

Homeopathy and Women's Health

The status of women's health in the United States leaves much to be desired. Perinatal mortality is increasing with significant racial disparities, and the caesarian delivery rate with its associated morbidities is unacceptably high.¹ There is a paucity of new drug development for perinatal conditions.² More than 200,000 women are newly diagnosed with breast cancer each year.³ Research in homeopathy pertaining to women's health is incomplete due to scientific disparagement and substantial barriers in funding, yet it offers useful insight into potential steps forward that would significantly enhance the health and quality of life of women and their families in the U.S. A review of some of this research follows.

Infertility

Infertility affects more than 10% of reproductive age women in the U.S.⁴ due to multiple factors such as irregular menses, endometriosis, tubal factors, and early miscarriages. Both animal and human data contribute support to possible homeopathic interventions. In one study, in vitro evaluation of homeopathic medicine demonstrated increased viability and ultrastructural integrity of follicles after 7 days of culture (p < 0.05). This group also showed higher follicle and oocyte growth than α -MEM+ controls (p < 0.05).⁵

A German study of infertility comparing homeopathy with placebo in 96 women resulted in twice as many pregnancies in the homeopathic group, but only one-third of adverse events when compared with the placebo group. The authors noted that in more than 1000 patients followed in post-marketing surveillance there was a 60% success rate with homeopathic treatment.⁶

A case series of female infertility in Greece demonstrated similar results of the effectiveness of homeopathy.⁷

Individualized homeopathic treatment of menstrual irregularities, including oligomenorrhea, amenorrhea, and oligo-amenorrhea demonstrated improvement rates of 50% with amenorrhea, and 100% with oligomenorrhea.⁸

A randomized controlled study of 50 Brazilian women demonstrated significant improvement of endometriosis following the administration of homeopathic medicine. The intervention group

¹ https://www.nytimes.com/2016/09/22/health/maternal-mortality.html

² Fisk NM, Atun R. "Systematic Analysis of Research Underfunding in Maternal and Perinatal Health." *BJOG: An International Journal of Obstetrics and Gynaecology* 2009;116(3): 347–56. https://doi.org/10.1111/j.1471-0528.2008.02027.x.

³ https://www.cdc.gov/cancer/uscs/index.htm

⁴ https://www.cdc.gov/nchs/fastats/infertility.htm

⁵ Lima L, Ferreira de R, Magalhães P, et al. "Dynamized Follicle-Stimulating Hormone Affects the Development of Ovine Preantral Follicles Cultured in Vitro." *Homeopathy* 2013;102(1): 41–48. https://doi.org/10.1016/j.homp.2012.11.002.

⁶ Gerhard I, Patek A, Monga B, et al. "Mastodynon(R) Bei Weiblicher Sterilität." *Forschende Komplementarmedizin* 1998;5(6): 272–78. https://doi.org/10.1159/000021154.

⁷ Kalampokas T, Botis S, Kedikgianni-Antoniou A, et al. "Homeopathy for Infertility Treatment: A Case Series." *Clinical and Experimental Obstetrics & Gynecology* 2014;41(2):158–59.

⁸ Cardigno P. "Homeopathy for the Treatment of Menstrual Irregularities: A Case Series." *Homeopathy* 2009;98(2): 97–106. https://doi.org/10.1016/j.homp.2009.01.004.

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experienced a significant reduction in endometriosis symptoms while subjects in the placebo group saw no change. Significant improvements in secondary outcomes including anxiety, depression, and quality of life were also noted in the homeopathic group.⁹

A case series of eight consecutive patients with endometriosis all demonstrated significant clinical and laparoscopic improvement while utilizing homeopathic treatment.¹⁰

A prospective multicenter observational study of 128 women with dysmenorrhea compared homeopathic treatment in primary care with conventional treatment. Both diagnosis, complaints of severity and use of other healthcare services improved markedly in the homeopathic group but only slightly in the conventional treatment group. Patients with dysmenorrhea consistently improved under homeopathic treatment.¹¹

Homeopathy demonstrates efficacy in the treatment of patients with fibromyoma of the uterus. A study of 84 patients receiving homeopathic treatment were evaluated with pelvic examination and real-time ultrasound and demonstrated both interruption of growth and reduced tumor size, reduced pain and abnormal endometrial bleeding over a period of three years. ^{12,13}

