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Effect of individualised homoeopathic intervention in dyslipidaemia: An open-label, randomised, controlled, exploratory trial

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Effect of individualised homoeopathic intervention in dyslipidaemia: An open-label, randomised, controlled, exploratory trial

Abstract

Background: Dyslipidaemia, the derangement of one or many of the lipoproteins is a major cause of cardiovascular events, causing 2.6 million deaths per year globally.

Objectives: This study evaluated the efficacy of individualised homoeopathic medicines with lifestyle modification in the management of dyslipidaemia.

Materials and Methods: This multicentric, open-label, randomised controlled exploratory trial was conducted at seven study sites under the Central Council for Research in Homoeopathy. Participants fulfilling the eligibility criteria were enrolled. The primary outcome was to evaluate changes in Low-Density Lipoprotein cholesterol at months 3 and 6. Secondary outcomes were to evaluate changes in total cholesterol, triglyceride, and high-density lipoprotein at months 3 and 6.

Results: All pre-determined study outcomes followed the intention-to-treat approach. 217 patients (Individualised Homoeopathy (IH) along with lifestyle modification (IH plus therapeutic lifestyle changes [TLC]) n = 107; Placebo along with TLC (n = 110) were enrolled and analysed. Independent t-test at month 6 showed a statistically significant reduction in LDL (mean difference ± standard error: 7.03 ± 3.3; 95% confidence interval = 0.5–13.5; p = 0.03) favouring IH over placebo. Improvement in secondary outcomes; reduction in total cholesterol (p > 0.05) and triglycerides (p > 0.05) was greater in the IH group but was statistically insignificant (p > 0.05). Associated symptoms such as rheumatological and neurological complaints also improved in the IH group. Frequently prescribed medicines were *Lycopodium*, *Sulphur*, and *Calcarea carbonica*.

Conclusion: IH along with lifestyle modification was found to play a potential role in reducing the LDL cholesterol and in the management of dyslipidaemia. Further blinded studies in different settings and long-term follow-up are warranted.

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Effect of individualised homoeopathic intervention in dyslipidaemia: An open-label, randomised, controlled, exploratory trial

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Abstract

Background: Dyslipidaemia, the derangement of one or many of the lipoproteins is a major cause of cardiovascular events, causing 2.6 million deaths per year globally. **Objectives:** This study evaluated the efficacy of individualised homoeopathic medicines with lifestyle modification in the management of dyslipidaemia. **Materials and Methods:** This multicentric, open-label, randomised controlled exploratory trial was conducted at seven study sites under the Central Council for Research in Homoeopathy. Participants fulfilling the eligibility criteria were enrolled. The primary outcome was to evaluate changes in Low-Density Lipoprotein cholesterol at months 3 and 6. Secondary outcomes were to evaluate changes in total cholesterol, triglyceride, and high-density lipoprotein at months 3 and 6. **Results:** All pre-determined study outcomes followed the intention-to-treat approach. 217 patients (Individualised Homoeopathy (IH) along with lifestyle modification (IH plus therapeutic lifestyle changes [TLC]) $n = 107$; Placebo along with TLC ($n = 110$) were enrolled and analysed. Independent t-test at month 6 showed a statistically significant reduction in LDL (mean difference ± standard error: 7.03 ± 3.3; 95% confidence interval = 0.5–13.5; $p = 0.03$) favouring IH over placebo. Improvement in secondary outcomes; reduction in total cholesterol ($p > 0.05$) and triglycerides ($p > 0.05$) was greater in the IH group but was statistically insignificant ($p > 0.05$). Associated symptoms such as rheumatological and neurological complaints also improved in the IH group. Frequently prescribed medicines were *Lycopodium, Sulphur,* and *Calcarea carbonica.* **Conclusion:** IH along with lifestyle modification was found to play a potential role in reducing the LDL cholesterol and in the management of dyslipidaemia. Further blinded studies in different settings and long-term follow-up are warranted.

Keywords: Dyslipidaemia, Individualised Homoeopathy, Lifestyle modification, Therapeutic lifestyle changes.

Introduction

Dyslipidaemia is the derangement of one or many lipoproteins; presenting with different combinations of elevated total cholesterol, low-density lipoprotein (LDL) cholesterol and/or triglycerides (TGL), with or without low levels of high-density lipoprotein (HDL) cholesterol and is one of the important atherosclerotic factors, fostering a third of ischaemic heart disease all over the world, and is estimated to cause 2.6 million deaths (4.5% of total) and 29.7 million disability-adjusted life years worldwide.[1,2] The pathways and means of lipid metabolism in the human body reflect interactions of genetics, and complex biochemical processes influenced by medical disorders, medications, and/or environmental factors.[2] Recent studies from India have shown an increase in total cholesterol levels, with an

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estimated prevalence of 25–30% of urban and 15–20% of rural population.[3]

Abnormal blood lipid levels have a strong correlation with increased risk of coronary artery disease, heart attack, and coronary death.[4] Because of its significant role in the development of atherosclerosis and clinical events, dyslipidaemia management is a high priority in cardiovascular disease prevention.[5] Asian individuals with abnormal fat distribution, characterised by a high waist-to-hip circumference ratio or high truncal subcutaneous fat appear to be pre-disposed to developing insulin resistance and dyslipidaemia. The most common dyslipidaemia in India is borderline high LDL cholesterol, low HDL cholesterol, and high TGL.[3]

There is a low awareness, treatment, and control of hypercholesterolemia in India.[3] The National Cholesterol Education Program[6] expert panel on the detection, evaluation, and treatment of high blood cholesterol in adults (Adult Treatment Panel III) emphasizes LDL as the main target for cholesterol-lowering therapy. It recommends lifestyle modifications when there are zero to one risk factors, with the optimal goal of achieving an LDL level of <160 mg/dL. The panel further recommends option drug therapy when the range of LDL is 190 mg/dL. A systematic review[7] of over 3600 reports, concluded that non-pharmacological methods in the form of lifestyle changes including diet, weight reduction, and increased physical activity provide initial as well as long-term measures to address hypercholesterolemia.

