopaus$ or perimenopaus$ or postmenopaus$).tw. (62709)
3 exp Climacteric/ (46017)
4 climacter$.tw. (3832)
5 vasomotor.tw. (9956)
6 hot flash$.tw. (1570)
7 hot flush$.tw. (1669)
8 night sweat$.tw. (1284)
9 nocturnal sweat$.tw. (79)
10 (sleep adj2 disturb$).tw. (9252)
11 or/1-10 (96466)
12 exp Relaxation/ or exp Muscle Relaxation/ or exp Relaxation Therapy/ (44392)
13 aromatherapy/ or breathing exercises/ or meditation/ or exp relaxation therapy/ or exp tai ji/ or exp therapeutic touch/ or exp yoga/ (11451)
14 relax$.tw. (114042)
15 breathing.tw. (47244)
16 meditation.tw. (2047)
17 massag$.tw. (6835)
18 yoga.tw. (1539)
19 (pac$ adj2 respiration$).tw. (75)
20 (cop$ adj2 technique$).tw. (2419)
21 or/12-20 (202595)
22 11 and 21 (2218)
23 randomized controlled trial.pt. (338451)
24 controlled clinical trial.pt. (85028)
25 randomized.ab. (255606)
26 placebo.tw. (143862)
27 clinical trials as topic.sh. (161921)
28 randomly.ab. (187126)
29 trial.ti. (109055)
30 (crossover or cross-over or cross over).tw. (55168)
31 or/23-30 (831347)
32 (animals not (humans and animals)).sh. (3659106)
33 31 not 32 (766620)
34 22 and 33 (297)
35 (2012$ or 2013$).ed. (1088248)
36 34 and 35 (32)

Appendix 4. EMBASE search strategy

Source: EMBASE
Search from 1980 to 2013 Week 3

1 exp MENOPAUSE/ or exp MENOPAUSE RELATED DISORDER/ or exp "MENOPAUSE AND CLIMACTERIUM"/ (91019)
2 (menopaus$ or perimenopaus$).tw. (46809)
3 climacter$.tw. (4599)
4 vasomotor.tw. (11683)
5 hot flash$.tw. (2165)
6 hot flush$.tw. (2334)
7 night sweat$.tw. (2091)

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8 nocturnal sweat$.tw. (124)
9 (sleep adj2 disturb$).tw. (13386)
10 or/1-9 (129829)
11 exp leisure/ (17018)
12 (relax$ or leisure).tw. (134118)
13 breathing.tw. (57337)
14 meditation.tw. (2684)
15 massag$.tw. (8572)
16 yoga.tw. (2046)
17 (pac$ adj2 respiration$).tw. (86)
18 (cop$ adj2 technique$).tw. (2082)
19 or/11-18 (211854)
20 10 and 19 (2939)
21 Clinical Trial/ (876008)
22 Randomized Controlled Trial/ (335805)
23 exp randomization/ (60515)
24 Single Blind Procedure/ (16894)
25 Double Blind Procedure/ (112757)
26 Crossover Procedure/ (36012)
27 Placebo/ (211904)
28 Randomi?ed controlled trial$.tw. (82815)
29 Rct.tw. (10760)
30 random allocation.tw. (1201)
31 randomly allocated.tw. (18191)
32 allocated randomly.tw. (1858)
33 (allocated adj2 random).tw. (716)
34 Single blind$.tw. (12962)
35 Double blind$.tw. (133481)
36 ((treble or triple) adj blind$).tw. (297)
37 placebo$.tw. (183892)
38 prospective study/ (223387)
39 or/21-38 (1302348)
40 case study/ (18321)
41 case report.tw. (237295)
42 abstract report/ or letter/ (855879)
43 or/40-42 (1106595)
44 39 not 43 (1266512)
45 20 and 44 (463)
46 (2012$ or 2013$).em. (1356428)
47 45 and 46 (62)

Appendix 5. AMED search strategy

Source: AMED (Allied and Complementary Medicine Database)
Searched from 1985 to January 2013
1 exp climacteric/ or exp menopause/ (504)
2 (menopaus$ or perimenopaus$).tw. (671)
3 climacter$.tw. (50)
4 vasomotor.tw. (86)
5 hot flash$.tw. (48)
6 hot flush$.tw. (33)
7 night sweat$.tw. (19)
8 nocturnal sweat$.tw. (0)

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9 (sleep adj2 disturb$).tw. (369)
10 or/1-9 (1176)
11 exp breathing therapies/ or exp meditation/ or exp relaxation/ or exp reiki/ (1379)
12 relax$.tw. (2739)
13 breathing.tw. (1239)
14 meditation.tw. (524)
15 massag$.tw. (2294)
16 yoga.tw. (472)
17 (pac$ adj2 respiration$).tw. (1)
18 (cop$ adj2 technique$).tw. (21)
19 or/11-18 (6658)
20 10 and 19 (50)
21 limit 20 to yr="2012 -Current" (1)

Appendix 6. PsycINFO search strategy

Source: PsycINFO
Searched from 1806 to January 2013 Week 3
1 exp menopause/ (2731)
2 (menopaus$ or perimenopaus$).tw. (3614)
3 climacter$.tw. (427)
4 vasomotor.tw. (1107)
5 hot flash$.tw. (273)
6 hot flush$.tw. (158)
7 night sweat$.tw. (100)
8 nocturnal sweat$.tw. (7)
9 (sleep adj2 disturb$).tw. (5367)
10 or/1-9 (10639)
11 exp Relaxation Therapy/ or exp Relaxation/ (5112)
12 relax$.tw. (16801)
13 breathing.tw. (5027)
14 meditation.tw. (4322)
15 massag$.tw. (1083)
16 yoga.tw. (1440)
17 (pac$ adj2 respiration$).tw. (39)
18 (cop$ adj2 technique$).tw. (540)
19 or/11-18 (27096)
20 10 and 19 (383)
21 limit 20 to "2000treatment outcome/randomized clinical trial" (17)
22 limit 21 to yr="2012 -Current" (1)

CONTRIBUTIONS OF AUTHORS

Suprawita Saensak: search, selection of studies, data extraction, drafting of protocol and review, data analysis, data presentation, result interpretation, publication.

Teraporn Vutyavanich: methods of the review, resolution of discrepancies, result interpretation, editing of the manuscript.

Woraluk Somboonporn: search, selection of studies, appraisal of quality of articles, data extraction, co-drafting of the protocol/review, assistance with statistics, data analysis.

Manit Srisurapanont: methods of the review, resolution of discrepancies, editing of the manuscript.

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DECLARATIONS OF INTEREST

None known.

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- MDSG, New Zealand.
- Information and helpful comments for developing protocol.

DIFFERENCES BETWEEN PROTOCOL AND REVIEW

Because of the limited number of studies included, we could not carry out subgroup analysis and investigation of heterogeneity.

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Appendix C

Saensak S, Vutyavanich T, Somboonporn W, Srisurapanont M.Effectiveness of a modified version of the applied relaxation technique in treatment of perimenopausal and postmenopausal symptoms. International Journal of Women's Health 2013:5; 765-771.

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ORIGINAL RESEARCH

Effectiveness of a modified version of the applied relaxation technique in treatment of perimenopausal and postmenopausal symptoms

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Background: Awareness of the risks associated with hormone therapy for menopausal symptoms has sparked a global decline in this treatment. Alternative treatments to relieve menopausal symptoms are therefore required. The applied relaxation (AR) technique has proven to be successful for symptom amelioration, but requires participation in 12 weekly classes. The purpose of this study was to determine the effectiveness of a modified relaxation version (MR) of AR for treatment of hot flashes, night sweats, and sleep disturbances.

Methods: We conducted a12-week, randomized, parallel, open-label, controlled trial in perimenopausal and postmenopausal women visiting the menopausal clinic. Participants were randomly assigned to an MR or AR group. The MR group (n=36) received a single session of (MR) training and the AR group (n=35) received conventional 12-week training. Participants were instructed to practice the techniques daily at home for 12 weeks. The main outcome was the measure on the severity scale and frequency of hot flashes, night sweats, and sleep disturbances.

Results: All participants completed the study. Total severity scores in both groups decreased after 12 weeks, but there was no difference between the groups (P=0.93). The severity score for hot flashes in the MR group decreased more than in the AR group (P=0.02). The severity scores for night sweats and sleep disturbances decreased in both groups. The frequency of hot flashes, night sweats, and sleep disturbances were also decreased in both groups.

Conclusion: A shorter, modified version of the AR was equally effective or slightly better than the conventional AR for the relief of hot flashes, night sweats, and sleep disturbances in perimenopausal and postmenopausal women. Recommendations for future research include confirmatory studies and trials with larger samples.

