

A COMPARATIVE STUDY ON THE EFFECTS OF NATUROPATHY AND CONVENTIONAL MEDICAL TREATMENT IN THE MANAGEMENT OF MENOPAUSAL SYNDROME

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ABSTRACT

Context: Menopause is one of the most significant events in women's life it due to number of physiological changes that effect the life of a woman. The factors of stress, less healthy diet and lifestyle can contribute for the hormonal dysfunction.

Aims: The aim of present study is to compare the efficacy of Naturopathy and Hormonal therapy in the management of severity of hot flushes, Insomnia, mental status and quality of life in patients with menopausal syndrome.

Designs: It's a Prospective Randomized Comparative study.

Materials and methods: 60 subjects who were aging between 40-60 years randomly allocated into 2 groups. Naturopathy and conventional therapies were given to group 1 and 2 respectively for duration of 10 days. The assessment tools were included WHQ (Women health questionnaire), VAS (Visual analogue scale), PSQI (Pittsburgh Sleep Quality Index) and MENQOL (Menopause Specific Quality Of Life).

Statistical analysis used: Efficacy was assessed using paired and unpaired t test

Results: The results showed a significant difference in both groups with respect to WHQ, VAS, PSQI and MENQOL ($p < 0.005$) for mental status, hot flushes, insomnia and quality of life respectively. But while comparing the results between 2 groups WHQ and VAS showed no significant difference but PSQI and MENQOL showed significant difference between the groups.

Conclusions: naturopathic practices can safely implement in the management of menopausal syndrome without any side effects and to avoid the adverse side reaction of drugs.

Keywords:

Menopausal syndrome, Naturopathy, Hormonal therapy, women health questionnaire, Visual analogue scale, Pittsburgh sleep quality index, Menopause specific quality of life.

INTRODUCTION

The World Health Organization (WHO) defines menopause as "the permanent cessation of menstruation resulting from the loss of ovarian follicular activity." WHO contends that natural menopause is recognized to have occurred after 12 months of amenorrhea, without any other obvious pathological or physiological cause. The mean age of menopause is 52 years [1]. During this transitional phase, woman exhibits severe and multiple symptoms they are mainly physiological disturbances such as hot flushes and psychological complaints such as mood swings, depression that may impair personal or social interactions and reduces the overall quality of life [2]. According to the Indian Menopause Society, Indian women suffering is more due to lack of awareness about normal physiological changes resulting in number of normal physiologic changes like joint and muscular pains 76%, physical and mental exhaustion 58% , insomnia 60 % , hot flushes and night sweating 66%, irritability 64%, anxiety 92%, depressive mood 80% and treatment modalities [3]. Hence it becomes very important to develop methods and treatment plans to control postmenopausal symptoms and thereby to improve the quality of life of this large group of women.

To manage the menopausal symptoms hormonal therapies have been using extensively. However, this has created new concerns about the increased risk of neoplasia of the endometrium, breast cancer. Hence several researchers have investigated the role of alternative therapies in the management of menopausal symptoms and quality of life [4-6].

Naturopathy is an old science based on philosophy of natural principles have been used effectively in various health disorders affecting almost all the major organ system including cardiovascular, respiratory, neuroendocrine, gastrointestinal and musculoskeletal system [7, 8]. Naturopathic medicine is of greatest interest as it is a whole-system of CAM most closely resembling conventional primary care in the scope of practice, but with greater delivery of healthy lifestyle counseling [9]. Naturopathy is a system of a man building in harmony with the constructive principles of nature on physical, mental, moral and spiritual planes of living and consists of drugless treatment modalities like diet therapy, fasting therapy, mud therapy, hydrotherapy, massage therapy, acupressure, acupuncture, chromotherapy, air therapy, and magnetotherapy [10].

Since the main aim of present study is to compare the effects of Naturopathy and Conventional conservative Medical treatment and investigate the most effective treatment among two groups which would help to manage the postmenopausal symptoms and prevent complications. There have been few studies reported which mentioned the effects of alternative and Hormonal therapies but no studies have been designed to compare the effectiveness of naturopathy and Hormonal therapy the best of our knowledge. Hence, this study has been designed for the same.