Pregnancy

Homeopathic treatment shortened the duration of labor by an average of 90 minutes in a double-blinded placebo controlled study with age-matched controls in a University-based trial in Italy (p<0.05).¹⁴

Both false labor and cessation of labor were effectively treated with homeopathic medicine in a double-blinded placebo-controlled randomized clinical trial at the University of Limoges. No adverse events were reported.¹⁵

In another double-blind, randomized placebo-controlled trial of 53 subjects at Universite Rene Descartes, homeopathic treatment not only shortened labor by an overage of 3.5 hours (p<0.001), but significantly reduced the incidence of dystocia to 11.3% in the homeopathic group compared with 40% in the placebo controls (p<0.01). No adverse events were reported.¹⁶

⁹ Teixeira MZ, Podgaec S, Chada Baracat E. "Potentized Estrogen in Homeopathic Treatment of Endometriosis-Associated Pelvic Pain: A 24-Week, Randomized, Double-Blind, Placebo-Controlled Study." *European Journal of Obstetrics and Gynecology and Reproductive Biology* 2017;21: 48–55. https://doi.org/10.1016/j.ejogrb.2017.01.052. Hunton, M. "Endometriosis and Homœopathy: An Audit Study of 8 Consecutive Patients." *British Homoeopathic Journal* 1993;82(2): 92–96. https://doi.org/10.1016/S0007-0785(05)81031-2.

¹¹ Witt, CM, Lüdtke R, Willich SN. "Homeopathic Treatment of Patients with Dysmenorrhea: A Prospective Observational Study with 2 Years Follow-Up." *Archives of Gynecology and Obstetrics* 2009;280(4): 603–11. https://doi.org/10.1007/s00404-009-0988-1.

¹² Gupta G. Uterine fibroids, A clinical study with USG follow-up. *Natl J Homoeopath* 2003;5(3): S. 172-179.

¹³ Gupta G.: Evidence based clinical study of uterine fibroid cases in response to homoeopathy. *Natl J Homoeopath* 2010, 12(8): 39-48

¹⁴ Eid P, Felisi E, Sideri M. "Applicability of Homoeopathic Caulophyllum Thalictroides during Labour." *British Homoeopathic Journal* 1983; 82: 245--248.

¹⁵ Deguillaume M. "Etude Experimentale de l'action Du Caulophyllum Dans Le Faux Travail et La Dystocie de Demarrage." Universite de Limoges, 1981.

¹⁶ Dorfman P, Tetau M. "Preparation a l'accouchement par homeopathic." *Cahiers de Biotherapie*, 1995;134: 33–38.

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An unpublished manuscript of 20 parturients at the Maternite de la Clinique Saint-Jean (Roubaix, France) treated for dystocia while in labor using a homeopathic protocol demonstrated improved labor progress with no apparent or reported adverse events. ¹⁷

An unblinded randomized study of 206 women at high risk of uterine contractile function disturbances compared homeopathic treatment with conventional medical care. The homeopathically treated group required less use of hypnotics, oxytocin, cesarean section, forceps, or manual delivery of placenta (p<0.05).¹⁸

A double-blind, placebo-controlled, randomized, clinical trial conducted by the Department of Gynecology, Shaare Zedek Medical Center, Jerusalem evaluated the effect of homeopathic treatment in 40 parturients with postpartum blood loss.

Blood loss in the homeopathic group was significantly less than in the placebo group (p < 0.05). ¹⁹

In a prospective, comparative, randomized placebo-controlled trial evaluating the incidence of quinine-induced side-effects in endemic gestational malaria in 211 women, homeopathy significantly improved outcome and reduced side-effects when compare with placebo (p < 0.0001).

Homeopathy has been successfully utilized in midwifery practice as numerous journal articles and texts describe during the perinatal period for labor preparation, intrapartum and postpartum applications as well as for menopausal symptoms and:

- Induction of labor.²¹
- General midwifery.²²
- Prolonged pregnancy.²³
- Use of a homeopathic childbirth 'kit'.²⁴
- General obstetrics.²⁵

¹⁷ Ducloy M. "Interet de trois remedes homeopathiques au cours de l'accouchement: Actea racemosa, Caulophyllum, Gelsemium." 1983. Boiron, Newtown Square, PA.

¹⁸ Ventoskovskiy BM, Popov AV. "Homœopathy as a Practical Alternative to Traditional Obstetric Methods." *Br Homeopath J* 2018;79(4): 201–5. https://doi.org/10.1016/S0007-0785(05)80452-1.