Keywords: alternative treatments, applied relaxation, menopausal symptoms, hot flashes

Introduction

Most women in menopause report at least one symptom, such as hot flashes, night sweats, or sleep disturbances.[1] The prevalence of these symptoms varies widely and is likely to be influenced by a range of factors, including climate, diet, lifestyle, women's roles and attitudes regarding aging, and the end of reproductive capacity.[1,2] Hot flashes are the most common symptom, reported in 30%–50% of perimenopausal women, and are a result of cutaneous vasodilatation.[1,3,4] This symptom usually begins as an ascending flash of the upper body, starting from the thorax, and results in a sensation of warmth. The vasodilatation also causes a decrease in body core temperature, resulting in a sensation of cold that often elicits shivering. Hot flashes often occur at night (night sweats) and disrupt normal sleep patterns.[5] Some studies have indicated

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that this symptom may peak during the later stages of the menopausal transition when women are missing periods,[6,7] and some recent studies have shown that these symptoms can continue for longer than previously thought.[8] In contrast, sleep disorders seem to increase in a linear fashion over the menopausal transition and the postmenopausal period.[6]

The perimenopausal period is defined as the period immediately before menopause when the endocrine, biological, and clinical manifestations begin to appear, and includes the first year after menopause begins. The postmenopausal period dates from the final menstrual period, regardless of whether menopause was induced or spontaneous. Nearly 10% of women in the US undergoing perimenopausal or menopausal changes seek medical advice from health care providers.[9] Estrogen therapy is a well established and effective treatment for menopausal symptoms.[10] However, following publication of the Women's Health Initiative study,[11] the prescription and use of hormone therapy has declined globally due to awareness of the risks associated with hormone therapy.[12] Therefore, many symptomatic women are seeking alternative treatments.[13–15] Relaxation techniques, such as paced respiration (a type of slow, deep breathing that uses the diaphragm to do the work of inhaling and exhaling), muscle relaxation or a combination of both (applied relaxation [AR]) are well known behavioral treatments for menopausal symptoms.[16] The goal of the AR technique is to achieve rapid relaxation by correct breathing in situations with bothersome symptoms, ie, hot flashes.[17] These techniques effectively attenuate the frequency[18] and intensity[18] of hot flashes, thereby minimizing discomfort and sleep disturbances.[12]

AR, the most commonly used relaxation method for treating menopausal complaints, shows promise for alleviating vasomotor and other symptoms.[19] However, the AR technique involves intensive training over 12 consecutive weeks. Each session lasts for 60 minutes, and individuals are asked to practice at home for at least 15–20 minutes per day. More than 25% of individuals drop out of the training course as a result of this time commitment. MR training is a modification of the AR technique that shortens the training time and emphasizes home practice. This shorter version requires participants to attend only one 60-minute session, which is expected to reduce the dropout rate. The results of this preliminary study of the modified relaxation (MR) technique at the Mahasarakham Provincial Hospital resulted in all participants completing the program and reporting dramatic improvement in their vasomotor symptoms.

The present randomized controlled trial compared the effects of traditional AR with those of a one-session MR intervention for the relief of menopausal symptoms in Thai women. Outcome variables included change in intensity and frequency of hot flashes, night sweats, and sleep disturbances in women who completed the program.

Materials and methods

Study design

The study was a parallel, randomized, open-label investigation of MR versus AR conducted over 12 weeks in perimenopausal and postmenopausal women. The investigation was conducted at the Menopausal Clinic of Mahasarakham Provincial Hospital in northeastern Thailand from July 2011 to January 2012. The Mahasarakham Provincial Hospital ethics committee approved the study and all participants gave written informed consent.

Participants

We recruited 105 perimenopausal and postmenopausal women who visited the menopause clinic at Mahasarakham Provincial Hospital in northeastern Thailand. Of these, 88 women experiencing hot flashes, night sweats, or sleep disturbances were potentially eligible, and 71 (81%) chose to participate. Figure 1 shows the reasons given for not participating in the study.

The inclusion criteria were age 45–65 years and irregular menstruation within the previous 12 months or menopause (either surgical or spontaneous). Women who received any hormone therapy in the 3 months before the study and those who had uncontrolled hypertension (>95 mmHg diastolic pressure) or used sedatives, tranquilizers, or antidepressant medication on a daily basis were excluded. Women visiting the clinic were questioned about their experience of hot flashes, night sweats, or sleep disturbances. Potential participants with menopausal symptoms underwent a medical examination by an attending gynecologist at the menopause clinic. Participants rated their symptoms subjectively using a severity rating scale, and those with a severity score ≥5 were invited to participate in the study. Those who expressed an interest in relaxation training to reduce hot flashes were randomly assigned to either the AR group or the MR group. Participants were given the option to discontinue their treatment at any time without jeopardizing their future care.

Severity rating scale

The severity rating scale was created by one of the investigators and validated in 10 menopausal women. Using this

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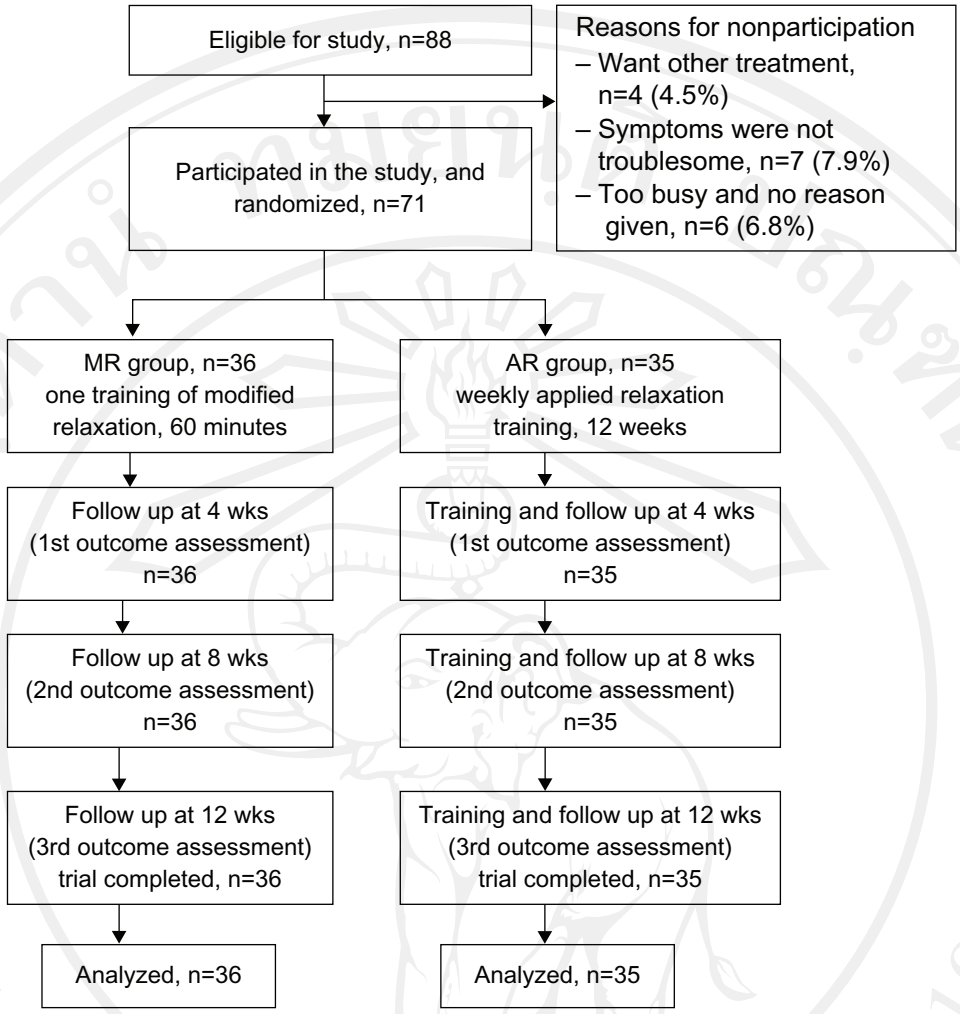

Figure 1 Patient recruitment and follow up.
Abbreviations: MR, modified version of AR; AR, applied relaxation; wks, weeks.

instrument, the severity of hot flashes, night sweats, and sleep disturbances are subjectively rated using a five-point scale from 0 ("not at all") to 4 ("extremely"). Items in scale consists of three menopausal symptoms as hot flashes, night sweats, and sleep disturbances. The total severity score ranges from 0 to 12.

Intervention procedures

Participants received relaxation training from two professional physical therapists under the supervision and care of their attending gynecologists. The physical therapists met before the start of the study to develop and standardize the scope and content of their teaching. One physical therapist was responsible for the AR training and the other supervised the MR training throughout the study. The trainer and participants met in small groups of 4–6 people.

Participants in the AR group attended 12 weekly sessions lasting 60 minutes each. Information about menopause, theories about hot flashes, and the rationale behind the use of AR as a coping technique for handling sudden, unanticipated symptoms was discussed during the first session. The first part of the progressive relaxation program (contraction and relaxation of muscles in the arms, face, neck, and shoulders) was taught following this discussion. In session 2, a program of progressive relaxation of the whole body was taught to participants. Session 3 provided a condensed version of progressive relaxation (relaxation without muscle straining). Cue-controlled relaxation was introduced (self-instructed relaxation) and practiced in session 4. Sessions 5 and 6 focused on differential relaxation (relaxation of non-used muscle groups), and sessions 7 and 8 focused on rapid relaxation. After completing session 8, participants were able to relax within 20–30 seconds. Application of the training began in sessions 9 and 10, in which participants were asked to use rapid relaxation as soon as their vasomotor symptoms

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appeared. Sessions 11 and 12 were used for rehearsal and a summary of the maintenance program. Participants were given a handout on AR after each session, and were asked to practice each component at home at least once a day. There were 12 total staff times and 12 telephone calls in this group.

Participants in the MR group received training from their physical therapist in one 60-minute session at the beginning of the study. The content of the MR technique has been validated in a study of 10 menopausal women, with a scale reliability coefficient of 0.76.

The physical therapist was in contact by telephone with each participant for 12 consecutive weeks and answered any questions relevant to the technique or education, encouraged practice, and addressed general well being. This was substituted for the once-weekly class to maintain a like amount of communication with participants. The session consisted of four parts. The first addressed menopausal symptoms, to enhance understanding among the participants and teach awareness of tension in a particular area of the body. In the second part, participants were encouraged to maximize tension in the affected area, followed by stretching and release of the tension. In the third part, participants were asked to focus their attention on a particular area of the body, to recognize relaxation, and practice relaxing that area. In the final part of the session, participants were asked to commit to practicing at home and were given a summary of the maintenance program. Participants were given a handout on MR after the training session. They were also asked to practice MR at home once a day for 15–20 minutes during their leisure time at least 5 days a week for the following 12 weeks.

Monitoring

Participants in both groups kept specific daily records of the frequency and severity of their menopausal symptoms in a logbook. They were also asked to check the completeness of the records once a week. The logbooks were collected when the subjects visited the menopause clinic at 4, 8, and 12 weeks after intervention. Participants also completed the severity rating scale and reported the frequency of symptoms at these visits. The research nurse determined completeness of the data, and all data were copied into a standardized medical record. Most participants (67, 94.4%) adhered to the protocol. The trainers contacted participants by telephone once a week to answer questions, resolve any problems, assess symptoms, and monitor AR/MR practice. One physical therapist was responsible for telephone calls in the AR group and another was responsible for telephone calls to the MR group throughout the study.