MATERIALS AND METHODS

76 menopausal women aged between 40-60 years who were not having menstrual period since 1 year were selected from the different Outpatient units : Group 1 (naturopathy) from the OPD of Government Nature Cure Centre, Puttur, Karnataka and group 2 (conventional medicine) from SDM College of Medical Sciences & Hospital, Dharwad were randomly recruited to 2 groups.

Criteria for Diagnosis

Women who have not had a period for at least 12 months aged between 40-60 years with these 4 symptoms of hot flushes, insomnia, altered mental status and quality of life [11].

Inclusion and exclusion criteria

All post-menopausal ladies who attained menopause more than one year willing to take part in the study were included aged between 40-60 years. Exclusion criteria were defined as the presence of following conditions: a) women with un natural menopause e.g. surgical or radiotherapy for cervix cancer b) women on medications such as anxiolytics, antidepressants and undergone hysterectomy to avoid treatment related effects c) Women having any serious diseases or mental retardation or those with any recent mishap or trauma in her life [12].

Intervention

Group 1 (Naturopathy group):

The subjects in group 1 were given the following treatments: cold hip bath, steam bath, cold spinal bath, full and partial body massage, foot reflexology followed by foot bath and diet therapy counseling for 10 days.

Cold hip bath

The hip bath (partial immersion bath of the pelvic region) is given in a specially constructed tub. The tub or basin was filled with enough water of temperature 18-24 °c to cover the buttocks and hips so that the water reaches the level of the navel [13]. Patients were asked to sit in the tub for 15 minutes.

Steam bath- prior to the intervention all the subjects were asked to be in minimum clothing and made to drink 2 glass of cold water. Throughout the intervention a small wet towel was placed on

their head and subjects were made to sit on the stool in the steam chamber. Steam temperature was maintained at 43 °c to 54°c with 100% relative humidity and total duration of intervention was 20 minute. Cold shower was advised after the intervention [14].

Massage – each subject received oil massage with different movements for 30 minutes by experienced massage therapist [15].

Foot bath – patient was made to immerse both legs up to calf muscles with temperature of 40–45° C for 20 minutes [16].

Foot Reflexology therapy -

In foot reflexology therapy the subjects were placed in a comfortable position, usually lying on the back. While standing in front of the patient, given pressure by using wooden stick over special reflex point (K1) in the plantar aspects of foot between 2nd and 3rd metatarsal junction. First for the left foot and then for the right foot 20 min each [17, 18]

Cold Spinal bath- cold spinal bath was given in tubs specially made for the purpose. The water level in the tub was an inch and a half to two inches. The temperature of the water in the spinal bath was 18-24° C and it was measured by using a digital thermometer. The patient lies down in a spinal bath tub with minimum dress, with the head on the side that is most slanted, buttocks at the opposite side end and feet outside and adjusted to the water of the tub such that water should touch the entire length of the spine, from the nape of the neck to the lowest portion of the spine. Intervention was given for 20 minutes [19, 20]

Diet counseling - The subjects were asked to consume natural fresh , wholesome diet which are rich in a) phytoestrogens(soy bean, chickpeas , flax seeds, whole grains) b) antioxidants (spinach, tomatoes, sunflower seeds, carrots, grapes) b) calcium (milk , yogurt, fish and egg. c) vitamin E (nuts and oil seeds, ghee and fish) d) high fiber diet (whole grains i.e. whole eat, millets like bajra, jowar, ragi salads, sprouts, pulses, fruits and vegetables) [21].

table 1: naturopathy(Group 1) intervention protocol for 10 day

Number of days	Treatment
1 st day	Cold Spinal bath
2 nd day	Steam bath
3 rd day	Full body Massage
4 th day	Foot reflexology and foot bath
5 th day	Neutral immersion bath
6 th day	Cold hip bath
7 th day	Steam bath
8 th day	Partial body Massage
9 th day	Foot reflexology and hot foot bath
10 th day	Neutral immersion bath

Group 2

(Conventional medical group):

In the Conventional medical group, as per standard clinical practice and guidelines by an expert panel of gynecology physicians from the department of OBG a drug protocol was developed based on the most commonly administered hormonal therapy (estrogen and progesterone)given to subjects. A treatment diary for the same was also maintained [22,23]

Consent

Signed voluntary informed consent forms were obtained from all subjects before their participation.