Homoeopathy being a popular treatment of choice, offers a safer and more cost-effective approach to managing the initial problem in low-risk individuals. A short review by Bhalerao *et al*[8] has shown the potential role of Homoeopathy in dyslipidaemia management through clinical and pre-clinical research evidences. Govekar *et al*[9] in their study on 290 patients showed a reduction in total cholesterol and TGL. Although this study gave insights on the role of individualised homoeopathic (IH) medicines on patients with lipoproteinaemia, it lacked statistical rigor and was methodologically weak. In a cohort study[10] on 57 patients suffering from hypercholesterolemia and treated with complex Homoeopathy (*Phosphorus 6, Calc.carb 6, Thuja 30*), has shown a significant reduction in lipid parameters. The homoeopathic mother tinctures, such as *Gautteria gaumeri*, *Fucus vesiculosis* were also found to be useful in managing abnormal lipid levels.[11,12] However, Naskar *et al*[13] in their double-blind placebo-controlled trial with *Dioscorea villosa* have shown non-significant outcomes in the lipid parameters. On the other hand, pre-clinical studies on animal models showed a reduction in lipid parameters with homoeopathic medicines, such as *Baryta carbonicum*,[14] *Baryta muriaticum*, *Syzygium jambolanum* and *Cholesterinum*.[15] Maiti *et al*[16] established the protective effect of *S jambolanum* (mother tincture) on diabetes-induced carbohydrate and lipid metabolic disorders in streptozotocin-induced diabetic animals. The lipid lowering effect of *Cholesterinum* has also been found in various studies.[15] Although above-mentioned research evidences have thrown light on the role of Homoeopathy in the management of lipid disorders but they are preliminary and scientifically designed control studies are required for a definitive inference. This study evaluated the effect of individualised homoeopathic medicines along with therapeutic lifestyle changes (TLC) compared with Placebo + TLC on serum LDL-cholesterol levels which is one of the core responsible factors for cardiac events from dyslipidaemia.

Materials and Methods

Trial design and settings

This study was a multicentric, open-label, randomised, placebo-controlled exploratory trial, conducted at seven centres: National Homoeopathy Research Institute for Mental Health, Kottayam (Kerala), Dr. D. P. Rastogi Central Research Institute (H), Noida; Regional Research Institute for Homoeopathy, Hyderabad (Telangana) and Gudivada (Andhra Pradesh); Homoeopathic Research Institute for Disabilities (earlier Clinical Research Unit for Homoeopathy, Chennai (Tamil Nadu), Clinical Research Unit for Homoeopathy, Tirupati (Andhra Pradesh), and Puducherry, under Central Council for Research in Homoeopathy, from October 2013 to March 2018. The study protocol was in accordance with the latest revision of the Helsinki Declaration on human experimentation and good clinical practices of India[17] with necessary clearance from the 17th Institutional Ethical Committee 1-3/2013-14/CCRH/Tech/17th EC/dated 14th August 2013. The trial was registered with the clinical trial registry of India: CTRI/2014/12/005257. The study protocol has been published.[18]

Participants

Patients aged between 30 and 60 years, with a serum LDL level of more than 160 mg/dL and willing to participate in the study were screened and enrolled as per the defined inclusion and exclusion criteria. Participants with controlled hypertension and pre-diabetic patients were also included in the study.

Patients with a family history of hypertriglyceridemia, with a history of any cardiac event, with any known systemic illness (such as cancer, hepatic diseases, renal diseases, diabetes and HIV), those under corticosteroids or other hormonal treatment, or with excessive alcohol uptake (60 mL for males and 30 mL for females) for the last one year, pregnant, lactating, not willing to participate in the study were excluded from the study.

Interventions

Individualised Homoeopathic medicines or identically similar placebo were used as interventions in the study. Both groups were given TLC which included diet and physical activity. The interventions were administered by a qualified homoeopathic practitioner at the study site.

Homoeopathy

Each patient was assessed after a detailed case taking as per the case recording format and patients in Group I were given homoeopathic treatment aligned with the principles

of Homoeopathy. Individual homoeopathic medicines were administered orally in centesimal potencies. The selection of medicine was done as per the totality of symptoms. The potency, dose, and repetition were as per discretion of the investigator and as per the patient's condition at that moment. Once the improvement started, the placebo was continued until the medicine continued to act.

Placebo

The patients allocated to the control group received an identical placebo similar to the verum group but the globules were impregnated with unsuccussed dispensing alcohol which had the taste and odour similar to the verum group.

Therapeutic lifestyle Changes

Therapeutic lifestyle changes (TLC) in the form of physical activity and diet modifications were advised to all the patients after eliciting baseline diet and information about physical activity. Based on the baseline physical activity assessed through the physical activity scoring system,[19] the patients whose routine involved walking/cycling for >30 min/day or those exercising regularly were asked to continue their routine. Whereas people with sedentary occupations/habits were encouraged for a 30-min brisk walk daily.