Statistical analyses

Randomization

The randomization sequence was created using Stata 10 (StataCorp LP, College Station, TX, USA) statistical software and was center-stratified with a 1:1 allocation using a computer-generated random block size of 4 and 8. The allocation sequence was placed in sequentially numbered, opaque, sealed, and stapled envelopes and concealed from the researcher enrolling and assessing participants.

Outcome variables

The outcome variables included change in severity rating scale score and change in frequency of hot flashes, night sweats, and sleep disturbances. Statistical analyses were performed using Stata software version 10 (StataCorp LP). The analysis was conducted as "intention-to-treat," with all participants included in the analysis. Descriptive statistics were applied to the baseline demographics, clinical characteristics, and dichotomous and continuous data. Chi-square (χ^2) and Student's *t*-tests were used to assess differences between groups. The Wilcoxon rank-sum test assessed differences in the rating scale variables. A *P*-value of 0.05 (two-tailed) was set for statistical significance.

Sample size

The sample size was based on a pilot study of 20 participants, comprising eleven in the AR group and nine in the MR group. Mean improvement in Menopausal Rating Scale (MRS) severity score after 4 weeks of treatment was 10.68±3.5 in the AR group and 15.33±3.11 in the MR group. Three subjects (28%) in the AR group dropped out before the end of the pilot study, while all subjects (100%) in the MR group completed the program. Using an alpha error of 0.05 (two-sided) and a power of 90%, the required sample size per group was five. Since this was a small number, we increased the sample size in each arm to a minimum of 30 to provide a normal acceptable approximation.[20]

Results

The age range of the participants was 45–60 years. The mean age of the groups was significantly different ($P<0.01$). There were no significant differences in mean age at perimenopause, mean age at post menopause, body mass index, or menopausal status. All participants were nonsmokers and did not consume alcoholic beverages, and all completed the study (Table 1).

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Table 1 Demographic characteristics of participants

Characteristics	MR group (n=36)	AR group (n=35)	Statistical test and *P*-value
	Mean (SD)	Mean (SD)	
Age, years	49.8 (3.8)	52.5 (5.1)	0.01[t]
Age at perimenopause, years	45.9 (6.0)	46.9 (3.9)	0.62[t]
Age at postmenopause	47.4 (0.6)	48.9 (0.8)	0.18[t]
BMI (kg/m^2)	25.6 (3.8)	25.2 (4.2)	0.15[t]
Menopausal status			0.18[χ^2]
• Perimenopausal, n (%)	18 (25.4)	12 (16.9)	
• Postmenopausal, n (%)	18 (25.4)	23 (32.4)	
Severity score at baseline			
Total severity	6.5 (4.5)	5.0 (2.0)	0.92[t]
Hot flashes	2.0 (1.0)	2.0 (1.0)	0.86[t]
Night sweats	2.0 (1.0)	2.0 (1.0)	0.69[t]
Sleep disturbances	2.0 (2.5)	2.0 (1.0)	0.82[t]

Notes: [t]Student's *t*-test; [χ^2]Chi-square test. Maximum range of total severity score at baseline and 12 weeks in MR group =11 and 3, in AR group =10 and 3. Maximum range of hot flashes severity score at baseline and 12 weeks in MR group =4 and 2, in AR group =3 and 2. Maximum range of night sweats severity score at baseline and 12 weeks in MR group =4 and 1, and in AR group =3 and 0. Maximum range of sleep disturbance severity score at baseline and 12 weeks in MR group =4 and 1, and in AR group =4 and 1.

Abbreviations: AR, applied relaxation; BMI, body mass index; MR, modified version of AR; SD, standard deviation.

Comparison between MR and AR

We tested the effectiveness of relaxation by comparing the two groups regarding changes in the severity rating scores for menopausal symptoms over time. There were decreases in total severity scores for hot flashes, night sweats, and sleep disturbances in both groups after 12 weeks (z=–0.09, P=0.93, Table 2). The severity score for hot flashes in the MR group was more decreased than in the AR group (z=–2.33, P=0.02). The severity of both night sweats and sleep disturbances decreased in both groups, but the changes were not statistically significant. The frequency of hot flashes, night sweats, and sleep disturbances was decreased in both groups but there were no statistically significant differences (Table 2).

Discussion

This prospective randomized study shows that total severity score improved in both treatment groups from baseline to the end of the 12-week treatment period. We also observed dramatic decreases in the outcomes of hot flashes, night sweats, and sleep disturbances.

Although the MR technique is a very brief training program, the present findings show equal effectiveness of the MR and AR techniques (decreased severity score in both groups). This result is similar to that of two previous studies reporting the AR technique to be effective in reducing hot flashes.[21–23]

While the present study was a randomized, open-label, intention-to-treat analysis, it does have some limitations. First, the sample size might have been too small to detect a benefit in reducing menopausal symptoms. Second, although the participants were assigned randomly to the intervention groups, the open-label design can still cause bias toward the study treatments. Third, the study duration of 12 weeks might have been too short to determine the effects of MR and AR in individuals with menopausal symptoms. Although a trend toward reduction in frequency and severity was observed, the treatment effect may not be sustained after 12 weeks.[20,22,23] This may be due to the study design. The MR intervention was a more intensive training program, which could extend the benefits beyond the learning phase. Fourth, we included women for whom menstruation had ceased for only a year or more. These women often experience particularly severe vasomotor symptoms and sleep disturbances. However, there was a risk that menstruation would return in some of these women, and this happened in two cases, both in the AR group. It is possible that these cases weakened the outcome of the study due to inconsistency of their symptoms. Fifth, the

Table 2 Change in severity and frequency of hot flashes, night sweats, and sleep disturbances

Variable	MR group (n=36)		AR group (n=35)		*z*, *P*-value
	Baseline	12 weeks	Baseline	12 weeks	
Total severity	6.5 (4.5)	–5.0 (3.5)	5.0 (2.0)	–5.0 (2.0)	z=–0.09, P=0.93
Severity by symptoms					
Hot flashes	2.0 (1.0)	–2.0 (1.0)	2.0 (1.0)	–1.0 (2.0)	z=–2.33, P>0.02*
Night sweats	2.0 (1.0)	–2.0 (1.0)	2.0 (1.0)	–2.0 (1.0)	z=–0.67, P=0.51
Sleep disturbance	2.0 (2.5)	–2.0 (2.0)	2.0 (1.0)	–2.0 (3.0)	z=0.34, P=0.74
Frequency by symptoms					
Hot flashes/day	2.0 (2.0)	–1.0 (1.0)	2.0 (2.0)	–1.0 (1.0)	z=–0.55, P=0.58
Night sweats/day	2.0 (2.0)	–2.0 (2.0)	2.0 (1.0)	–2.0 (1.0)	z=–0.60, P=0.55
Sleep disturbance/week	2.0 (3.0)	–2.0 (3.0)	2.0 (3.0)	–2.0 (3.0)	z=–0.19, P=0.85

Notes: Severity score expressed as median (interquartile range); *Wilcoxon rank-sum test, P<0.05.

Abbreviations: AR, applied relaxation; MR, modified version of AR.

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severity scale for measuring the menopausal symptoms was relatively specific. Other methods could have been used to evaluate the effects of therapy. For example, a visual analog scale[24] can be used as a measure of menopausal symptoms because it is a simple technique for measuring subjective experiences. However, studies using the visual analog scale have not found improvements in night sweats and sleep disturbance symptoms. Accordingly, we used a nonstandard instrument to assess menopausal symptom severity and this may limit the generalizability of the results. Sixth, the study assessed only a few types of menopausal symptoms (ie, vasomotor symptoms). Although this limitation was expected at the inception of the study, to err on the side of caution we only assessed vasomotor symptoms (hot flashes and night sweats) and sleep disturbances. The generalization of these findings to perimenopausal and postmenopausal women with other symptoms (cognitive and sexual problems) may not be possible. Seventh, there was no monitoring of adherence to treatment. We could not determine the duration and frequency of MR practice or any lifestyle changes in the intervention and control groups. Last, other benefits of MR, for example, enhanced quality of life, were not assessed.

Our findings are in contrast with those reported by Freedman and Woodward,[25] who found no reduction in hot flashes with muscle relaxation, but are consistent with the findings of Hunter and Liao[26] who found that hot flashes were reduced using behavioral therapy techniques.

This study also has several strengths. First, the recruitment interview assessed women's experience of menopausal symptoms and included a discussion of management strategies. The patient-therapist relationship was maintained by weekly telephone calls throughout the trial. We feel that the benefits obtained by the participants were achieved as a result of this frequent contact. We also believe that participants should be advised to practice regularly and that more follow-ups should be included in the program to maintain the therapeutic effects. Second, although self-reported measures of vasomotor symptoms and sleep disturbances have been shown to correspond well with other methods of measurement, the use of diaries may introduce bias. However, relaxation training is a behavioral modification, and writing down the number of practice sessions in a diary may be helpful for consistency. We suggest that the availability of a variety of behavior modification-based techniques for relieving symptoms associated with menopause will allow women to choose a therapy that meets their individual needs, and this increases the probability of selecting the most effective response from among these behavioral therapy techniques.[27]

Since MR and AR techniques had equal success in relieving menopausal symptoms, MR techniques could complement or be used as an alternative to AR. The use of relaxation training reduced both the frequency and severity of menopausal symptoms, and this effect may have been related to practice after the training sessions. Although the mean frequency score reduction and median score severity appear to be small, this may represent a real benefit for some women. We suggest that both MR and AR be made available so that women may make a personal choice. However, we believe that the relationship between MR, AR, and menopausal symptoms should be evaluated further.

Conclusion

The total severity score, as well as frequency and severity scores for hot flashes, night sweats, and sleep disturbances tended to decrease in perimenopausal and postmenopausal women in the MR and AR groups. Studies with large sample sizes are necessary to clarify or confirm our results.

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Disclosure

The authors report no conflicts of interest in this work.

