

## Clinical Research

**2013-14**

No. of studies undertaken	No. of publication
6	5

The details of the studies undertaken year wise along with the outcomes is given below:

Sl. No.	Name of Project	Period of study	Stat us	Outcome	Public ation
1.	Effects of homoeopathic intervention in stage I Essential Hypertensive patients: a randomized double blind, placebo controlled trial(Pre trial phase)	October 2013 to till date	ongoing	A total of 1434 patients are screened and 182 cases are enrolled	
2.	Management of Polycystic Ovarian Syndrome with homoeopathic intervention versus placebo -A randomized controlled pilot study	February 2014-May 2015	Concluded Submitted for publication	Polycystic ovarian syndrome (PCOS) is an emerging health problem in young females characterized by ovarian dysfunction and hyperandrogenism affecting approximately 5-10% of the female population in developed countries. However, recent findings from countries like India indicate similar prevalence rates of PCOS. This study was conducted with the primary objective to determine the feasibility of the study to evaluate the efficacy of homoeopathic intervention in PCOS in establishing the menstrual regularity with either ultrasonological improvement of PCO or improvement in hirsutism/ acne and the secondary objectives to	

			<p>assess the changes in ultrasound of polycystic ovaries and quality of life through domain scores of Polycystic Ovary Syndrome Questionnaire (PCOSQ).</p> <p><b>Methods/Design:</b> A randomized, placebo controlled pilot study was conducted from February 2014 to May 2015 by Central Council for Research in Homoeopathy (India) at its institutes namely Central Research Institute (H), Noida and Drug Standardization Unit, Ext. Unit, Hyderabad. Sixty cases fulfilling the eligibility criteria were enrolled and randomized to receive either the homoeopathic intervention or identical placebo. Both the arms followed uniformly advised lifestyle modification (LSM).</p> <p><b>Result:</b> Sixty cases fulfilling the eligibility criteria were enrolled and randomized to receive either the homoeopathic intervention or the identical placebo. The primary objective was achieved in establishing the menstrual regularity with either ultrasonological improvement of PCO or improvement in hirsutism/ acne in 60% of the cases (n=18) in the homoeopathy+LSM and none (n=0) in placebo +LSM group with p=0.001. Statistically significant difference (p= 0.016) was</p>	
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				<p>observed in reduction of inter menstrual duration (from 76.1±37.7to 46.6 ± 38.7 days) in the homoeopathy when compared to placebo group (from 93.0±65.2to 93.9±96.2 days). As per PCOSQ, significant improvement was observed in the verum group in the domains of weight, fertility, emotions and menstrual problems and no difference in body hair. Improvement in the ultrasound of polycystic ovaries was not statistically significant. Pulsatilla was the most frequently indicated medicine (n=10, 33.3%).</p> <p><b>Conclusion:</b> Homoeopathic intervention along with LSM when compared with LSM alone is effective in the management of PCOS.</p>	
3.	A multi-centric single blind randomized placebo controlled trial to evaluate the efficacy of individualized homeopathic intervention in Breast Fibroadenoma	January 2014 to till date	ongoing	A total of patients are 488 screened and 141 cases are enrolled.	
4.	Effects of Homoeopathic intervention in pre-diabetes (EHIP): An open label randomized controlled exploratory trial. (Pre- trial phase)	October 2013 to till date	Ongoing	A total of 3153 patients are screened and 353 cases are enrolled.	
5.	Effects of individualized homoeopathic intervention in Dyslipidemia: an open label randomized controlled exploratory trial. (Pre- trial phase)	October 2013 to till date	Ongoing	A total of 2544 patients are screened and 197 cases are enrolled.	

6.	Efficacy of homoeopathic treatment for Diabetic Distal Symmetric Polyneuropathy: A multicentric randomized double blind placebo controlled clinical trial.	June 2013 to July 2014	Concluded	A total of 522 patients are screened and 92 cases are enrolled	
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### **Publications under Clinical Research Program (2013-14)**

1. Effect of homoeopathic LM potencies in acute attacks of haemorrhoidal disease: A multicentric randomized single-blind placebo-controlled trial. Indian Journal of Research in Homoeopathy 2013; 7 (2): 72-80
2. Homoeopathic management in depressive episodes: A prospective, unicentric, non-comparative, open-label observational study Indian Journal of Research in Homoeopathy 2013; 7 (3): 126-32
3. Homoeopathic management of attention deficit hyperactivity disorder: A randomised placebo-controlled pilot trial Indian Journal of Research in Homoeopathy 2013; 7 (4): 158-69
4. Efficacy of homoeopathic treatment for diabetic distal symmetric polyneuropathy: A multi-centric randomised double-blind placebo-controlled clinical trial (Study protocol). Indian Journal of Research in Homoeopathy 2013; 7 (4): 145-152
5. Homoeopathy in polycystic ovarian syndrome: A randomized placebo-controlled pilot study (Study protocol). Indian Journal of Research in Homoeopathy 2014: 8 (1): 3-8