¹⁹ Oberbaum M, Galoyan N, Lerner-Geva L, et al. The Effect of the Homeopathic Remedies Arnica Montana and Bellis Perennis on Mild Postpartum Bleeding—A Randomized, Double-Blind, Placebo-Controlled Study—Preliminary Results." *Complementary Therapies in Medicine* 2005;13(2): 87–90. https://doi.org/10.1016/j.ctim.2005.03.006.

²⁰ Danno K, Rerolle F, de Sigalony S, et al. "China Rubra for Side-Effects of Quinine: A Prospective, Randomised Study in Pregnant Women with Malaria in Cotonou, Benin." *Homeopathy* 2014;103(3):165–71. https://doi.org/10.1016/j.homp.2014.03.002

²¹ Kistin SJ, Newman AD. "Induction of Labor with Homeopathy: A Case Report." *Journal of Midwifery & Women's Health* 2007;52(3): 303–7. https://doi.org/10.1016/j.jmwh.2006.12.013.

²² Smith V. "Evidence for Homeopathy in Childbirth." *The Practising Midwife* 2013;16(8): S10-12.

²³ Steinberg D, Beal MW. "Homeopathy and Women's Health Care." *Journal of Obstetric, Gynecologic & Neonatal Nursing* 2003;32(2):207–14. https://doi.org/10.1177/0884217503252125.

²⁴ Steen M, Calvert J. "Self-Administered Homeopathy Part Two: A Follow-up Study." *British Journal of Midwifery* 2007;15(6):359–65. https://doi.org/10.12968/bjom.2007.15.6.23680.

²⁵ Münstedt K, Brenken A, Kalder M. "Clinical Indications and Perceived Effectiveness of Complementary and Alternative Medicine in Departments of Obstetrics in Germany: A Questionnaire Study." *European Journal of*

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- Pregnancy and childbirth.²⁶
- The pre-conceptual period.²⁷
- Women's health, and the need for a research agenda.²⁸
- The menopause.²⁹

Lactation

Seventy-one patients were included a double-blind placebo-controlled study of pain or difficulty during lactation. Those treated homeopathically noted significant improvement of lactation pain (p<0.01), breast tension and spontaneous milk flow (p<0.05).³⁰

Premenstrual syndrome/dysphoria

In an observational, prospective study of 23 women treated homeopathically for premenstrual syndrome, a statistically significant reduction of symptoms was noted (p < 0.0001). Most women treated homeopathically also reported significant quality of life improvements (p < 0.0001). 31

A randomized, controlled double-blind clinical trial conducted at Hadassah Hospital outpatient gynecology clinic in Jerusalem, Israel evaluated homeopathic treatment of premenstrual syndrome in 21 women. Significant reduction of symptoms was noted in >90% of women receiving homeopathic treatment (P=0.048).³²

Individualized homeopathic prescribing for PMS was evaluated using a computerized diagnostic algorithm in 30 patients. Symptom scores improved by 50% or more in 12 patients, and by 30–50% in an additional 6 patients.³³

A multi-center, international, randomized, controlled pragmatic trial of two parallel groups investigated the feasibility individualized homeopathic add-on treatment using a semi-standardized computerized algorithm in 60 women with premenstrual disorders compared with conventional care only. After four months, the relative mean change of symptom scores in the

Obstetrics & Gynecology and Reproductive Biology 2009;146(1): 50–54. https://doi.org/10.1016/j.ejogrb.2009.05.013.

²⁶ Kalder M, Knoblauch K, Hrgovic I, et al. Arch Gynecol Obstet 2011;283: 475. https://doi.org/10.1007/s00404-010-1388-2

²⁷ Kaplan B. "Homoeopathy: 2. In Pregnancy and for the under-Fives." *Professional Care of Mother and Child* 1994;4(6): 185–87.

²⁸ Murphy PA, Kronenberg F, Wade C. "Complementary and Alternative Medicine in Women's Health. Developing a Research Agenda." *J Nurse-Midwifery* 1999;44(3):192–204.

²⁹ Katz T. "Homoeopathic Treatment during the Menopause" *Complementary Therapies Nursing & Midwifery* 1997;3(2): 46–50.

³⁰ Berrebi A, Parant O, Ferval F, et al. "Treatment of Pain Due to Unwanted Lactation with a Homeopathic Preparation given in the Immediate Post-Partum Period" *Journal de Gynecologie, Obstetrique et Biologie de La Reproduction* 2001;30(4): 353-357. http://europepmc.org/abstract/MED/11431615.