References

1. McKinlay MS, Brambilla JD, Posner J. The normal menopause transition. *Maturitas*. 1992;14(2):103–115.
2. Freeman EW, Sammel MD, Lin H, et al. Symptoms associated with menopausal transition and reproductive hormones in midlife women. *Obstet Gynecol*. 2007;110(2 Pt 1):230–240.
3. Kaufert AP, Gilbert P. The Manitoba Project: a re-examination of the link between menopause and depression. *Maturitas*. 1992;14(2):143–155.
4. Dennerstein L, Smith MA, Morse AC, et al. Menopausal symptoms in Australian women. *Med J Aust*. 1993;159(4):232–236.
5. Lopez FJ, Finn PD, Lawson MA, Negro-Vilar A. Regulation of the hypothalamic-pituitary-gonadal axis: role of gonadal steroids and implications for the menopause. In: Lobo RA, Kelsey J, editors. *Menopause: Biology and Pathobiology*. San Diego, CA: Academic Press; 2000.
6. Dennerstein L, Dudley E, Hopper J, Guthrie J, Burger H. A prospective population-based study of menopausal symptoms. *Obstet Gynecol*. 2000;96(3):351–358.
7. Gold BE, Sternfeld B. Relation of demographic and lifestyle factors to symptoms in a multi-racial/ethnic population of women 40–55 years of age. *Am J Epidemiol*. 2000;152(5):463–473.
8. Col NF, Guthrie JR, Politi M, Dennerstein L. Duration of vasomotor symptoms in middle-aged women: a longitudinal study. *Menopause*. 2009;16:453–457.

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9. Soules MR, Sherman S, Parrott E, et al. Executive summary: stages of reproductive aging workshop (STRAW) Park City, Utah, Jul 2001. *Menopause*. 2001;8(6):402–407.
10. Hickey M, Davis SR, Sturdee DW. Treatment of menopausal symptoms: what shall we do now? *Lancet*. 2005;366(9483):409–421.
11. Rossouw JE, Anderson GL, Prentice RL, et al. Risks and benefits of estrogen plus progestin in healthy postmenopausal women: principal results from the Women's Health Initiative Randomized Control Trial. *JAMA*. 2002;288(3):321–333.
12. North American Menopause Society. Treatment of menopause-associated vasomotor symptoms: position statement of The North American Menopause Society. *Menopause*. 2004;11(1):11–33.
13. Newton K, Buist DS, Keenan NL, Anderson LA, LaCroix AZ. Use of alternative therapies for menopause symptoms: results of a population based survey. *Obstet Gynecol*. 2002;100(1):18–25.
14. Blair YA, Gold EB, Azari RA, et al. Use of conventional and complimentary health care during the transition to menopause: longitudinal results from the Study of Women's Health Across the Nation (SWAN). *Menopause*. 2005;12(1):31–39.
15. Daley AJ, MacArthur C, McManus R, et al. Factors associated with the use of complementary medicine and non-pharmacological interventions in symptomatic menopausal women. *Climacteric*. 2006;9(5):336–346.
16. Hoffman WJ, Benson H, Arns AP. Reduced sympathetic nervous system responsivity associated with the relaxation response. *Science*. 1981;215(4529):190–192.
17. Nedstrand E, Wijma K, Wyon Y, Hammar M. Applied relaxation and oral estradiol treatment of vasomotor symptoms in postmenopausal women. *Maturitas*. 2005;51(2):154–162.
18. Freedman RR, Woodward S, Brown B, Javaid IJ, Pandey GN. Biochemical and thermoregulatory effects of behavioral treatment for menopausal hot flushes. *Menopause*. 1995;2(4):211–218.
19. Innes KE, Selfe TK, Vishnu A. Mind-body therapies for menopausal symptoms: a systematic review. *Maturitas*. 2010;66(2):135–149.
20. Lachin JM. Introduction to sample size determination and power analysis for clinical trials. *Control Clin Trials*. 1981;2(2):93–113.
21. Germaine LM, Freedman RR. Behavioral treatment of menopausal hot flashes: evaluation by objective methods. *J Consult Clin Psychol*. 1984;52(6):1072–1079.
22. Nedstrand E, Wijma K, Wyon Y, Hammar M. Vasomotor symptoms decrease in women with breast cancer randomized to treatment with applied relaxation or electro-acupuncture: a preliminary study. *Climacteric*. 2005;8(3):243–250.
23. Zaborowska E, Brynhildsen J, Damberg S, et al. Effects of acupuncture, applied relaxation, estrogens and placebo on hot flush in postmenopausal women: an analysis of prospective, parallel randomized studied. *Climacteric*. 2007;10(1):38–45.
24. McCormack HM, Horne DJ, Sheather S. Clinical applications of visual analogue scales: a critical review. *Psychol Med*. 1988;18(4):1007–1019.
25. Freedman RR, Woodward S. Behavioral treatment of menopausal hot flushes: evaluation by ambulatory monitoring. *Am J Obstet Gynecol*. 1992;167(2):436–439.
26. Hunter M, Liao KLM. Evaluation of four session cognitive behavioral intervention for menopausal hot flushes. *Br J Health Psychol*. 1996;1:113–125.
27. D'Zurilla, Goldfried TJ, Marvin R. Problem solving and behavior modification. *J Abnorm Psychol*. 1971;78(1):107–126.

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ORIGINAL RESEARCH

Modified relaxation technique for treating hypertension in Thai postmenopausal women

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Aim: To examine the effectiveness of a modified relaxation (MR) technique in reducing blood pressure levels in Thai postmenopausal women with mild hypertension, compared with a control group who received health education.

Methods: This is a 16-week, randomized, parallel, open-label, controlled trial in a menopausal clinic in a tertiary health care center in Northeastern Thailand. The intervention group received a 60-minute session of MR training and were encouraged to practice 15–20 minutes a day, at least 5 days a week. The control group received lifestyle education, including diet and exercise. The primary and secondary outcomes were systolic and diastolic blood pressure (SBP and DBP).

Results: Of 432 participants, 215 and 217 were randomly allocated to the MR and control groups, respectively. Of those, 167 participants in the MR group and 175 participants in the control group completed the study. The SBP was significantly more reduced in the MR group, with a mean of 2.1 mmHg ($P < 0.001$). There was no significant difference between groups on the changed DBP.

Conclusion: The MR technique may be effective in lowering SBP in Thai postmenopausal women visiting a menopause clinic. Its efficacy may be observed as soon as 4 weeks after start of treatment. Long-term and combined relaxation therapy and antihypertensive agents are warranted in a large cohort of this population. This trial is registered in clinicaltrials.gov (number NCT01429662).

Keywords: relaxation, hypertension, postmenopause

Introduction

Menopause is defined as the permanent cessation of menstrual periods that occurs naturally or is induced by surgery, chemotherapy, or radiation.[1,2] The menopausal transition concludes with the final menstrual period and the beginning of postmenopause. Despite its clear definition, such a transition may not be recognized until after 12 months of amenorrhea.[2]

Hypertension (HT) (blood pressure [BP] of 140/90 mmHg or higher), especially high systolic BP (SBP), is by far the most important risk factor that affects women in the early postmenopausal years.[3] Early onset of menopause and a long postmenopausal period are associated with higher BP levels.[4–6] Menopause increases the risk for HT twofold, even after adjusting for factors such as age and body mass index.[7,8] The onset of HT can cause a variety of symptoms that are often attributed to menopause.[9,10] About 30%–50% of women develop HT before the age of 60 years. Lowering BP can reduce cardiovascular morbidities and mortality. Reduction of SBP by 5 mmHg can decrease the risk for stroke by 34% and the risk for ischemic heart disease by 21%.[11]

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The likelihood of dementia, heart failure, and mortality from cardiovascular disease, is also greatly reduced.[11]

Although antihypertensive medications are the treatment of choice for HT, concerns persist about the potential adverse effects of pharmacologic agents and the necessity for a long-term course of medication. In general practice, the compliance rate for antihypertensive medications may be as low as 81.6% for patients referred to clinical studies, and 50.6% for nonreferral cases in general clinics. As an intervention without adverse effects, psychosocial treatment, either alone at the early stage of mild HT, or combined with antihypertensive drugs for moderate/severe HT, should be considered.

Among psychosocial treatments, relaxation therapy is a promising intervention for individuals with HT. Possibly because of its effectiveness in reducing plasma norepinephrine levels and sympathetic nervous system responsivity, this therapy is effective in lowering BP in patients with HT.[12–16] A 3-month, single-blind, randomized controlled trial was conducted on patients in middle adulthood with HT.[17] In this sample of 127 African Americans aged 55–70 years, transcendental meditation (TM) and progressive muscle relaxation (PMR) were superior to a lifestyle modification education control program. Although TM reduced SBP by 10.7 mmHg and diastolic blood pressure (DBP) by 6.4 mmHg, PMR lowered SBP by 4.7 mmHg and DBP by 3.3 mmHg, all of which were significantly higher reductions than those seen in the control group. Compliance was high in both the TM and PMR groups.

To our knowledge, only a community trial of relaxation therapy has been carried out in Asian patients with HT.[18] In this study, 590 Taiwanese individuals with HT were randomly assigned to have relaxation therapy at home, self-learning packages, or routine BP measurement by a health professional. At 2 months, the SBP of the relaxation therapy group was lowered an average of 11.0 mmHg compared with 5.1 mmHg for the self-learning group.