After the recording of baseline dietary patterns, all the participants were given customised dietary advice specific to local habits aimed at appropriate reduction in total calories, refined carbohydrates, and fats, with an increase in the intake of fibre-rich foods, such as whole grains, vegetables and fruits. Scoring of adherence to diet was periodically recorded based on self-reported adherence.[19]

Random allocation sequence and allocation concealment

The patients were assigned to one of the intervention groups with the aid of computer-generated random numbers in the ratio of 1:1, generated at headquarters, New Delhi by the coordinator along with the biostatistician. Each study centre was given a separate randomisation chart for the allocation of study participants who were blinded for the study. The investigator accordingly, assigned the patient to one of the intervention groups that is, either IH + TLC or PL + TLC. The assigned groups were maintained throughout the study.

Outcome measures

The primary outcome measure was to evaluate the changes in LDL cholesterol levels at months 3 and 6 and the secondary outcome measures were to evaluate the changes in Total Cholesterol (TC), TGL and HDL at months 3 and 6. Other outcome measures included assessment of symptoms presented by the participants for treatment apart from the laboratory elevated LDL cholesterol (LDL-C).

Sample size

Being an exploratory study and with limited preliminary evidence from the literature review, no definite calculation of sample size was made. However, in this study, 100 patients

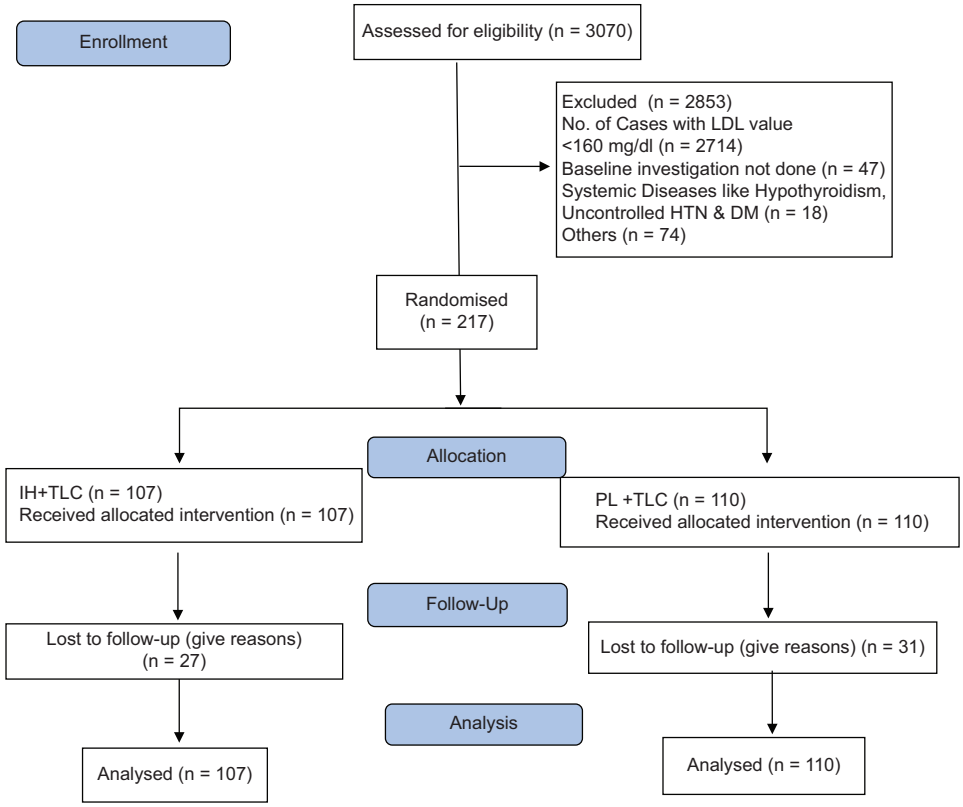

Figure 1: CONSORT flow diagram.
HTN=Hypertension; DM=Diabetes mellitus; IH=Individualised Homoeopathy; PL=Placebo; TLC=Therapeutic lifestyle changes

(50 in each group) were proposed to be enrolled with a dropout rate of 20%, with a total sample size of 120 (60 in each group). After the initiation of the study, considering the rampant prevalence of the problem, and a greater number of asymptomatic cases with a probability of having more number of dropouts, the study team felt the need to recruit a larger sample. Hence, a sample of 217 patients was enrolled.

Statistical methods

The statistical analysis was performed using SPSS version 20. The Intention to Treat (ITT) approach was applied to all analyses. The data were normally distributed. The last observations were carried forward to fill in the missing values. The baseline comparison between the groups was done by applying a t-test for continuous data and a Chi-square test for nominal data. The changes in the outcomes measured from the baseline (0 time) and at time point at months 3 and 6 were calculated. The changes obtained at different time points were compared by applying an independent t-test. The overall significance level of the primary outcome was explorative. The proportion of patients adhering to diet and physical activity and improvement in associated symptoms between the groups was also compared by applying the Chi-square test. The outcomes are reported as mean difference±standard error (SE), 95% confidence interval (CI), and effect size (cohen d). The resulting *p*-values for treatment-group effects are considered explorative and $p < 0.05$ is considered significant.

Results

Baseline characteristics

Of the 3070 patients screened, 2853 patients were excluded, and 217 (IH+TLC: 107; Placebo + TLC: 110) participants were enrolled under the study during the period October 2013–October 2017. The main cause of exclusion was LDL level <160 mg/dL (94%). Other causes of exclusion were patients not meeting the inclusion criteria, the presence of systemic diseases, such as hypothyroidism, uncontrolled diabetes mellitus/hypertension and non-compliance of patients for baseline investigations. At the end of the study, 27 patients in the IH + TLC group and 31 patients in the Placebo + TLC group dropped out. The participant flow throughout the trial is given in Figure 1. The baseline characteristics of the recruited population is given in Table 1.