³¹ Danno K, Colas A, Terzan L, et al. "Homeopathic Treatment of Premenstrual Syndrome: A Case Series." *Homeopathy* 2013;102(1):59–65. https://doi.org/10.1016/j.homp.2012.10.004.

³² Yakir M, Kreitler S, Brzezinski A, et al. "Effects of Homeopathic Treatment in Women with Premenstrual Syndrome: A Pilot Study" *Br Homoeopathic J* 2001;90(3):148–53. https://doi.org/10.1038/sj/bhj/5800491.

³³ Klein-Laansma CT, Jansen JCH, van Tilborgh AJW, et al. "Semi-Standardised Homeopathic Treatment of Premenstrual Syndrome with a Limited Number of Medicines: Feasibility Study." *Homeopathy* 2010;99(3):192–204. https://doi.org/10.1016/j.homp.2010.05.007.

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homeopathically treated group was significantly better than in the conventional group (p = 0.0028).³⁴

A series of cases of hyper-estrogenic breast disease benefiting from homeopathic treatment were presented and reviewed.³⁵

Surgery

A two-year study evaluating benefits of homeopathy on post-operative blood loss and seroma production in 53 women undergoing unilateral total mastectomy demonstrated statistically significant reduction of intra and post-operative blood loss.³⁶

Menopause

For women who do not want to use, or cannot use, hormone replacement therapy, safe homeopathic alternatives exist. There are numerous excellent homeopathic drugs that can be purchased over the counter for these symptoms. A woman can also choose to be evaluated by a homeopathic practitioner and have an individualized program designed specifically for her health needs. Although there has been limited clinical research of homeopathic therapies for the menopause, when taken according to directions, they have the potential for being extremely safe and efficacious.³⁷

Menopause is a highly variable adjustment period for some women. Homeopathy has been delivered within the UK National Health Service since its inception and has been used to alleviate symptoms both in the climacteric, and more recently in breast cancer survivors. Individualized treatment by a homeopathic practitioner, regarded as the gold standard of homeopathic care, is a complex intervention where the homeopathic medicine is matched to a woman presenting with a range of symptoms such as hot flushes, sleep and mood disturbance, joint pains and fatigue.³⁸

An audit of Sheffield's National Health Service Community Menopause Clinic revealed significant benefits from incorporating homeopathic treatments. The greatest response was seen in those reporting headaches, vasomotor symptoms, emotional/psychological symptoms, and tiredness/fatigue as their primary symptoms during menopause.³⁹

³⁴ Klein-Laansma C, Christien T, Jong M, et al. "Semi-Individualized Homeopathy Add-On Versus Usual Care Only for Premenstrual Disorders: A Randomized, Controlled Feasibility Study." *J Alternative Complementary Medicine* 2018; 24(7):684–93. https://doi.org/10.1089/acm.2017.0388.

³⁵ Jones A. "Homeopathic Treatment for Premenstrual Symptoms." *J Family Planning Reproductive Health Care* 2003;29(1):25. https://doi.org/10.1783/147118903101196855.

³⁶ Sorrentino L, Piraneo S, Riggio E, et al. "Is There a Role for Homeopathy in Breast Cancer Surgery? A First Randomized Clinical Trial on Treatment with Arnica Montana to Reduce Post-Operative Seroma and Bleeding in Patients Undergoing Total Mastectomy." *J Intercultural Ethnopharmacology* 2017;6(1): 1–8. https://doi.org/10.5455/jice.20161229055245.

³⁷ Kass-Annese B. "Alternative Therapies for Menopause." *Clinical Obstetrics and Gynecology* 2000;43(1): 162–83. ³⁸ Thompson EA. "Alternative and Complementary Therapies for the Menopause: A Homeopathic Approach." *Maturitas* 2010;66(4): 350–54. https://doi.org/10.1016/j.maturitas.2010.02.003.

³⁹ Relton C, Weatherley-Jones E. "Homeopathy Service in a National Health Service Community Menopause Clinic: Audit of Clinical Outcomes." *J British Menopause Society* 2005;11(2): 72–73.