Relaxation therapy for the treatment of HT is of particular interest for postmenopausal symptoms. Deep breathing, muscle relaxation, guided imagery, body scans, sitting meditation, and mindful stretching may be methods for the self-treatment of hot flashes.[19] A mindfulness-based stress reduction program also showed that it is effective not only in reducing hot flashes but also in improving the overall quality of life in this population.[20]

The aforementioned evidence suggests that relaxation therapy should be an option for the treatment of HT in postmenopausal women. However, there are limitations to such evidence. First, most studies had several training sessions, which may not be applicable for low-resource health settings. Second, most studies were carried out in Caucasians, who may physically and/or culturally differ from Asians. The only study in Taiwanese people showed only short-term (2-month) benefits of relaxation therapy in individuals with HT living in the community. In this study, we proposed to carry out a medium-term, randomized controlled trial of a modified relaxation (MR) technique to reduce HT in Thai postmenopausal women with mild HT. We included only patients with mild HT because little is known about the efficacy of relaxation therapy for HT, and antihypertensive drug treatment for mild HT is still controversial.[21]

Methods

This was a 16-week, randomized, parallel, open-label, controlled trial to determine the efficacy of an MR technique in reducing BP in Thai postmenopausal women with mild HT. The study was approved by the Mahasarakham Provincial Hospital ethics committee. After the study detail was fully explained, all participants gave written informed consent before taking part in this trial.

Participants

This study was carried out at the Menopausal Clinic of Mahasarakham Provincial Hospital, a tertiary health care setting in Northeastern Thailand. The inclusion criteria included postmenopausal women aged 45–65 years who had mild HT (SBP, 140–159 mmHg or DBP, 90–99 mmHg). The exclusion criteria were as follows: using antihypertensive medications, sedatives, tranquilizers, or antidepressants during the previous 2 months before the study; and a language or geographical barrier.

A woman visiting the menopausal clinic would receive medical interviewing, a pelvic examination, and other laboratory tests as required by her attending gynecologist. BP measurement was taken, using the right arm, with a digital sphygmomanometer, using a standardized procedure after the patient sat and rested for 5 minutes. If the first measurement was abnormal, a second one was taken 30 minutes later, and the averages of the two measurements were recorded by a research nurse.

Interventions

The MR technique was a shortened version of the applied relaxation (AR) technique, provided by a physical therapist, which emphasizes self-practice at home. The AR technique consisted of group instructions 1 hour per

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week for a 12-week duration.[22] The AR training generally involves 10–12 sessions and consists of the following components: progressive relaxation; release-only relaxation; cue-controlled relaxation; differential relaxation; rapid relaxation; application training; and maintenance program. The MR technique is a manual, group-based intervention needing only a single 60-minute training session. The training consists of education on HT in postmenopausal women, breathing training, stretching and releasing muscle tension, and focusing attention on the whole body. Patients were encouraged to practice this MR technique at home 15–20 minutes per day for 5 days a week or more.

The control group received 30 minutes of education and an educational leaflet from a research nurse. The education covered diet, exercise, and smoking/alcohol cessation.

Follow-up assessment

Both groups received phone calls from the physical therapist or research nurses at 2, 4, 6, 8, 10, 12, and 14 weeks to answer any questions relevant to the technique or education, encourage the practice, and for the patients' general well-being. All participants visited the clinic at 4, 8, 12, and 16 weeks to have their BP measured, using the same digital sphygmomanometer and procedure.

The primary outcome was the changed SBP. The secondary outcome was the changed DBP.

Sample size

According to the 3-month study of a 12-session relaxation therapy program for HT in older African Americans, the intervention group had a mean decreased SBP (standard deviation [SD]) of −6.0 (3.0) mmHg.[17] Because the MR technique proposed in this study was far less intensive than the 12-session technique, we estimated that the MR technique might decrease SBP (SD) by −1.0 (3.0) mmHg. By setting the alpha level and power of 5% and 90%, respectively, the sample size needed for this study was 191 patients per group. To compensate for a 15% dropout rate, the target sample size of this study was, therefore, set at 218 patients per group.

Randomization and blinding

The allocation ratio for being an intervention participant or a control participant was 1:1. Random allocation sequences at a blocks of 8 were generated by computer. The random number indicating intervention or control was kept in an opaque and sealed envelope. The envelope was opened after the baseline assessment of each participant had been completed. No blindness was applied in this study.

Statistical analysis

Mean differences between groups on SBP and DBP throughout the study were calculated using multilevel mixed-effect modeling for repeated measures, adjusting for baseline values by entering treatment, time, and baseline values as covariates. The mixed-effect model allowed for random effects on treatment group and time. This assumed there was a population effect for treatment and time but that it varied between individuals. Data were assumed to be missed at random. In addition, a last observation carried forward, intention-to-treat analysis was also conducted to determine the onset of efficacy.

For dichotomous, ordinal, and scale data, the differences between groups were assessed by using chi-square, Mann–Whitney U (Z), and Student's t tests, respectively. A significant difference was set at $P < 0.05$ (two-tailed). All analyses were performed using STATA software version 10 (StataCorp LP, College Station, TX, USA).

Results

This study was carried out between July 2011 and May 2012. Four hundred eighty-eight patients were potential participants. Of these, 432 patients were eligible and randomly allocated to the intervention (n = 215) and control (n = 217) groups, and 167 and 175 patients of the intervention and control groups completed the study, respectively. Dropouts and their reasons for discontinuation are shown in Figure 1.

Demographic and clinical characteristics

Mean ages (SDs) of the participants were 55.7 (5.2) years for the MR group and 56.2 (5.5) years for the control group. Average age at postmenopause was 48.5 years. There was no significant difference between groups in body mass index and comorbidity of diabetes mellitus. There was, however, a trend of higher SBP and a significantly lower DBP in the MR group (Table 1). All participants were nonsmokers and drank nonalcoholic beverages.

Efficacy

The data of participants receiving the study interventions and having at least a single assessment at week 4 were included in the analyses (n = 176 for the MR group and n = 217 for the control group). By using a mixed-effect model of the repeated measure analysis, the changed SBP of the MR group during the 16-week period was significantly lower than that of the control group ($P < 0.001$). The intention-to-treat analysis revealed that the significantly lowered SBP could be observed as soon as 4 weeks after the initiation of treatment

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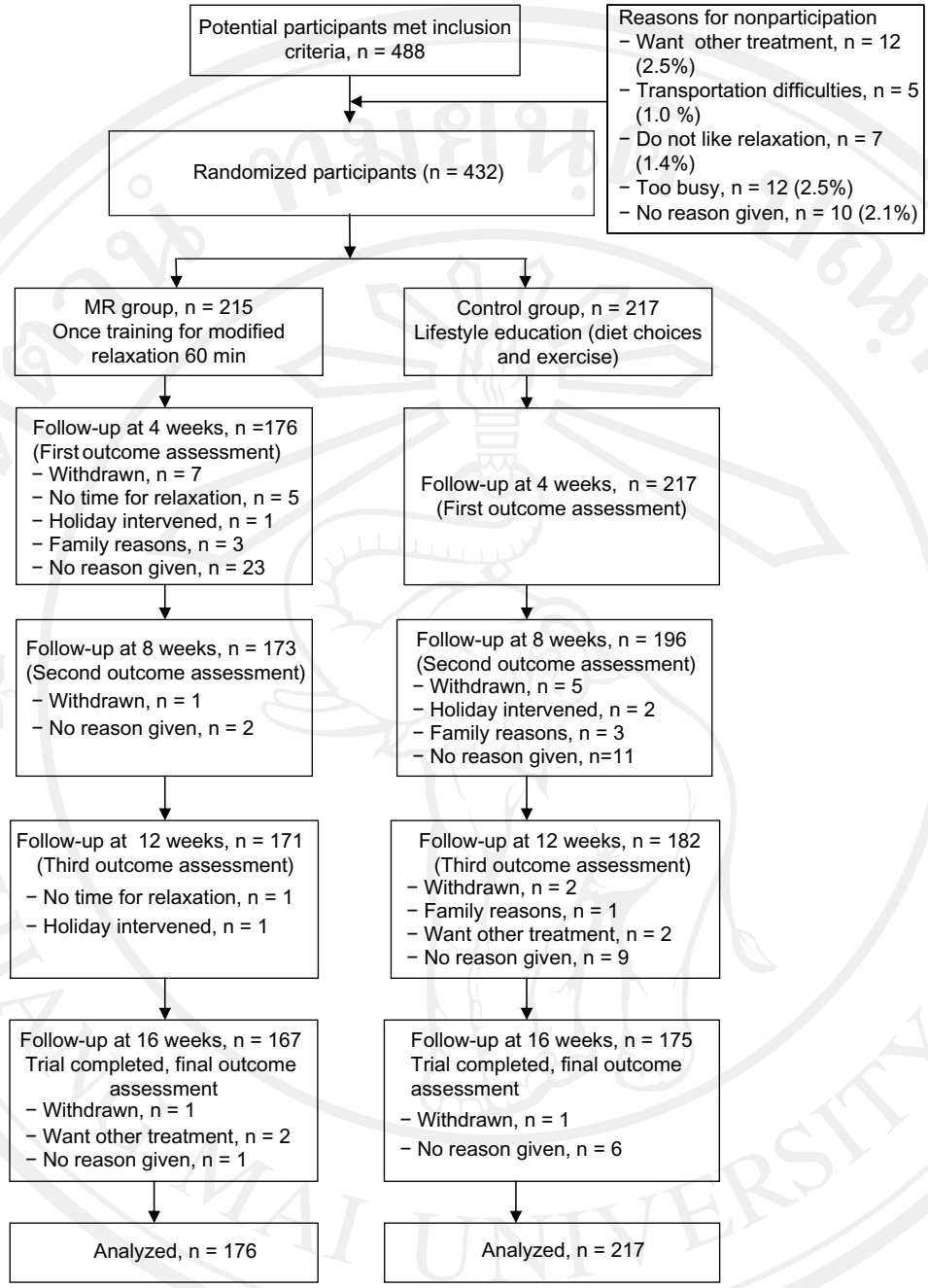

Figure 1 Patient recruitment and follow-up.
Abbreviation: MR, modified relaxation.

($P = 0.04$). The changed DBP levels were not significantly different between groups (Table 2).

Discussion

The MR technique may be effective in lowering SBP in a postmenopausal woman visiting a menopause clinic. Its efficacy may be observed as soon as 4 weeks after start of treatment and last for at least 16 weeks. However, this technique may not be able to lower DBP in this population.