Primary and secondary outcomes

Table 2 shows the difference in the reduction of LDL cholesterol between the two groups at the end of month 3 (mean difference ± SE: 3.49 mg/dL ± 2.7 mg/dL; 95% CI: −1.94–8.92, $p = 0.20$) and at month 6 (mean difference ± SE:7.03 mg/dL ± 3.3 mg/dL; 95% CI: 0.53–13.5, $p = 0.03$), cohen d:0.29, favouring IH+ TLC over Placebo + TLC at month 6.

In the secondary outcome measures, HDL cholesterol also showed significant reduction at months 3 and 6 in both groups. Although there was a reduction in HDL, it remained within normal limits. However the difference in reduction was more in placebo group compared to IH group (mean difference ± SE: −4.5 mg/dL ± 1.8 mg/dL; 95% CI: −8.2 to −0.8, $p = 0.01$) at month 3 and similarly at month 6 (mean difference ± SE: −4.2 mg/dL ± 1.6 mg/dL; 95% CI: −7.5–−0.9, $p = 0.01$).

The findings in VLDL cholesterol showed a positive trend in the reduction but were statistically inconclusive. However, the difference in reduction was more toward IH group compared to placebo group (mean difference ± SE: 3.7 mg/dL ± 1.9 mg/dL; 95% CI: −0.1–7.6, $p = 0.05$) at month 3 and similarly at month 6 (mean difference ± SE: −3.8 mg/dL ±2.0 mg/dL; 95% CI: −0.1–7.8, $p = 0.05$).

There was no difference in the mean reduction in TGL or total cholesterol. The difference in mean reduction was statistically insignificant in TGL either at month 3 (mean difference: 7.0 mg/DL ±4.3 mg/dL; 95% CI: −1.5–15.6; $p = 0.10$) or at month 6 (mean difference: 1.5 mg/dL ± 4.0 mg/dL; 95% CI: −6.4–9.5; $p = 0.69$). The results were similar for total cholesterol also.

Adherence to physical activity and diet

Table 3 shows the proportion of participants having compliance to physical activity and diet. It was observed that both groups had similar compliance. At month 3, 86.0% and 87.3% of participants from both IH+TLC and PL+TLC were adherent to physical activity, $p = 0.78$) Similarly by the end of month 6, 75.7% and 80% of participants from IH+TLC and Placebo +TLC group 80% were adherent ($p = 0.44$).

Similarly, with respect to diet, it was observed that at month 3, 90.7% and 81.3% of participants from both IH+TLC and PL+TLC were adherent to diet, $p = 0.87$). Similarly, by the end of month 6,81.3% and 88.2% of participants from IH+TLC and Placebo +TLC group 80% were adherent ($p = 0.15$).

Outcome of associated symptoms

The clinical symptoms for which the participants sought treatment, apart from those related to dyslipidaemia are given in Table 4. Out of all the participants, 65.4% presented with rheumatological complaints, 13.4% with neurological complaints, 12.4% with respiratory complaints, 11.9% with dermatological complaints, and a minor percentage of cases presented with gynaecological, cardiac complaints, and sleeplessness. The improvement in the clinical complaints was significant in IH+TLC compared to PL+TLC. 79% of 67 patients reported significant relief in their rheumatological complaints in the IH+TLC arm compared to 49% of 75 patients in the PL+TLC group ($p = 0.0002$). Improvement in neurological complaints was 78.5% in IH+TLC, 46.6% in PL+TLC ($p = 0.07$); 81.2% in respiratory complaints in IH+TLC, 45.4% in PL+ ($p = 0.10$) and 80% in dermatological complaints in IH+TLC and 54.5% in PL+TLC ($p = 0.16$) groups.

Homoeopathic medicines

The homoeopathic medicines prescribed and found most useful in the trial were *Lycopodium, Sulphur, Calcarea carbonica, Phosphorus, Natrum muriaticum, Nux vomica, Pulsatilla nigricans, Arsenicum album* and *Aurum metallicum*. The

Table 1: Baseline characteristics of the study sample

Variable	IH+TLC (*n*=107)	PL+TLC (*n*=110)	*p*-value
Age in years	45.9±8.4	44.7±6.8	0.27
Height (mt.)	1.59±0.1	1.58±0.1	0.46
Weight (kg)	78.4±16.9	75.8±13.9	0.23
Body mass index (kg/m^2)	31.0±6.2	30.5±5.3	0.48
Waist (cm)	92.1±25.7	90.4±25.6	0.61
Gender			
Male	48 (44.9)	42 (38.2)	0.31
Female	59 (55.1)	68 (61.8)	
Religion			
Hindus	88 (82.2)	88 (80.0)	0.87
Muslims	6 (5.6)	6 (5.5)	
Christians	13 (12.1)	16 (14.5)	
Occupation			
Office work	11 (11.7)	14 (14.4)	0.39
Self-employed	33 (35.1)	41 (42.3)	
House Wife/retired personals/students	50 (53.2)	42 (43.3)	
Diet			
Vegetarian	16 (17.0)	10 (10.3)	0.17
Non-vegetarian	78 (83.0)	87 (89.7)	
Smoking habit			
Yes	6 (6.4)	4 (4.1)	0.48
No	88 (93.6)	93 (95.9)	
Alcohol addiction			
Yes	11 (11.7)	10 (10.3)	0.75
No	83 (88.3)	87 (89.7)	
Blood pressure			
SBP	125.1±12.8	125.9±11.2	0.61
DBP	81.8±6.9	81.2±6.4	0.49
Lipid profile			
LDL	173.0±14.5	176.3±17.8	0.14
HDL	45.2±8.7	46.7±9.0	0.22
VLDL	32.2±11.8	30.7±10.5	0.30
TGL	153.7±53.7	146.9±45.6	0.31
TC	253.9±19.2	254.0±23.3	0.71
PAS	22.4±12.3	23.9±10.5	0.34

Data are presented in *n* (%), mean±SD. LDL: Low-density lipoprotein, HDL: High-density lipoprotein, VLDL: Very low-density lipoprotein, TGL: Triglycerides, TC: Total cholesterol, IH: Individualised homoeopathy, TLC: Therapeutic lifestyle changes, SD: standard deviation

percentage of their prescriptions is depicted in Figure 2. No adverse events were reported during the study period.