Data Extraction

The data was collected using 4 outcomes variables like WHQ, VAS, PSQI and MENQOL. The assessments were done on the first day (pre data) and of 10th day (post data). The data was organized in Microsoft Excel sheets for statistical analysis.

Data Analysis

Statistical analysis of the data was done using SPSS statistics (version 20 release 20.0) software package. The data was checked for normality and student t dependant and independent test used for analysis of difference within group and between the groups respectively. For equality of means in all the two groups were accepted as indicating significant difference within the groups. And for the analysis, we present 95% confidence intervals and considered $p < 0.005$ as significant.

RESULTS

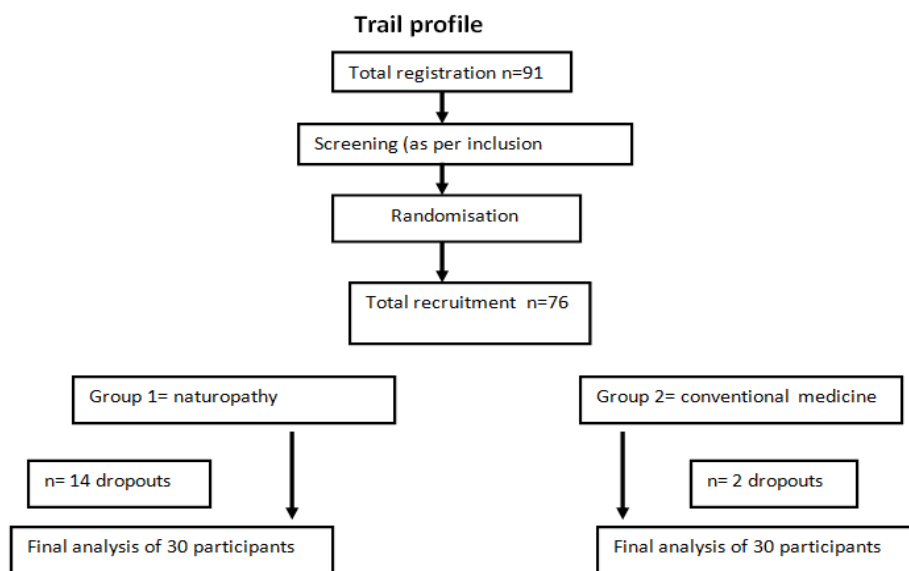


figure 1 : flow chart

Figure 1 91 participants, there were 16 dropouts, 14 in naturopathy and 2 in CM due to (a) unexpected events in the family (b)severe ill health.

table 2: results of descriptive statics of study variables

Variables	Assessment	Within group analysis of N group (n=30)		Within group analysis of CM group (n=30)		Between group analysis with respect to post test scores p value
			P value		P value	
WHQ	Pre test	53.73±4.57	0.0003*	51.70±4.47	0.00001*	0.1983
	Post test	66.50±7.56		67.96±5.49		
VAS	Pre test	9.26±0.82	0.0001*	9.36±0.61	0.00002*	0.3891
	Post test	3.76±1.10		3.83±0.92		
PSQI	Pre test	12.80±1.24	0.0001*	11.80±2.34	0.00003*	0.00007*
	Post test	4.16±1.20		6.30±1.23		
MENQOL	Pre test	62.83±11.36	0.0003*	73.76±10.05	0.00002*	0.000001*
	Post test	42.40±11.64		28.26±8.04		

Note: All values are in mean±standard deviation. *represents significant p values($p \leq 0.05$)
 WHQ= Women health questionnaires, VAS= Visual analogue scale, PSQI= Pittsburgh sleep quality index, MENQOL= Menopause specific quality of life.