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A retrospective, single cross-sectional descriptive study conducted on women experiencing vasomotor symptoms after withdrawal from hormone replacement therapy across the U.S. sampled 563 menopausal women and revealed that nearly half used complementary and alternative medicine including homeopathy.⁴⁰

A multicenter, randomized, double-blind, placebo-controlled study conducted in 35 active centers in France evaluating the use of homeopathy in reducing hot flashes in menopausal women studied 101 menopausal women. Global symptoms demonstrated significant improvement in the homeopathic group compared with the placebo group (p = 0.0411). Treatment was well tolerated and no serious adverse effects were attributable to homeopathy.⁴¹

An open, multicenter, prospective, observational study to evaluate homeopathic treatment of menopausal women found it useful in relieving menopausal symptoms including hot flashes, night sweats, anxiety, palpitation, depression, and insomnia.⁴²

Breast cancer

A prospective observational study of individualized homeopathic treatment of estrogen withdrawal in 40 women with breast cancer demonstrated significant improvement in withdrawal symptoms as well as fatigue, mood disturbances, anxiety, depression, and quality of life.⁴³

A randomized, double-blind placebo-controlled trial of 83 breast cancer survivors with hot flashes from estrogen withdrawal demonstrated a significant positive trend towards fewer hot flashes after individualized homeopathic treatment.⁴⁴

Nine patients suffering from a high level of pain after breast cancer therapy, despite use of standard postoperative treatment with conventional analgesics, were treated homeopathically and experienced a marked reduction in pain. Similarly, health-related quality of life also improved.⁴⁵

⁴⁰ Kupferer EM, Dormire SL, Becker H. "Complementary and Alternative Medicine Use for Vasomotor Symptoms Among Women Who Have Discontinued Hormone Therapy" *J Obstetric, Gynecologic Neonatal Nursing* 2009;38(1):50–59. https://doi.org/10.1111/j.1552-6909.2008.00305.x.

⁴¹ Trial registration number (EudraCT): 2009-016959-21. Bordet MF, Colas A, Marijnen P, et al.. "Treating Hot Flushes in Menopausal Women with Homeopathic Treatment–Results of an Observational Study." *Homeopathy* 2008;97(1): 10–15. https://doi.org/10.1016/j.homp.2007.11.005.

⁴² Chaturbhuja N, Singh V, Singh K, et al. "Management of Distress during Climacteric Years by Homeopathic Therapy." *J Alternative Complementary Med* 2011;17(11):1037–42. https://doi.org/10.1089/acm.2010.0301.

⁴³ Thompson EA, Reilly D. "The Homeopathic Approach to the Treatment of Symptoms of Oestrogen Withdrawal in Breast Cancer Patients. A Prospective Observational Study." *Homeopathy* 2003;92(3):131–34. https://doi.org/10.1016/S1475-4916(03)00035-3.

⁴⁴ Jacobs J, Herman P, Heron P, et al. "Homeopathy for Menopausal Symptoms in Breast Cancer Survivors: A Preliminary Randomized Controlled Trial." *J Alternative Complementary Med* 2005;(11):21–27. https://doi.org/10.1089/acm.2005.11.21.

⁴⁵ Orellana Alvarellos G, Ruiz de Viñaspre Alvear P, Kaszkin-Bettag M. "A Series of Case Reports: Clinical Evaluation of a Complex Homeopathic Injection Therapy in the Management of Pain in Patients after Breast Cancer Treatment." *Alternative Therapies Health Medicine* 2010;16(1): 54–59.

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A randomized, double-blind placebo-controlled trial of 66 women with breast cancer undergoing radiotherapy demonstrated that homeopathy was effective in preventing and treating acute radiodermatitis and was statistically more effective than placebo.⁴⁶

Homeopathic treatment of radiation-induced itching following breast cancer surgery was found effective in 84% of women.⁴⁷

A prospective, unrandomized observational study to evaluate the effectiveness of preventing aromatase inhibitor-associated joint pain and/or stiffness in 40 women with early, hormone-receptor positive, breast cancer, demonstrated a significant difference in the homeopathic treated group (p = 0.0001), while members of the control group exhibited an increased need for analgesics (p = 0.0076).⁴⁸

In vitro effects of homeopathic medicines on cancer cells demonstrate highly significant results initiating cytotoxicity, apoptosis, cell shrinkage, chromatin condensation, and DNA fragmentation while decreasing cancer cell proliferation, and providing preliminary laboratory evidence indicating the ability of homeopathic medicines to act as anticancer agents.⁴⁹

Homeopathic medicines exhibited a concentration-dependent anti-proliferative effect on breast cancer cells (MCF-7) in vitro, while having no effect on non-malignant mammary epithelial cells (MCF-10A).⁵⁰