Discussion

In the light of increasing urbanisation and rising incidence of dyslipidaemia in India, along with the issues of compliance, financial burden and side effects of conventional treatment, alternative treatment options are being sought for a suitable solution. To the best of our knowledge, this is the first exploratory randomised controlled trial that provides insights to the positive and potential role of IH medicines in the management of dyslipidaemia. There was a significant difference in the reduction in LDL cholesterol favouring the role of IH along with therapeutic lifestyle modification over 6 months. There was also relief in the presenting complaints reported by the patients.

Govekar *et al*,[9] in their long cohort study on lipoproteinaemia, showed improvement with indicated homoeopathic medicines, such as *Lycopodium*, *Calcarea carbonica*, *Pulsatilla*, *Rhus tox*, *Sulphur* and *Nux vomica*. The homoeopathic medicines prescribed in this study were also similar. The most commonly prescribed medicines were: *Lycopodium, Sulphur, Calcarea carbonica, Phosphorus, Natrum muriaticum, Nux vomica, Pulsatilla nigricans, Arsenicum album,* and *Aurum metallicum*. Pay[10] in his study prescribed a complex way (combination of more than one homoeopathic medicine), such as *Phosphorus* 6, *Calcarea carb*. 6 and *Thuja* 30 in daily doses and found it reduced the serum cholesterol levels in a span of 8–12 weeks. This combination includes the medicines found effective in our study as individual prescriptions. Systematic review and meta-analysis of studies with non-IH[20] have shown some lead with directions for rigorous trials. However, model validity questions posed by Mathie *et al*[21] satisfy the methodology of this reported study.

Table 2: Outcome at the end of months 3 and 6 (change from baseline)

Variable	IH+TLC (*n*=107) Mean±SD	PL+TLC (*n*=110) Mean±SD	Mean difference±standard error	95% confidence interval	*p*-value; Cohen's d
Primary outcome					
LDL					
0–3	15.70±20.04	12.21±20.54	3.49±2.7	−1.94–8.92	0.20; 0.17
0–6	28.20±25.86	21.16±22.69	7.03±3.3	0.53–13.5	0.03; 0.29
Secondary outcome					
HDL					
0–3	2.59±13.87	7.10±13.71	−4.50±1.87	−8.20–−0.81	0.01; 0.32
0–6	2.71±11.89	6.97±12.73	−4.26±1.66	−7.55–−0.98	0.01; 0.34
VLDL					
0–3	−1.44±14.57	−5.23±14.52	3.79±1.97	−0.10–7.68	0.05; 0.26
0–6	0.46±13.22	−3.40±16.37	3.87±2.02	−0.11–7.86	0.05; 0.26
TGL					
0–3	8.39±32.73	1.32±31.31	7.06±4.34	−1.50–15.63	0.10; 0.22
0–6	10.41±31.36	8.81±28.36	1.59±4.05	−6.40–9.59	0.69; 0.05
TC					
0–3	19.42±26.90	13.53±25.38	5.88±3.54	−1.11–12.88	0.09; 0.22
0–6	32.89±29.50	26.31±30.36	6.57±4.06	−1.43–14.58	0.10; 0.21

LDL: Low-density lipoprotein, HDL: High-density lipoprotein, VLDL: Very low-density lipoprotein, TGL: Triglycerides, TC: Total cholesterol, IH: Individualised homoeopathy, TLC: Therapeutic lifestyle changes, SD: standard deviation

Table 3 TLC: Diet and physical activity (Adherence and non-adherence)

Variable	Month 3			Month 6		
	IH+TLC (*n*=107) (%)	PL+TLC (*n*=110) (%)	*p*-value	IH+TLC (*n*=107) (%)	PL+TLC (*n*=110) (%)	*p*-value
Physical activity						
Adherent	92 (86.0)	96 (87.3)	0.783	81 (75.7)	88 (80.0)	0.446
Non-Adherent	15 (14.0)	14 (12.7)		26 (24.3)	22 (20.0)	
Diet						
Adherent	97 (90.7)	99 (90.0)	0.871	87 (81.3)	97 (88.2)	0.159
Non-adherent	10 (9.3)	11 (10.0)		20 (18.7)	13 (11.8)	

IH: Individualised homoeopathy, TLC: Therapeutic lifestyle changes

In various pre-clinical and clinical studies, the efficacy of homoeopathic remedies, such as *Baryta carbonicum, Baryta muriaticum,*[14] *Syzygium jambolanum,*[16] *Cholesterinum,*[15] *Fucus vesiculosis*[12,22] and *Guatteria gaumeri*[11] in lipid metabolic disorders was well documented. However, in this study, these drugs were not prescribed. Future studies may be undertaken with these drugs on the basis of pathological similimum[23] for specific effects.