Table 2 A study done among the menopause syndrome women’s has shown that 10 days of naturopathy treatments and conventional medicine resulted in a significant changes in within the groups of Naturopathy and Conventional medicine($p < 0.05$) . In between the comparison of 2 groups WHQ ($p = 0.1983$) and VAS ($p = 0.3891$) has not shown any significant changes in improvement of mental status and hot flushes severity while PSQI ($p = 0.00007$) and MENQOL ($p = 0.000001$) shown significant difference in improvement of sleep quality and life respectively

In naturopathy group, there was improvement seen in mental status 53.73 ± 4.57 to 66.50 ± 7.56 and quality of life 62.83 ± 11.36 to 42.40 ± 11.64 , reduced hot flushes 9.26 ± 0.82 to 3.76 ± 1.10 and insomnia 12.80 ± 1.24 to 4.16 ± 1.20

In conventional medicine group, there was improvement seen in mental status 51.70 ± 4.47 to 67.96 ± 5.49 and quality of life 73.76 ± 10.05 to 28.26 ± 8.04 , reduced hot flushes 9.36 ± 0.61 to 3.83 ± 0.92 and insomnia 11.80 ± 2.34 to 6.30 ± 1.23

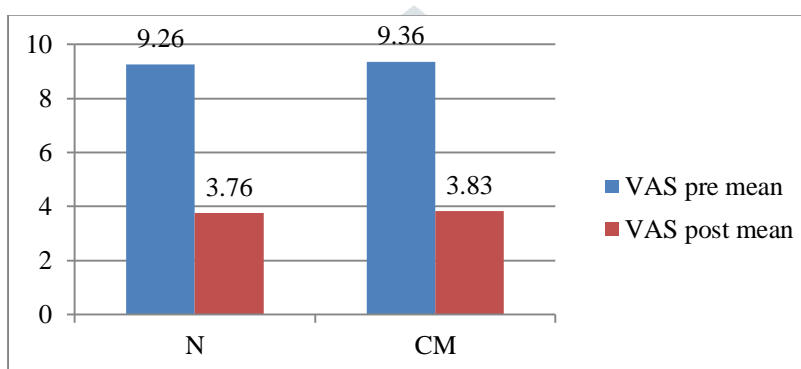


figure 2: comparison of naturopathy (n) and conventional medicine (cm) vas pre-post mean score

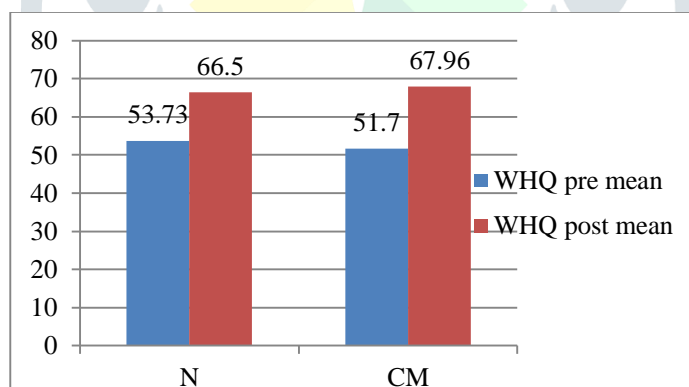


figure 3: comparison of naturopathy (n) and conventional medicine (cm) whq pre-post mean score

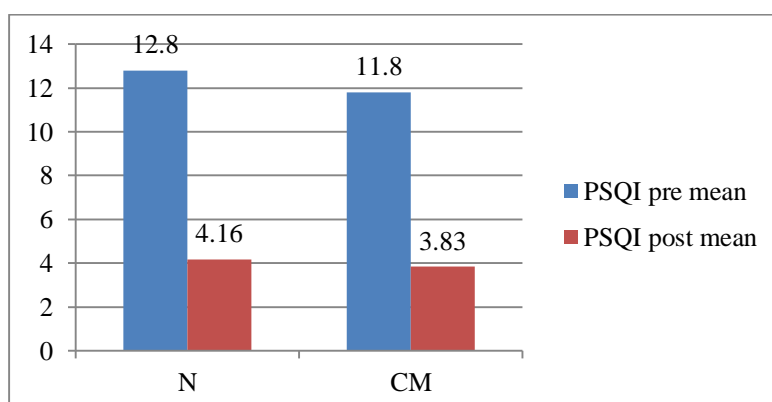


figure 4: comparison of naturopathy (n) and conventional medicine(cm) PSQI pre-post mean score