Four different homeopathic medicines were studied to determine their effects on two human breast adenocarcinoma cell lines (MCF-7 and MDA-MB-231) and a cell line derived from immortalized normal human mammary epithelial cells (HMLE). The medicines exerted preferential cytotoxic effects against the two breast cancer cell lines, causing cell cycle delay/arrest and apoptosis accompanied by altered expression of the cell cycle regulatory proteins, downregulation of phosphorylated Rb and upregulation of the CDK inhibitor p27. The findings demonstrate active biological activity of homeopathic products.⁵¹

Homeopathic induced tumor regression was studied using Trypan blue dye-exclusion, flow cytometry, Western blot, reverse transcriptase-PCR techniques, siRNA transfections and inhibitor studies to validate the p53 pathway of induced apoptosis in Ehrlich's ascites carcinoma (EAC)- and Sarcoma-180 (S-180) in mice. Homeopathic medicine prevented loss of effector T

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⁴⁶ <u>Balzarini A, Felisi E, Martini A</u>, et al. (2000). "Efficacy of homeopathic treatment of skin reactions during radiotherapy for breast cancer: a randomised, double-blind clinical trial." *Brit Homoeopathic J* 2000;89(1):8-12.
⁴⁷ Schlappack O. "Homeopathic Treatment of Radiation-Induced Itching in Breast Cancer Patients. A Prospective Observational Study." *Homeopathy: J Faculty Homeopathy* 2004;93(4): 210–15.

⁴⁸ Karp JC, Sanchez C, Guilbert P, et al. Treatment with Ruta Graveolens 5CH and Rhus Toxicodendron 9CH May Reduce Joint Pain and Stiffness Linked to Aromatase Inhibitors in Women with Early Breast Cancer: Results of a Pilot Observational Study." *Homeopathy* 2016;105(4): 299–308. https://doi.org/10.1016/j.homp.2016.05.004.

⁴⁹ Arora S, Agganwal A, Singla P, et al. Anti-proliferative effects of homeopathic medicines on human kidney, colon and breast cancer cells . *Homeopathy* 2013;102(4): 274-282.

⁵⁰ Ahn KH, Yi KW, Park HT, et al. "Anti-Proliferative Effect of Klimaktoplan® on Human Breast Cancer Cells." *Arch Gynecology Obstetrics* 2013;288(4):833–38. https://doi.org/10.1007/s00404-013-2849-1.

⁵¹ Frenkel M, Mishra BM, SenS, et al. "Cytotoxic Effects of Ultra-Diluted Remedies on Breast Cancer Cells." *International J Oncology* 2009;36(2). https://doi.org/10.3892/ijo.00000512.

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cell repertoire, reversed type-2 cytokine bias and attenuated tumor-induced inhibition of T cell proliferation in tumor-bearing hosts, which translates as enhanced anti-tumor activity.⁵²

Antitumorigenic activity of homeopathic medicine was evaluated, and the molecular mechanisms of apoptosis and functional p53-expression of mammary epithelial carcinoma cells was elucidated demonstrating abrogation of intracellular reactive oxygen species (ROS), prevention of p53-activation, knockdown of p53 or inhibition of its functional activity and significantly abridged ROS generation. These results open the horizon for developing a targeted therapy by modulating the redox status of functional p53-expressing mammary epithelial carcinoma cells using homeopathy.⁵³

Depression

In a prospective, randomized, double-blind double-dummy single-center trial, 91 outpatients with moderate to severe depression were assigned to receive either an individualized homeopathic medicine or fluoxetine 20 mg to 40 mg day. Results demonstrated no significant differences in responses or remissions between the two groups, and there were no significant differences between rates of side effects, but a higher percentage of patients treated with fluoxetine reported troublesome side effects leading to greater tendency toward treatment interruption.⁵⁴

A randomized, placebo-controlled, double-blind, double-dummy, superiority, three-arm trial in 133 peri- and post-menopausal women with moderate-to-severe depression demonstrated significantly superior response and remission rates from homeopathy compared with both placebo and Fluoxetine. No differences were observed in the Beck Depression Inventory, but homeopathy was superior to placebo in Greene Climacteric Scale, while Fluoxetine was not different from placebo in the same Scale.⁵⁵