The study faced many challenges. The biggest challenge was screening a large number of patients to enrol as per the inclusion criteria as dyslipidaemia, a pathological finding is generally asymptomatic[24] and requires screening for detection. Screening involves blood tests that may be obtained in a fasting or non-fasting state. Although present recommendations generally recommend testing TC and LDL-C levels, they differ on the inclusion of other lipid components, the age at which to start testing, and the frequency of screening.[25] Recently, the Lipid Association of India came up with a consensus statement guided by an expert panel to adapt the western guidelines for Indians.[26] However, once the patients were screened and enrolled, follow-up, weekly monitoring of compliance to diet and activity guidelines was proved to be a tedious and cumbersome task, nonetheless accomplished.

The basic principles of the homoeopathic prescription are customised to each individual based on their presenting totality of symptoms. As stated by Close[27] 'In general, it may be stated that any curable diseases may be cured by any potency, when the indicated remedy is administered; but that the cure may be much accelerated by selecting the potency or dose appropriate to the individual case', on considering the five factors which influence the choice of the dose such as the susceptibility of the patient, the seat of the disease, the nature and intensity of the disease, the stage and duration of the disease and the previous treatment of the disease. Future studies may consider adaptive trial designs[28] for different aspects of dose, potency and treatment schedule.

Table 4: Clinical symptoms from specific systems reported with outcomes

System/region of body	Total	IH+TLC	PL+TLC	Chi-Square; *p*-value
Rheumatic complaints	142	67	75	13.5; 0.0002
Improved	90	53 (79.1)	37 (49.3)	
Not improved	52	14 (20.9)	38 (50.7)	
Neurological complaint	29	14	15	3.131; 0.07
Improved	18	11 (78.6)	7 (46.7)	
Not improved	11	3 (21.4)	8 (53.3)	
Respiratory complaint	27	16	11	4.4; 0.10
Improved	18	13 (76.5)	5 (45.5)	
Not improved	9	3 (17.6)	6 (54.5)	
Dermatological complaint	26	15	11	1.930; 0.16
Improved	18	12 (80.0)	6 (54.5)	
Not improved	8	3 (20.0)	5 (45.5)	
Sleeplessness	6	2	4	3.000; 0.08
Improved	3	2 (100)	1 (25.0)	
Not improved	3	0 (0.0)	3 (50.0)	
Cardiac complaints	4	2	2	0.0; 1.00
Improved	2	1 (50.0)	1 (50.0)	
Not improved	2	1 (50.0)	1 (50.0)	
Gynaecological complaints	3	0	3	-
Improved	2	0	2 (66.7)	
Not improved	1	0	1 (33.3)	

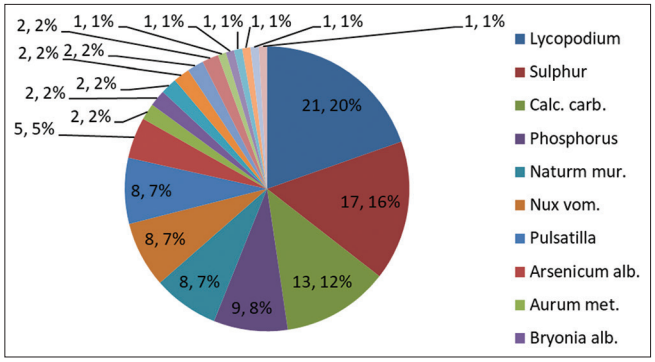

Figure 2: Homoeopathic medicines prescribed

Being exploratory in nature, and LDL cholesterol being a biochemical primary outcome parameter, this open-label clinical trial was designed. Future studies may be undertaken with double-blind study designs and longer follow-ups. Organ-specific remedies, which have an affinity for reduction in lipids, may also be considered in the future. Comparative studies with homoeopathic intervention and conventional treatment are other options to explore the strengths of Homoeopathy. The range of potencies from mother tinctures, lower to higher dilutions, may also be explored using adaptive designs. In the light of the increasing burden of the disease, the results of this study support the employment of IH medicines, along with TLC, in the management of dyslipidaemia.

Conclusion

The results of this study lay emphasis on the positive role of IH treatment, together with TLC, in the management of dyslipidaemia. Apart from the reduction in serum LDL levels, there was a notable improvement in the other presenting complaints of the patients. Further double-blind studies in different settings are warranted to substantiate the results of this study.

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Effet d'une intervention homéopathique individualisée sur la dyslipidémie : essai exploratoire ouvert, randomisé et contrôlé

Contexte : La dyslipidémie, dérèglement d'une ou plusieurs lipoprotéines, est une cause majeure d'événements cardiovasculaires, causant 2,6 millions de décès par an dans le monde. **Objectifs:** Cette étude a évalué l'efficacité de médicaments homéopathiques individualisés associés à une modification du mode de vie dans la prise en charge de la dyslipidémie. **Matériel et méthodes:** Cet essai exploratoire multicentrique, ouvert, randomisé et contrôlé a été mené sur sept sites d'étude sous l'égide du Conseil central de recherche en homéopathie. Les participants remplissant les critères d'éligibilité ont été recrutés. Le résultat principal était d'évaluer les changements du cholestérol des lipoprotéines de basse densité aux mois 3 et 6. Les résultats secondaires étaient d'évaluer les changements du cholestérol total, des triglycérides et des lipoprotéines de haute densité aux mois 3 et 6. **Résultats:** Tous les résultats d'étude prédéterminés ont suivi l'approche en intention de traiter. Français 217 patients (homéopathie individualisée (HI) associée à une modification du mode de vie (HI plus changements thérapeutiques du mode de vie [TLC]) n = 107 ; placebo associé à TLC (n = 110) ont été recrutés et analysés. Un test t indépendant au mois 6 a montré une réduction statistiquement significative du LDL (différence moyenne ± erreur standard : 7,03 ± 3,3 ; intervalle de confiance à 95 % = 0,5–13,5 ; p = 0,03) favorisant l'HI par rapport au placebo. Amélioration des critères d'évaluation secondaires ; la réduction du cholestérol total (p > 0,05) et des triglycérides (p > 0,05) était plus importante dans le groupe IH mais était statistiquement non significative (p > 0,05). Les symptômes associés tels que les plaintes rhumatologiques et neurologiques se sont également améliorés dans le groupe IH. Les médicaments fréquemment prescrits étaient *Lycopodium, Sulphur* et *Calcarea carbonica*. **Conclusion:** IH Il a été démontré que l'association d'une modification du mode de vie et d'une réduction du cholestérol LDL et d'une prise en charge de la dyslipidémie pouvait jouer un rôle potentiel. D'autres études en aveugle, menées dans différents contextes et assorties d'un suivi à long terme, sont nécessaires.