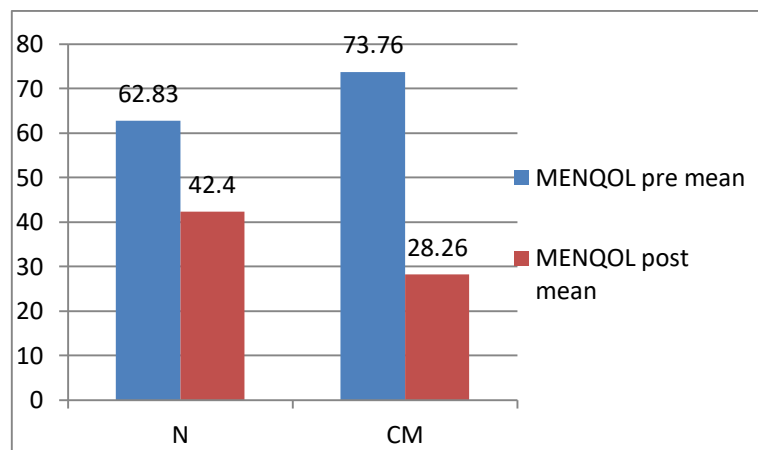


figure 5: comparison of naturopathy (n) and conventional medicine (cm) MENQOL pre-post mean score

DISCUSSION

The results of present study suggest that both interventions Naturopathy and conventional medicine were effective in improving mental status, quality of sleep, quality of life and reducing hot flushes. While comparing in between the group showed significant changes between both the group of PSQI and MENQOL score but not significant changes in WHQ and VAS score. The main areas to address in any case of hormonal balance are the contributing factors like stress, diet, lifestyle etc. Treatment modalities in naturopathy helps in bringing balance in the impaired mechanism of the body and regulates the hormonal cycles [24, 27].

The following reports of previous studies help in understanding the possible mechanism for the results of this study.

cold water therapy may be useful to treat chronic fatigue, stress and depression, as the density of cold receptors in the skin is thought to be three to ten times higher than warm receptors, simultaneous firing of all cutaneous cold receptors could be quite overwhelming and shocking for the brain which may result in positive therapeutic effect of sympathetic activation and also showed that lowering the temperature of brain is known to have neuro protective and therapeutic effects which can be helpful in depressive illness and increases the plasma levels of endorphin which helps to relieve stress in menopausal women as the naturopathy group showed significant changes in mental status cold water therapy might have contributed for that [23-26].

Previous study of warm foot bath has been shown to induce relaxation and also improves sleep by decreasing the stress response by calming down the sympathetic nervous system. [27-29]

Evidences suggest that massage improves visceral functioning and re-establishes the internal environment of the body by acting on the somatic, autonomic and central nervous system (CNS) and has cutaneo- muscle stimulation on the surface of the body [30,31]. Also it activates the receptors of touch, pressure, heat, vibration and pain which in turn, are transported to the autonomous and CNS to reveal the positive effects of massage therapy on various conditions such as depression, anxiety, insomnia and the quality of sleep in post menopausal women [32, 33]. As naturopathy group showed good results in the sleep duration and quality of life, massage therapy would have been one of the reasons to achieve this change.

Previous studies noted that reflexology helps to restore balance to the endocrine system by working with the hypothalamus and pituitary gland. It is also proven to reduce stress and anxiety levels by calming the central nervous system thereby improve the quality of life [34-37].

Many studies shown that reduction in estrogen level will increase the level of oxidative stress in body. During pre menopause the high concentration levels of estrogen have beneficial antioxidant effect by inhibiting the 8-hydroxylation of guanine DNA bases. But during post menopausal state low concentration of estrogen tend to have pro-oxidant effect and leads to breaking in genetic material formation .The serum concentration of inflammatory cytokines, pro-oxidant markers will increase in menopausal women which suggest the high degree of oxidative stress. So consumption of food rich in antioxidants like vitamin C, vitamin E, and phytoestrogens might help in reducing oxidative stress [39,40].

The findings of present study indicate naturopathy interventions were effective in reducing hot flushes, insomnia and improvement of mental status and quality of life.

Future prospects emerging through this study

- Future studies must have better objective variables, larger sample and a longer follow-up duration to authenticate the reported benefits of this study.
- Measures for assessment of stress, anxiety, pain can be included
- Generalizability of this program among different cultures should be assessed and reported.