Although the MR technique is a very brief training program, the present findings were in line with previous results showing that relaxation therapy was effective in reducing BP levels in middle-adulthood African Americans and general Asian patients with HT.[17,18] The changed SBPs (2.1 mmHg) found in this trial appeared to be smaller than those of previous studies (6.0 mmHg).

Although the present sample was large enough to detect a small effect size, there were some limitations of this study.

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Table 1 Demographic characteristics of modified relaxation and control group

Characteristics	MR (n = 215)	Control (n = 217)	Significant difference
Age (year)	55.7 (5.2)	56.2 (5.5)	$t = -1.03$, $P = 0.85$
Age menopause established (year)	48.6 (4.3)	48.4 (4.9)	$t = 0.49$, $P = 0.31$
Body mass index (kg/m^2)	25.3 (4.3)	26.6 (4.2)	$t = -3.16$, $P = 0.99$
Diabetes mellitus (DM)			$\chi^2 = 3.26$, $P = 0.19$
Non-DM	149 (34.5)	135 (31.3)	
DM (insulin dependent)	5 (1.2)	10 (2.3)	
DM (non-insulin dependent)	61 (14.1)	72 (16.7)	
Clinical systolic blood pressure, mmHg	148.6 (6.3)	147.5 (6.4)	$t = 1.71$, $P = 0.09$
Clinical diastolic blood pressure, mmHg	88.1 (9.9)	90.5 (10.1)	$t = -2.36$, $P = 0.02$

Notes: Data of age, age at postmenopause, body mass index, clinical systolic blood pressure, and clinical diastolic blood pressure were mean ± standard deviation. Modified relaxation (MR), control, systolic blood pressure, and diastolic blood pressure were modified relaxation, lifestyle education, systolic blood pressure, and diastolic blood pressure, respectively.

Table 2 Changed systolic blood pressure and diastolic blood pressure from baseline comparison between the modified relaxation and the control groups

Outcomes	MR (n = 176)	Control (n = 217)	MEM, RP	ITT
Changed SBP, mmHg			$P < 0.001$	
4 weeks	−4.7 ± 5.9	−3.4 ± 6.6		$t = 2.04$, $P = 0.04$
8 weeks	−6.7 ± 6.9	−5.2 ± 7.5		$t = 2.04$, $P = 0.04$
12 weeks	−7.9 ± 5.7	−5.4 ± 7.8		$t = 3.55$, $P < 0.001$
16 weeks	−8.5 ± 5.8	−6.4 ± 7.6		$t = 3.02$, $P = 0.002$
Changed DBP, mmHg			NS	
4 weeks	−2.5 ± 7.2	−3.1 ± 7.8		$t = 0.65$, $P = 0.51$
8 weeks	−4.3 ± 7.8	−4.8 ± 10.1		$t = 0.32$, $P = 0.75$
12 weeks	−5.0 ± 7.9	−4.5 ± 7.8		$t = 0.89$, $P = 0.37$
16 weeks	−5.2 ± 7.4	−5.6 ± 8.3		$t = 0.38$, $P = 0.70$

Notes: MEM, RP Changed systolic blood pressure and diastolic blood pressure adjusted model by baseline systolic blood pressure, age, and age at postmenopause. Last observation was carried forward of the intention-to-treat analysis.

Abbreviations: MR, modified relaxation; MEM, RP, mixed-effect model for repeated measured analysis; ITT, intention-to-treat analysis; SBP, systolic blood pressure; DBP, diastolic blood pressure; NS, nonsignificant difference.

First, the sample size might be too small to detect the benefit in lowering the DBP, which was usually smaller than that of SBP.[18] Second, although the applied randomization might reduce the bias toward the participants, the open-label design can still cause a bias toward study treatments. Third, the study duration of 16 weeks might be too short to determine the long-term effects of MR in individuals with HT. However, previous findings suggest that the 2 mmHg of DBP lowered by relaxation therapy might be sustained for a year.[23] Fourth, the present sample was relatively specific. Although this limitation has been expected since study inception, to be on the safe side, we carried out this study only in postmenopausal women with mild HT. The generalization of these findings to postmenopausal women with moderate or severe HT may not be possible. Fifth, there was no monitoring of adherence to treatments: we could not determine the duration and frequency of MR practice, as well as lifestyle changes in both intervention and control groups. Last, other benefits of MR, eg, the reduction of postmenopausal symptoms, were not assessed.

Despite the aforementioned limitations, the present findings gave another perspective of the MR technique for postmenopausal women with mild HT. A brief (60-minute) training program of relaxation therapy may be helpful in reducing BP levels in this population. Findings of a comprehensive review support that the 2 mmHg reduction of SBP, which was similar to the 2.1 mmHg reduction of SBP found in this study, could significantly reduce the risks for stroke and heart failure.[24] The results of a Cochrane review also concluded that antihypertensive drugs used in the treatment of otherwise healthy adults with mild HT (SBP, 140–159 mmHg, and/or DBP, 90–99 mmHg) have not been shown to reduce mortality or morbidity in randomized clinical trials.[21] The conflicting evidence obtained from these two reviews would cause an inconclusive decision on antihypertensive drug treatment but support the role of lifestyle modifications, eg, relaxation therapy, in this population. However, because of the small effect size of treatment (−2.1 mmHg of SBP) in 16 weeks of treatment, it should not be a choice for patients with moderate or severe HT, who need more than 10 mmHg reduction of SBP. It would be of interest to further examine whether this technique would add any benefit to pharmacotherapy of moderate or severe HT in this population (eg, lowering the doses of medications or the reduction of postmenopausal symptoms).

Conclusion

In conclusion, the MR technique may be effective in lowering SBP in Thai postmenopausal women visiting a

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menopause clinic. Its efficacy may be observed as soon as 4 weeks after treatment was started. Long-term and combined relaxation therapy and antihypertensive agents are warranted in a large cohort of this population.

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Disclosure

The authors report no conflicts of interest in this work.

References

1. Peck AC, Chervenak JL, Santoro N. Decisions regarding treatment during the menopause transition. In: Lobo RA, editor. *Treatment of the Postmenopausal Woman*. 3rd ed. London, United Kingdom: Academic Press; 2007:157–165.
2. National Institutes of Health. *NIH State-of-the-Science Conference Statement on Management of Menopause-Related Symptoms*. Betheseda: US Department of Health and Human Servies; 2005 Available from: http://consensus.nih.gov/2005/menopausestatement.pdf. Accessed July 1, 2013
3. National Heart, Lung, and Blood Institute [homepage on the Internet]. The Seventh Report of the Joint National Committee on Prevention, Detection, Evaluation, and Treatment of High Blood Pressure; 2004. Available from: http://www.nhlbi.nih.gov/guidelines/hypertension/. Accessed July 1, 2013.
4. Izumi Y, Matsumoto K, Ozawa Y, et al. Effect of age at menopause on blood pressure in postmenopausal women. *Am J Hypertens*. 2007;20(10):1045–1050.
5. Mercuro G, Zoncu S, Saiu F, Mascia M, Melis GB, Rosano GM. Menopause induced by oophorectomy reveals a role of ovarian estrogen on the maintenance of pressure homeostasis. *Maturitas*. 2004;47(2):131–138.
6. Barton M, Meyer MR, Haas E. Hormone replacement therapy and atherosclerosis in postmenopausal women: does aging limit therapeutic benefits? *Arterioscler Thromb Vasc Biol*. 2007;27(8):1669–1672.
7. Staessen J, Bulpitt CJ, Fagard R, Lijnen P, Amery A. The influence of menopause on blood pressure. *J Hum Hypertens*. 1989;3(6):427–433.
8. Amigoni S, Morelli P, Parazzini F, Chatenoud L. Determinants of elevated blood pressure in women around menopause: results from a cross-sectional study in Italy. *Maturitas*. 2000;34(1):25–32.
9. Burt VL, Whelton P, Roccella EJ, et al. Prevalence of hypertension in the US adult population. Results from the Third National Health and Nutrition Examination Survey, 1988–1991. *Hypertension*. 1995;25(3):305–313.
10. Wassertheil-Smoller S, Anderson G, Psaty BM, et al. Hypertension and its treatment in postmenopausal women: baseline data from the Women's Health Initiative. *Hypertension*. 2000;36(5):780–789.
11. Law M, Wald N, Morris J. Lowering blood pressure to prevent myocardial infarction and stroke: a new preventive strategy. *Health Technol Assess*. 2003;7(31):1–94.
12. Lee DD, Kimura S, DeQuattro V, Davison G. Relaxation therapy lowers blood pressure more effectively in hypertensives with raised plasma norepinephrine and blunts pressor response to anger. *Clin Exp Hypertens A*. 1989;11 Suppl 1:191–198.
13. Hoffman JW, Benson H, Arns PA, et al. Reduced sympathetic nervous system responsivity associated with the relaxation response. *Science*. 1982;215(4529):190–192.
14. Hjemdahl P, Fagius J, Freyschuss U, et al. Muscle sympathetic activity and norepinephrine release during mental challenge in humans. *Am J Physiol*. 1989;257(5 Pt 1):E654–E664.
15. Jacob RG, Kraemer HC, Agras WS. Relaxation therapy in the treatment of hypertension. A review. *Arch Gen Psychiatry*. 1977;34(12):1417–1427.
16. Blumenthal JA, Sherwood A, Gullette EC, Georgiades A, Tweedy D. Biobehavioral approaches to the treatment of essential hypertension. *J Consult Clin Psychol*. 2002;70(3):569–589.
17. Schneider RH, Staggers F, Alxander CN, et al. A randomised controlled trial of stress reduction for hypertension in older African Americans. *Hypertension*. 1995;26(5):820–827.
18. Yen LL, Patrick WK, Chie WC. Comparison of relaxation techniques, routine blood pressure measurements, and self-learning packages in hypertension control. *Prev Med*. 1996;25(3):339–345.
19. Fisher TE, Chervenak JL. Lifestyle alterations for the amelioration of hot flashes. *Maturitas*. 2012;71(3):217–220.
20. Carmody JF, Crawford S, Salmoirago-Blotcher E, Leung K, Churchill L, Olendzki N. Mindfulness training for coping with hot flashes: results of a randomized trial. *Menopause*. 2011;18(6):611–620.
21. Diao D, Wright JM, Cundiff DK, Gueyffier F. Pharmacotherapy for mild hypertension. *Cochrane Database Syst Rev*. 2012;8:CD006742.
22. Wijma K, Melin A, Nedstrand E, Hammar M. Treatment of menopausal symptoms with applied relaxation: a pilot study. *J Behav Ther Exp Psychiatry*. 1997;28(4):251–261.
23. van Montfrans GA, Karemaker JM, Wieling W, Dunning AJ. Relaxation therapy and continuous ambulatory blood pressure in mild hypertension: a controlled study. *BMJ*. 1990;300(6736):1368–1372.
24. Black HR. The paradigm has shifted to systolic blood pressure. *J Hum Hypertens*. 2004;18 Suppl 2:S3–S7.