Wirkung individualisierter homöopathischer Interventionen bei Dyslipidämie: Eine offene, randomisierte, kontrollierte, explorative Studie

Hintergrund: Dyslipidämie, die Störung eines oder mehrerer Lipoproteine, ist eine Hauptursache für kardiovaskuläre Ereignisse und verursacht weltweit jährlich 2,6 Millionen Todesfälle. **Ziele:** Diese Studie untersuchte die Wirksamkeit individualisierter homöopathischer Arzneimittel in Kombination mit Lebensstiländerungen bei der Behandlung von Dyslipidämie. Material und **Methoden:** Diese multizentrische, offene, randomisierte, kontrollierte, explorative Studie wurde an sieben Studienzentren unter der Leitung des Zentralrats für Homöopathieforschung durchgeführt. Teilnehmer, die die Teilnahmekriterien erfüllten, wurden aufgenommen. Das primäre Ergebnis war die Bewertung der Veränderungen des Low-Density-Lipoprotein-Cholesterins nach 3 und 6 Monaten. Sekundäre Ergebnisse waren die Bewertung der Veränderungen des Gesamtcholesterins, der Triglyceride und des High-Density-Lipoproteins nach 3 und 6 Monaten. Ergebnisse: Alle vorab festgelegten Studienergebnisse folgten dem Intention-to-Treat-Ansatz. 217 Patienten (Individualisierte Homöopathie (IH) zusammen mit Lebensstiländerung (IH plus therapeutische Lebensstiländerung [TLC]) n = 107; Placebo zusammen mit TLC (n = 110) wurden aufgenommen und analysiert. Ein unabhängiger t-Test im sechsten Monat zeigte eine statistisch signifikante Senkung des LDL (mittlere Differenz ± Standardfehler: 7,03 ± 3,3; 95 %-Konfidenzintervall = 0,5 – 13,5; P = 0,03) zugunsten von IH gegenüber Placebo. Verbesserung der sekundären **Ergebnisse:** die Senkung des Gesamtcholesterins (P > 0,05) und der Triglyceride (P > 0,05) war in der IH-Gruppe größer, aber statistisch nicht signifikant (P > 0,05). Begleitsymptome wie rheumatologische und neurologische Beschwerden besserten sich in der IH-Gruppe ebenfalls. Häufig verschriebene Medikamente waren *Lycopodium*, *Sulphur* und *Calcarea carbonica*. **Schlussfolgerung:** IH spielt in Kombination mit einer Lebensstiländerung eine potenzielle Rolle bei der Senkung des LDL-Cholesterins und der Behandlung von Dyslipidämie. Weitere Blindstudien in verschiedenen Settings und eine langfristige Nachbeobachtung sind erforderlich.

डिस्लिपिडेमिया में व्यक्तिगत होम्योपैथिक हस्तक्षेप का प्रभाव: एक ओपन-लेबल, यादृच्छिक, नियंत्रित, अन्वेषणात्मक परीक्षण

पृष्ठभूमि: डिस्लिपिडेमिया, एक या कई लिपोप्रोटीन का असंतुलन हृदय संबंधी घटनाओं का एक प्रमुख कारण है, जिससे दुनिया भर में हर साल 2.6 मिलियन मौतें होती हैं। **उद्देश्य:** इस अध्ययन ने डिस्लिपिडेमिया के प्रबंधन में जीवनशैली में बदलाव के साथ व्यक्तिगत होम्योपैथिक दवाओं की प्रभावकारिता का मूल्यांकन किया। **सामग्री और विधियाँ:** यह बहु-केन्द्रित,ओपन -लेबल, यादृच्छिक नियंत्रित अन्वेषणात्मक परीक्षण केंद्रीय होम्योपैथी अनुसंधान परिषद के तहत सात अध्ययन स्थलों पर आयोजित किया गया । पात्रता मानदंडों को पूरा करने वाले प्रतिभागियों को नामांकित किया गया । प्राथमिक परिणाम 3 और 6 महीने में कम घनत्व वाले लिपोप्रोटीन कोलेस्ट्रॉल में परिवर्तन का मूल्यांकन करना था। द्वितीयक परिणाम 3 और 6 महीने में कुल कोलेस्ट्रॉल, ट्राइग्लिसराइड और उच्च घनत्व वाले लिपोप्रोटीन में परिवर्तन का मूल्यांकन करना था। **परिणाम:** सभी पूर्व निर्धारित अध्ययन परिणामों ने इंटेंशन टू ट्रीट दृष्टिकोण का पालन किया। 217 मरीज़ (व्यक्तिगत होम्योपैथी (IH) के साथ जीवनशैली में बदलाव (IH के साथ चिकित्सीय जीवनशैली में बदलाव [TLC]) n = 107; प्लेसबो के साथ TLC (n = 110) को