CONCLUSION

The present study has shown significant beneficial results in mental status, quality of sleep, hot flushes and quality of life in both naturopathy and conventional medicine groups for menopausal syndrome. Since conventional medicine is known to have adverse effects the use of Naturopathy and Yoga treatment modalities in the management of symptoms in patients with menopausal syndrome is found to be safe and effective.

BIBLIOGRAPHY

1. World Health Organization (1996). "Research on the menopause in the 1990's. Report of a WHO Scientific Group." World Health Organisation Technical Report Series 866:pp. 12–14.
2. Speroff L. The menopause a signal for the future. In: Lobo RA, editor. Treatment of the Postmenopausal Women. 2nd ed. Philadelphia: Lippincott Williams and Wilkins; 1999. pp. 1– 10.
3. Hunter M, Gentry-Maharaj A, Ryan A, Burnell M, Lanceley A, Fraser L et al. Prevalence, frequency and problem rating of hot flushes persist in older postmenopausal women: impact of age, body mass index, hysterectomy, hormone therapy use, lifestyle and mood in a cross-sectional cohort study of 10 418 British women aged 54-65. BJOG. 2011;119(1):40-50.
4. Hulley S. Randomized Trial of Estrogen Plus Progestin for Secondary Prevention of Coronary Heart Disease in Postmenopausal Women. JAMA.1998;280(7):605.
5. JE Rossouw, GL Anderson, RL Prentice et.all. Risks and Benefits of Estrogen Plus Progestin in Healthy Postmenopausal Women: Principal Results From the Women's Health Initiative Randomized Controlled Trial. JAMA. 2002;288(3):321-333.
6. Helmond F. Breast cancer and hormone-replacement therapy: the Million Women Study. The Lancet.2003;362(9392):1330.
7. Sengupta P. Health Impacts of Yoga and Pranayama: A State-of-the-Art Review . Int J Prev Med. 2012 Jul; 3(7): 444–458.
8. Woodyard C. Exploring the therapeutic effects of yoga and its ability to increase quality of life. Int J Yoga.2011; 4(2):49.
9. Bradley R, Kozura E, Buckle H,Kaltunas J, Tais S, Standish L. Description of clinical risk factor changes during naturopathic care for type 2 diabetes. J Altern Complement Med2009;15:633-38
10. Nair PM, Nanda A. Naturopathic medicine in India. Focus Altern Complement Ther.2014; 19:140-7.
11. Burger HG.Unpredictable endocrinology of the menopause transition: clinical, diagnostic and management implications. Menopause Int.2011;17:153
12. McKinlay SM, Brambilla DJ, Posner JG. The normal menopause transition.Maturitas.1992;14:103
13. Kellogg JH. Rational hydrotherapy, 2nd edition. Pune: National Institute of Naturopathy,Dept. of AYUSH, Ministry of health and FW. Govt of India, Bapubhavan, Tadiwala Road; 2005. P.100.
14. <https://simplicityofnature.wordpress.com/5-0-illustrative-case-studies/5-1-case-study-1/>
15. Cowen VS, Burkett L, Bredimus J. A comparative study of Thai massage and Swedish massage