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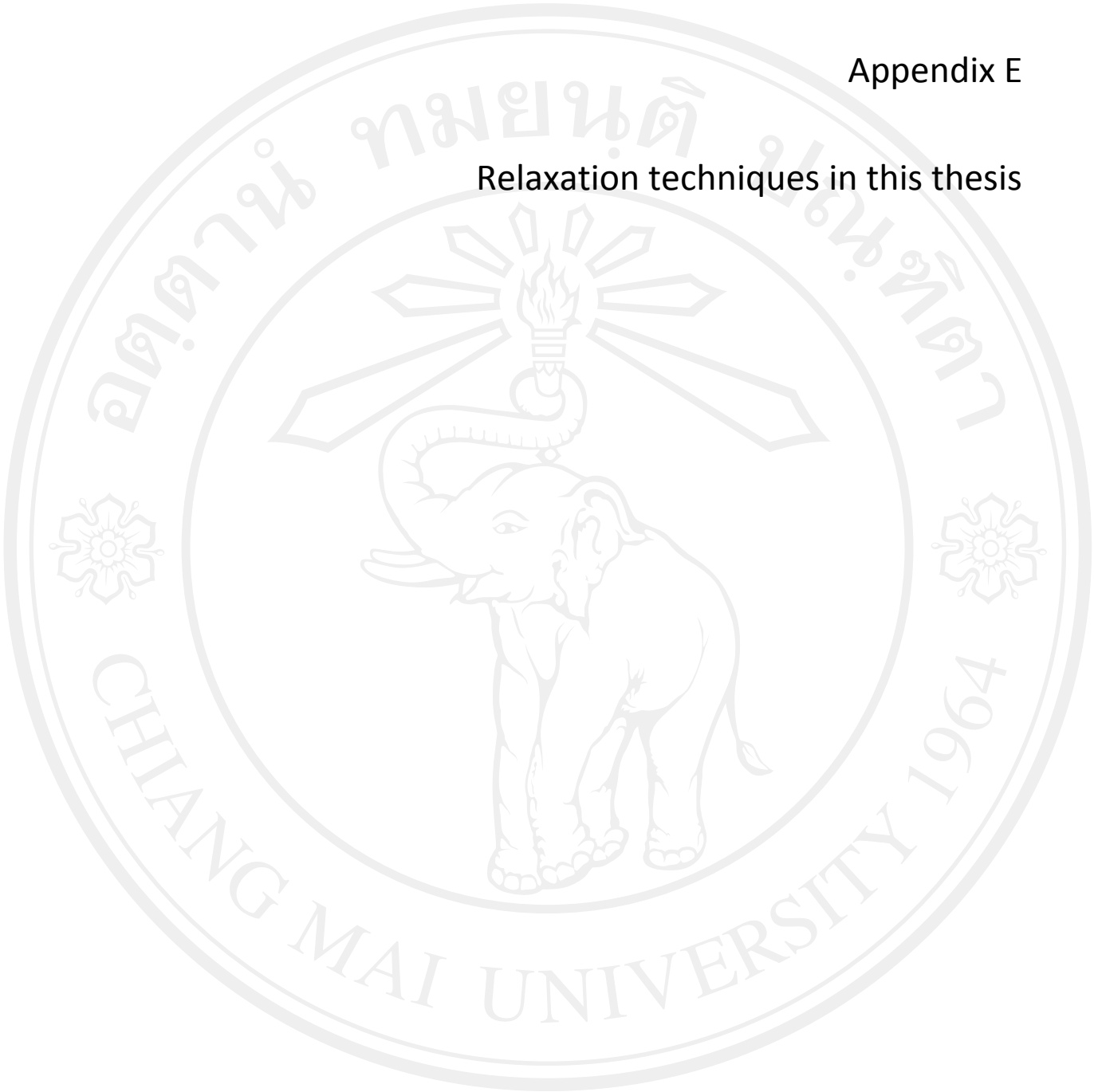
Appendix E

Relaxation techniques in this thesis



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Applied Relaxation (AR)

Applied Relaxation (AR) included 12 sessions, lasting 60 minutes each.

The first session: information about menopause, theories about hot flashes, and the rationale behind the use of AR as a coping technique for handling sudden, unanticipated symptoms was discussed during. Then the progressive relaxation program (contraction and relaxation of muscles in the arms, face, neck, and shoulders) was taught following this discussion.

Session 2: a program of progressive relaxation of the whole body was taught to participants.

Session 3: provided a condensed version of progressive relaxation (relaxation without muscle straining).

Session 4: introduced and practiced to cue-controlled relaxation (self-instructed relaxation).

Sessions 5 and 6: focused on differential relaxation (relaxation of non-used muscle groups).

Sessions 7 and 8: focused on rapid relaxation. After completing session 8, participants were able to relax within 20–30 seconds.

Sessions 9 and 10: participants were asked to use rapid relaxation as soon as their vasomotor symptoms appeared and application of the training began to use.

Sessions 11 and 12: used for rehearsal and a summary of the maintenance program.

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Modified Relaxation (MR)

The Modified Relaxation (MR) technique was a shortened version of the applied relaxation (AR) technique, provided by a physical therapist, which emphasizes self-practice at home. This technique is a manual, group-based intervention needing only a single 60-minute training session. The training consists of four parts as follow:

The first: addressed menopausal symptoms, to enhance understanding among the participants and teach awareness of tension in a particular area of the body.

The second part: participants were encouraged to maximize tension in the affected area, followed by stretching and release of the tension.

The third part, participants were asked to focus their attention on a particular area of the body, to recognize relaxation, and practice relaxing that area.

The final part of the session, participants were asked to commit to practicing at home and were given a summary of the maintenance program.

The MR postures were mention in Thai language for Thai participants described as follow:

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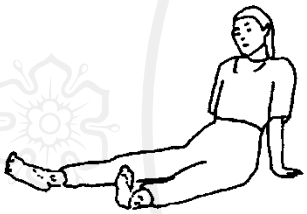
ท่าที่ใช้ในการฝึกปฏิบัติ

1. ท่านอนราบ

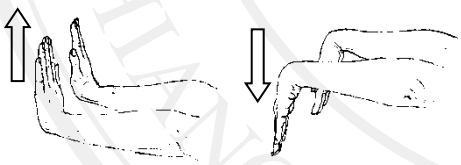
นอนราบ หงายฝ่ามือ กางแขนและขาจากลำตัวเล็กน้อย หายใจเข้าและออกปกติ ทำ 8-10 รอบ

2. ท่านั่ง



นั่งบนพื้นราบเหยียดขาไปด้านหน้าเอนตัวไปด้านหลังเล็กน้อยฝ่ามือยันตัวไว้พักร่างกายสบายๆหายใจเข้าและออกตามปกติทำ 8-10 รอบ

3. ท่าเหยียดแขนและมือ



เหยียดแขนออกทั้ง 2 ข้างตั้งฝ่ามือขึ้นฉากแล้วเกร็ง จากนั้นผ่อนคลายแล้วพับฝ่ามือลง ปลายนิ้วชี้พื้นข้อมือเหมือนบานพับ ทำ 8-10 รอบ

4. ท่าเกร็งและยกไหล (นั่งพื้นหรือเก้าอี้)

ปล่อยมือวางข้างลำตัวค่อยๆยกไหล่ขึ้นและเกร็งเต็มที่พร้อมหายใจเข้าแล้วผ่อนคลายโดยการลดไหล่ลงช้าพร้อมหายใจออกทำ 6-8 รอบ

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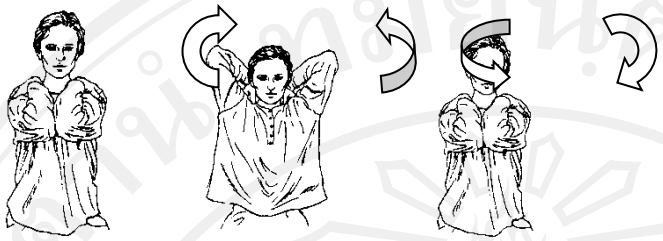
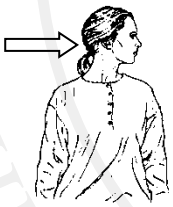
5. **ท่านั่งยกข้อศอก และไหล่ ทำ 6-8 รอบ**



นำมือแตะไหล่พับวาดศอกขึ้นด้านบนสลับวาดศอกย้อน
ศอกเข้าชิดกันยกไหล่ เป็นวงกลมโดยให้ทิศทางลงด้านล่าง
ไหล่เป็นจุดศูนย์กลางเต็มที่พร้อมหายใจ
แล้วอ้อมไปด้านหลังออกและผ่อนคลาย
เกร็งเต็มที่หายใจเข้าช้าๆ

6. ท่านั่งหันหน้าสลับซ้าย-ขวา



หัวหน้าไปทางขวา เกร็งเต็มที่ และสลับหันหน้าไปทางซ้าย ทำสลับกันข้างละ 5-8 รอบ

7. ท่านั่งก้มและเงยคอ

เงยคอ เกร็งกล้ามเนื้อคอเต็มที่ มองหน้าตรง ผ่อนคลาย แล้วก้มคอ เกร็งกล้ามเนื้อ แล้วมองหน้าตรง ผ่อนคลาย ทำ 5-8 รอบ