An epidemiological cohort study (EPI3) of 710 patients in general practice in France compared utilization of conventional psychotropic drugs among patients seeking care for anxiety and depression disorders from general practitioners who strictly prescribe conventional medicines (GP-CM), regularly prescribe homeopathy in a mixed practice (GP-Mx), or are certified homeopathic GPs (GP-Ho). Adjusted multivariate analyses showed that GP-Ho and GP-Mx patients were less likely to use psychotropic drugs compared to GP-CM patients. The rate of clinical improvement was marginally superior for the GP-Ho group as compared to the GP-CM

⁵² Saha S, Hossain DMS, Mukherjee S, et al. "Calcarea Carbonica Induces Apoptosis in Cancer Cells in P53-Dependent Manner via an Immuno-Modulatory Circuit." *BMC Complementary Alternative Med* 2013;13(1):230. http://www.biomedcentral.com/1472-6882/13/230/.

⁵³ Saha S, Bhattacharjee P, Mukherjee S, et al. Contribution of the ROS-p53 feedback loop in thuja-induced apoptosis of mammary epithelial carcinoma cells. *Oncology Reports* 2014; 31:1589-1598. https://doi.org/10.3892/or.2014.2993

⁵⁴ Adler UC, Paiva NMP, Cesar AT, et al. "Homeopathic Individualized Q-Potencies versus Fluoxetine for Moderate to Severe Depression: Double-Blind, Randomized Non-Inferiority Trial." *Evidence-Based Complementary Alternative Med: ECAM* 2011: 520182–520182. https://doi.org/10.1093/ecam/nep114.

⁵⁵ del Carmen Macías-Cortés E, Llanes-González L, Aguilar-Faisal L, et al. "Individualized Homeopathic Treatment and Fluoxetine for Moderate to Severe Depression in Peri- and Postmenopausal Women (HOMDEP-MENOP Study): A Randomized, Double-Dummy, Double-Blind, Placebo-Controlled Trial." *PLoS ONE* 2015;10(3). https://doi.org/10.1371/journal.pone.0118440.

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group. Those patients who chose to consult GPs prescribing homeopathy reported less use of psychotropic drugs, and were marginally more likely to experience clinical improvement, than patients managed with conventional care.⁵⁶

Thirty databases/sources were screened to identify 18 studies reporting the effects of homeopathy in treating depression, including a double-blind placebo-controlled trials of 91 patients demonstrating that it was non-inferior to fluoxetine at four (p = 0.654) and eight weeks (p = 0.965). A second trial of 133 patients found that homeopathy was comparable to fluoxetine (p = 0.082) and superior to placebo (p < 0.005) at six weeks. A third non-placebo-controlled randomized controlled trial found homeopathy comparable to fluoxemine. A cohort study of patients receiving homeopathic treatment reported significantly lower use of psychotropic drugs and improved depression. Patient-reported outcomes demonstrated at least moderate improvement in 10 out of 12 uncontrolled studies. All adverse events were mild or moderate, and transient. No evidence suggested that homeopathic treatment was unsafe. 57

Fibromyalgia

A double-blind, randomized, parallel-group, placebo-controlled trial of individualized homeopathy evaluating 53 women with fibromyalgia demonstrated significantly greater improvements in tender point count, tender point pain, quality of life, global health and a trend toward less depression when compared with those on placebo.⁵⁸

A double-blinded, randomized, placebo-controlled clinical trial of 53 patients with physician-confirmed fibromyalgia characterized initial central nervous system responses to administration of homeopathic medicines in the right prefrontal region. Cordance findings correlated with subsequently reduced pain (p=0.03), better global health (p=0.10), and trait absorption (p=0.012) suggesting that prefrontal EEG-C's provide a reliable early biomarker of individualized homeopathic medicine response.⁵⁹

A randomized, placebo-controlled double-blind trial with a crossover phase of 48 patients with Fibromyalgia using individualized homeopathic medicine demonstrated EEG changes demonstrating progressive amplification of host responses. The study demonstrated significant increase signal strength, while the placebo group demonstrated a decrease in global alpha-1 and alpha-2 activity (p=0.003).⁶⁰

⁵⁶ Grimaldi-Bensouda L, Abenhaim L, Massol J, et al. "Homeopathic Medical Practice for Anxiety and Depression in Primary Care: The EPI3 Cohort Study." *BMC Complementary and Alternative Medicine* 2016;16: 125. https://doi.org/10.1186/s12906-016-1104-2.