- relative to physiological and psychological measures. *Journal of Bodywork and Movement Therapies*. 2006; 10:266-75.
16. Suneesh P, Thangavel K, Doss K. A Study to Assess the Effectiveness of Warm Foot Bath on Sleep Onset Time among Cancer Patients with Insomnia in Nath Lal Parekh Cancer Hospital at Rajkot. *Asian Journal of Nursing Education and Research*. 2017;7(2):231.
 17. How to Manage Your Menopause Symptoms with Acupressure Therapy? [Internet]. Knoji. 2019 [cited 22 March 2019]. Available from: <https://medicaladvice.knoji.com/how-to-manage-your-menopause-symptoms-with-acupressure-therapy>
 18. Blunt E. Foot Reflexology. *Holistic Nursing Practice*. 2006;20(5):257-259.
 19. Blazicková S, Rovenský J, Koska J, Vígas M. Effect of hyperthermic water bath on parameters of cellular immunity. *Int J Clin Pharmacol Res*. 2000;20:41–6. [PubMed]
 20. Jurcovicová J, Vígas M, Palát M, Jezová D, Klimes I. Effect of endogenous GH secretion during hyperthermic bath on glucose metabolism and insulin release in man. *Endocrinol Exp*. 1980;14:221–6.
 21. Ranasinghe C, Shettigar P, Garg M. Dietary intake, physical activity and body mass index among postmenopausal women. *Journal of Mid-life Health*. 2017;8(4):163.
 22. Unni J. Third consensus meeting of Indian menopause society (2008): A summary. *J Midlife Health* 2010;1:43-7.
 23. *International Journal of Obstetrics & Gynaecology*. 2008;115(8):991-1000.
 24. Nair P. Naturopathy and yoga in ameliorating multiple hormonal imbalance: a single casereport. *International Journal of Reproduction, Contraception, Obstetrics and Gynecology*. 2016;;916-918.
 25. Mooventhan A, Nivethitha L. Scientific evidence-based effects of hydrotherapy on various systems of the body. *North American Journal of Medical Sciences*. 2014;6(5):199.
 26. Shevchuk N. Adapted cold shower as a potential treatment for depression. *Medical Hypotheses*. 2008;70(5):995-1001.
 27. Barry R, Lewis D. Hydrotherapy. In: Pizzorno, JE, Murray, MT eds. *The Textbook of Natural Medicine*. 3rd Edition. Elsevier/Churchill Livingstone. 2006:401-416.
 28. 23 Proven Ways to Reduce Stress and Relax | Health Grinder [Internet]. Health Grinder. 2019 [cited 22 March 2019]. Available from: <https://healthgrinder.com/ways-to-reduce-stress/>
 29. Yamamoto K, Aso Y, Nagata S, Kasugai K, Maeda S. Autonomic, neuro-immunological and psychological responses to wrapped warm footbaths—A pilot study. *Complementary Therapies in Clinical Practice*. 2008;14(3):195-203.
 30. Zhou YF, Wei YL, Zhang PL, Gao S, Ning GL, Zhang ZQ et al. Multicentral controlled study on three-part massage therapy for treatment of insomnia of deficiency of both the heart and spleen. *Zhongguo Zhen Jiu*. 2006; 26:385-8
 31. Hachul H, Oliveira D, Tufik S, Bittencourt L. Effect of massage in postmenopausal women with insomnia: a pilot study. *Clinics*. 2011;66(2):343-346.
 32. Oliveira D, Hachul H, Goto V, Tufik S, Bittencourt L. Effect of therapeutic massage on insomnia and climacteric symptoms in postmenopausal women. *Climacteric*. 2011;15(1):21-29.
 33. Abd Allah I. Massage Therapy for Alleviating Menopausal Transitional Period Symptoms among Women employed at Suez Canal University Hospital. *Iosrjournals.org*. 2018.
 34. Asltoghiri M, Ghodsi Z. The effects of Reflexology on sleep disorder in menopausal women. *Procedia - Social and Behavioral Sciences*. 2012;31:242-246.
 35. Gozuyesil E, Baser M. The effect of foot reflexology applied to women aged between 40 and 60 on vasomotor complaints and quality of life. *Complementary Therapies in Clinical Practice*. 2016;24:78-85.
 36. Williamson J. Randomised controlled trial of reflexology for menopausal symptoms. *BJOG: An International Journal of Obstetrics and Gynaecology*. 2002;109(9):1050-1055.
 37. Pinto P, Paul S. Effect of foot reflexology on the quality of life among menopausal women in selected schools in Mangalore. *Nitte.edu.in*. 2012.
 38. Lewis J, Nickell L, Thompson L, Szalai J, Kiss A, Hilditch J. A randomized controlled trial of the effect of dietary soy and flaxseed muffins on quality of life and hot flashes during menopause. *Menopause*. 2006;13(4):631-642.
 39. Bedell S, Nachtigall M, Naftolin F. The pros and cons of plant estrogens for menopause. *The Journal of Steroid Biochemistry and Molecular Biology*. 2014;139:225-236.
 40. Agarwal A, Doshi S. The role of oxidative stress in menopause. *Journal of Mid-life Health*. 2013;4(3):140