8. ท่านั่งยืดศีรษะและคอ

มือขวาแตะศีรษะข้างซ้าย ยืดคอเกร็งเต็มที่ แล้วศีรษะตั้งตรง ผ่อนคลาย ทำสลับข้างขวา ทำข้างละ 5-8 รอบ

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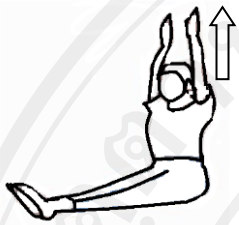
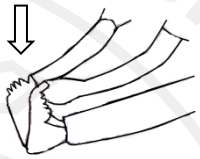
9. **ท่านั่งยืดตัว ก้มหน้า ทำ 2-3 รอบ**

(1) (2) (3)

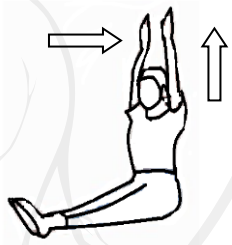




รวบขาชิดนั่งหลังตรงค่อยๆยก ค่อย ๆ เหยียดหลังไปข้างหน้าและก้ม หากมือแตะถึงเท้าได้ทำนิ้วชี้ให้
ยืดลำตัวเต็มที่พร้อมหายใจเข้า แผ่นหลังลงจนสุด พร้อมหายใจออกช้า ๆ เป็นตะขอเพื่อเกี่ยวนิ้วหัวแม่โป้ง
เหยียดแขนตรงแขนทั้ง ขึ้น 2 พร้อมหายใจออกจนหมด
จนลำตัวตั้งตรง

(4) (5) (6)

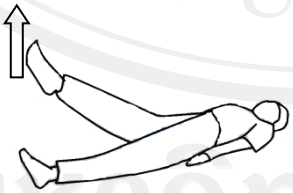
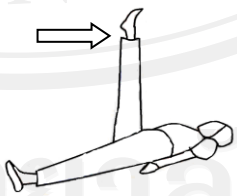




ลดทรวงอกลงแล้วจึงลดศีรษะลง ค่อยยกแขนศีรษะและลำตัวขึ้น ยืดแขนเหนือศีรษะและยืดลำตัว
พร้อมกลั้นหายใจ พร้อมหายใจเข้า ให้ตั้งตรงพร้อมหายใจเข้าเต็มที่

10. **ท่านอน ยกขาข้างขวาและซ้ายสลับกัน ทำ 2-3 รอบ**

(1) (2) (3)

นอนราบ รวบขาชิด ยกขาข้างขวาถึง 30 องศา ยกขาขึ้นสุด เท่าที่ทำ
แขนชิดลำตัวคว่ำฝ่ามือ รอสักครู่ยกถึง 60 องศา ได้โดยไม่เกินมุมฉาก
และหายใจเข้า รอสักครู่พร้อมหายใจเข้าเต็มที่ รอสักครู่พร้อมกลั้นหายใจ

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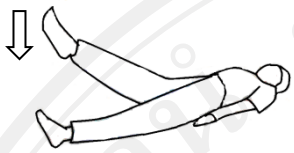
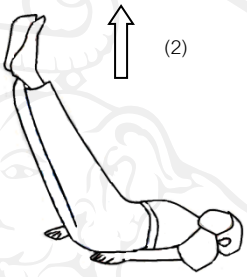
(4) (5)



ค่อยๆลดขาลงพร้อมหายใจออก วางขาราบไปกับพื้นพร้อมหายใจเข้าเต็มที่

11. ยกขาทั้งสองข้าง ทำ 2-3 รอบ

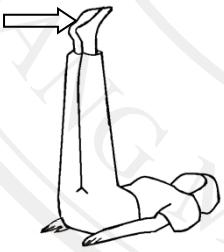
(1) (2)

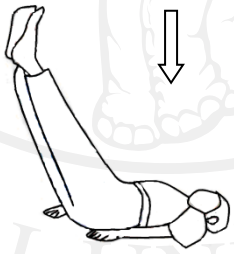


นอนราบ รวบขาชิดกันแขนชิดลำตัว ยกขา 2 ข้างพร้อมกันถึง 30 องศา

คว่ำฝ่ามือหายใจเข้าเต็มที่รอสักครู่ รอสักครู่ แล้วยกถึง 60องศา รอสักครู่

(3) (4)





ยกขาทั้ง 2 ข้างขึ้นยกเท่าที่ยกได้แต่ ค่อย ๆ ลดขาทั้ง 2 ข้างลงพร้อมหายใจออก

อย่ายกเกินมุมฉากพร้อมกลั้นหายใจ ช้า ๆ จนหมด

(5)

วางขาราบไปกับพื้นพร้อมหายใจเข้าเต็มที่

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12. **ท่ายืนยืดลำตัวข้างขวาและซ้าย ทำ 2-3 รอบ**

(1)

ยืนหลังตรง ส้นเท้าชิดลำตัว ไม่เกร็ง

(2)

ยกแขนข้างขวาขึ้นทางด้านข้างลำตัวแล้วยกต่อเนื่องจนแขนแนบชิดหูเหยียดข้างทั้งหมดพร้อมหายใจเข้า

(3)

ค่อย ๆโน้มตัวไปทางข้างเหยียดกล้ามเนื้อข้างลำตัวทุกส่วนให้มากที่สุด ค่อย ๆ กลั้นหายใจ

(4)

ค่อย ๆ ยกแขนและลำตัว ขึ้นพร้อมหายใจออก

(5)

กลับมาเป็นท่ายืนยกแขนแนบชิดหูพร้อมหายใจออกจนสุด

(6)

ยืนหลังตรง ส้นเท้าชิด ไม่เกร็งพร้อมหายใจเข้าเต็มที่

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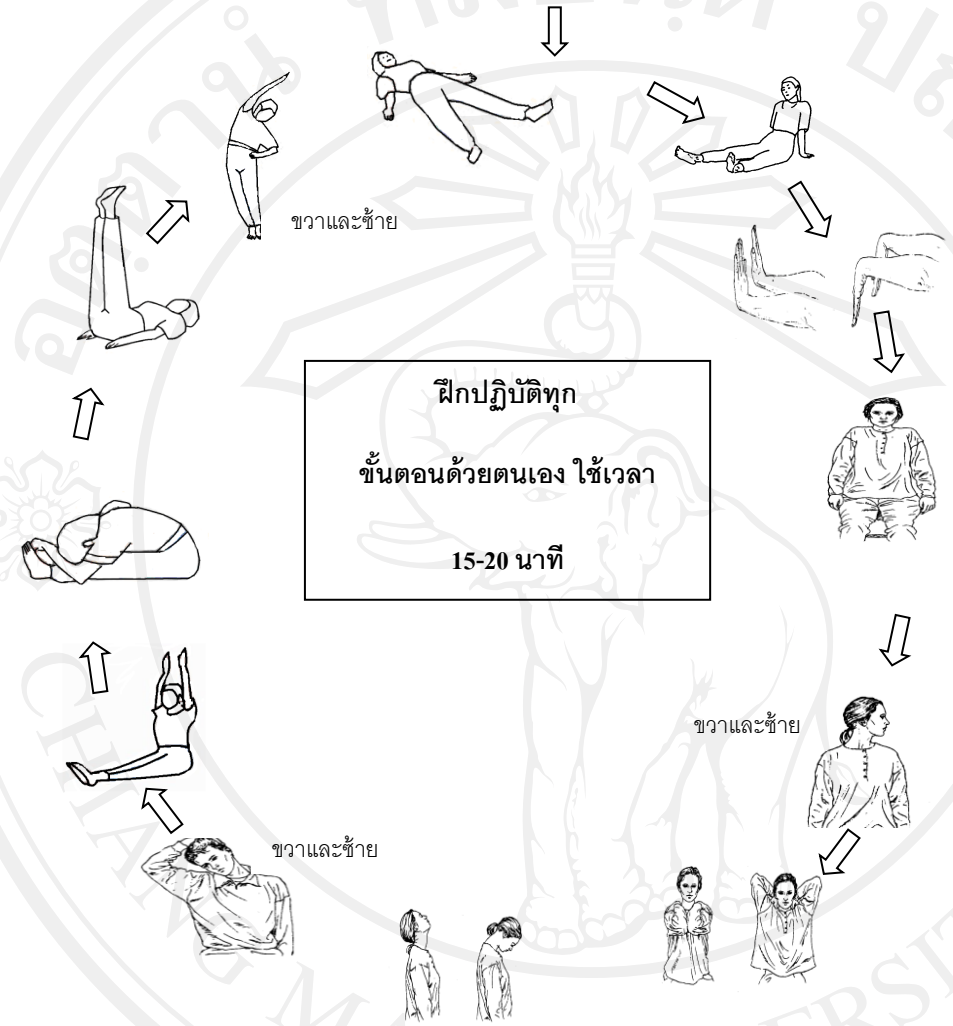
ภาพสรุปการฝึกทุกขั้นตอน



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1997-1999	MS. (Reproductive Health and Population Planning), Mahidol University, Bangkok, Thailand
2007-2013	Ph.D. candidate in Clinical Epidemiology, Faculty of Medicine, Chiang Mai University, Chiang Mai, Thailand

Publications

1. Saensak S, Vutyavanich T, Somboonporn W, Srisurapanont M. Relaxation for perimenopausal and postmenopausal symptoms. Cochrane Database of Systematic Reviews 2013, Issue 6. Art. No.: CD008582. DOI: 10.1002/14651858.CD008582.pub2.

2. Saensak S, Vutyavanich T, Somboonporn W, Srisurapanont M. Effectiveness of a modified version of the applied relaxation technique in treatment of perimenopausal and postmenopausal symptoms. International Journal of Women's Health 2013: 5; 765-771.

3. Saensak S, Vutyavanich T, Somboonporn W, Srisurapanont M.Modified relaxation technique for treating hypertension in Thai postmenopausal women. Journal of Multidisciplinary Healthcare 2013: 6; 373–378.

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