⁵⁷ Viksveen P, Fibert P, Relton C. "Homeopathy in the Treatment of Depression: A Systematic Review." *European J Integrative Med* 2018;22:22–36. https://doi.org/10.1016/j.eujim.2018.07.004.

⁵⁸ Bell IR, Lewis DA II, Brooks AJ, et al. "Improved Clinical Status in Fibromyalgia Patients Treated with Individualized Homeopathic Remedies versus Placebo." *Rheumatology* 2004;43(5):577–82. https://doi.org/10.1093/rheumatology/keh111.

⁵⁹ Bell IR, Lewis DA, Schwartz GE, et al. "Electroencephalographic Cordance Patterns Distinguish Exceptional Clinical Responders with Fibromyalgia to Individualized Homeopathic Medicines." *J Alternative Complementary Med* 2004;10(2): 285–99. https://doi.org/10.1089/act.2004.10.285.

⁶⁰ Bell IR, Lewis DA, Lewis SE, et al. "EEG Alpha Sensitization in Individualized Homeopathic Treatment of Fibromyalgia." *Int J Neuroscience* 2004;114(9):1195–1220. https://doi.org/10.1080/00207450490475724.

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In a pragmatic parallel group randomized controlled trial, adults with fibromyalgia were treated with or without adjunctive homeopathic care. The drop-out rate was significantly lower in the homeopathic care group, and there was a significantly greater mean reduction of total function score in the homeopathic group when compared with the conventional care group. The homeopathic group had significantly greater reductions in the McGill pain score, and fatigue and tiredness upon waking scores. There were no reported adverse events.⁶¹

Conclusion

Women's health in the U.S could be significantly improved by integrating homeopathy into the existing health care system. Potential benefits include lower costs, greater safety, improved efficacy and higher rates of patient and clinician satisfaction.

A substantial body of peer-reviewed research data already justifies the use of public funds to increase public awareness of homeopathy and promote physician education into its use. Homeopathy offers a unique system of medical therapeutics capable of significantly improving public health. Nowhere is that more evident than in the realm of Women's Health.

Further research into the clinical application of homeopathy, exploring its mechanisms of action, ideal posology and potential for positively affecting public health is most certainly warranted.

About the author:

Joyce Frye DO, MBA, MSCE is a retired obstetrician/gynecologist who was introduced to homeopathy through a series of coincidences. She began to study it seriously after her son who had been diagnosed with acute nephrotic syndrome responded to an homeopathic prescription in what his pediatric nephrologist described as a "miracle". She went on to serve as the president of both the National Center for Homeopathy and the American Institute of Homeopathy and as the Chair of the Pharmacopoeia Revision Committee of the Homeopathic Pharmacopeia Convention of the United States. In acquiring her MS with the Center for Clinical Epidemiology and Biostatistics at the University of Pennsylvania, she focused on potential homeopathic interventions in obstetrics and obtained an IND for Blue Cohosh/Caulophyllum.

⁶¹ Relton C, Smith C, Raw J, et al. "Healthcare Provided by a Homeopath as an Adjunct to Usual Care for Fibromyalgia (FMS): Results of a Pilot Randomised Controlled Trial." *Homeopathy* 2009;98(2):77–82. https://doi.org/10.1016/j.homp.2008.12.004.

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Conclusion from Americans for Homeopathy Choice

When properly manufactured and applied, homeopathic medicine plays an important role in the treatment of patients with major health problems across the globe. Homeopathy is inexpensive, effective, and inherently safe. When properly utilized, homeopathy makes it possible to make what already exists currently in the conventional health care system, more effective. For example, homeopathy makes it possible to avoid overuse of antibiotics, reserving antibiotics for when they are actually needed. Homeopathy also reduces the need to rely on dangerous and addictive painkillers in various situations including postoperatively, and after injury. Among many other benefits, homeopathy also helps reduce the incidence of polypharmacy.

Positive results such as these are achieved because homeopathy is a well-developed system of individualized medicine.. Those who use homeopathy consider it a "designer" medicine, customized to their specific needs.

We are concerned that the proposed Draft Guidance on homeopathy will undermine the right of individuals to choose homeopathy, and also undermine the very important role homeopathy has to play in addressing these health problems. This paper gives an example of how homeopathy can address serious problems in our current healthcare system - specifically the issue of **women's health.** It is important that FDA actions strengthen rather than undermine homeopathy so that it can meaningfully contribute to and support the American healthcare system.