नामांकित किया गया और उनका विश्लेषण किया गया। 6वें महीने में स्वतंत्र टी-परीक्षण ने LDL (औसत अंतर ± मानक त्रुटि: 7.03 ± 3.3; 95% विश्वास अंतराल = 0.5-13.5; p = 0.03) में सांख्यिकीय रूप से महत्वपूर्ण कमी दिखाई, जो प्लेसबो की तुलना में IH को तरजीह देता है। द्वितीयक परिणामों में सुधार; कुल कोलेस्ट्रॉल (p > 0.05) और ट्राइग्लिसराइड्स (p > 0.05) में कमी IH समूह में अधिक थी, लेकिन सांख्यिकीय रूप से महत्वहीन (p > 0.05) थी। IH समूह में रुमेटोलॉजिकल और न्यूरोलॉजिकल शिकायतों जैसे संबंधित लक्षणों में भी सुधार हुआ। आमतौर पर निर्धारित दवाएं *लाइकोपोडियम, सल्फ़र और कैलकेरिया कार्बोनिका* थीं | **निष्कर्ष:** जीवनशैली में बदलाव के साथ-साथ IH एलडीएल कोलेस्ट्रॉल को कम करने और डिस्लिपिडेमिया के प्रबंधन में एक संभावित भूमिका निभाता है। आगे भी ब्लाइंडिड अध्ययन तथा विभिन्न सेटिंग्स और दीर्घकालिक अनुवर्ती की आवश्यकता है।

Efecto de la intervención homeopática individualizada en la dislipidemia: Un ensayo exploratorio, aleatorizado, controlado y abierto

Antecedentes: La dislipidemia, la alteración de una o varias lipoproteínas, es una causa importante de eventos cardiovasculares, causando 2,6 millones de muertes al año en todo el mundo. **Objetivos:** Este estudio evaluó la eficacia de los medicamentos homeopáticos individualizados con la modificación del estilo de vida en el tratamiento de la dislipidemia. **Materiales y métodos:** Este ensayo exploratorio, multicéntrico, abierto, aleatorizado y controlado, se llevó a cabo en siete centros de estudio del Consejo Central para la Investigación en Homeopatía. Se inscribieron los participantes que cumplían los criterios de elegibilidad. El resultado principal fue evaluar los cambios en el colesterol de lipoproteínas de baja densidad (LDL) en los meses 3 y 6. Los resultados secundarios fueron evaluar los cambios en el colesterol total, los triglicéridos y las lipoproteínas de alta densidad en los meses 3 y 6. **Resultados:** Todos los resultados predeterminados del estudio siguieron el enfoque por intención de tratar. Se incluyeron y analizaron 217 pacientes (homeopatía individualizada (IH) junto con modificación del estilo de vida (IH más cambios terapéuticos en el estilo de vida [TLC]) n = 107; placebo junto con TLC (n = 110). La prueba t independiente en el mes 6 mostró una reducción estadísticamente significativa en LDL (diferencia media ± error estándar: 7,03 ± 3,3; intervalo de confianza del 95 % = 0,5– 13,5; P = 0,03) a favor de IH sobre placebo. Mejora en los resultados secundarios; la reducción del colesterol total (P > 0,05) y los triglicéridos (P > 0,05) fue mayor en el grupo IH, pero fue estadísticamente insignificante (P > 0,05). Los síntomas asociados, como las quejas reumatológicas y neurológicas, también mejoraron en el grupo IH. Los medicamentos recetados con frecuencia fueron Lycopodium, Sulphur y Calcarea. carbonica. **Conclusión:** Se ha demostrado que la HI, junto con la modificación del estilo de vida, desempeña un papel potencial en la reducción del colesterol LDL y en el manejo de la dislipidemia. Se justifican estudios ciegos adicionales en diferentes entornos y un seguimiento a largo plazo.

个性化顺势疗法干预对血脂异常的影响：一项开放标签、随机对照、探索性试验

背景：血脂异常，一种或多种脂蛋白的紊乱是心血管事件的主要原因，每年在全球造成 260 万人死亡。**目的：**本研究评估了个性化顺势疗法药物与生活方式改变在血脂异常管理中的疗效。材料和方法：这项多中心、开放标签、随机对照探索性试验在顺势疗法中央研究委员会下的七个研究地点进行。符合资格标准的参与者被招募。主要结果是评估第 3 个月和第 6 个月低密度脂蛋白胆固醇的变化。次要结果是评估第 3 个月和第 6 个月总胆固醇、甘油三酯和高密度脂蛋白的变化。**结果：**所有预先确定的研究结果均遵循意向治疗方法。共纳入 217 名患者（个体化顺势疗法（IH）联合生活方式改变（IH 加治疗性生活方式改变 [TLC]）n = 107；安慰剂联合 TLC（n = 110）并进行分析。第 6 个月的独立 t 检验显示，LDL 显著降低（平均差异±标准误差：7.03±3.3；95% 置信区间 = 0.5– 13.5；P = 0.03），IH 优于安慰剂。次要结果的改善；IH 组的总胆固醇（P > 0.05）和甘油三酯（P > 0.05）降低幅度较大，但统计学上不显著（P > 0.05）。IH 组的风湿病和神经系统疾病等相关症状也有所改善。常用的处方药是石松、硫磺和碳酸钙。**结论：**IH结合生活方式的改变，研究发现，在降低 LDL 胆固醇和控制血脂异常方面具有潜在作用。有必要在不同环境中进行进一步的盲法研究和长期随访。