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Efficacy of individualised homoeopathic medicines as an adjunct to conventional iron and folic-acid supplementation in iron deficiency anaemia among reproductive-aged women: Single-blind, randomised, placebo-controlled trial

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Abstract

Background: Iron deficiency anaemia (IDA) is a major public health concern affecting women of reproductive age globally. If left untreated, it can cause various health issues including fatigue, shortness of breath, abnormal heart rhythms, chest pain, and complications during pregnancy. Objectives: To evaluate the efficacy of individualised homoeopathic medicines (IHMs) with iron and folic acid supplement (IFS) in treatment of iron deficiency among reproductive-aged women, in comparison with placebos with IFS. Methods: Single-blind, randomised, placebo-controlled clinical trial was conducted over total six months at the outpatient-department, of which participants received interventions and outcome assessments for three months. Reproductive women (15–49 years) with IDA were included based on haemoglobin (Hb) level ≤ 11.9 mg/dl to ≥ 7.1 mg/dl with serum ferritin <15 >µ g/l; randomised to receive either IHMs with IFS (IHMs-IFS, n = 30) or identical-looking placebos with IFS *(placebo-IFS, n = 30)* for 3 months. The outcomes included haemoglobin, Mean Corpuscular Volume (MCV), Mean Corpuscular Haemoglobin (MCH), serum ferritin (SF) levels measured at baseline and after three-months of intervention. Results: Of 110 screened participants, 60 were included after their consent and intervened; entered into intention-to-treat analysis. Inter-group differences shown Hb, MCV, SF values were statistically significant with medium effect size. Intra-group differences showed in Hb (IHMs-IFS: $p < 0.001$; placebos-IFS: $p < 0.01$), MCV (IHMs-IFS: $p < 0.001$; placebos-IFS: $p < 0.01$), MCH (IHMs-IFS: $p < 0.001$, placebos-IFS: $p < 0.01$), SF (IHMs-IFS: $p < 0.001$; placebos-IFS: $p < 0.001$) significant increases in both groups. Conclusion: Significant improvement was observed, within and between the groups. However, the magnitude of improvement was slightly greater in IHMs-IFS group compared with placebo-IFS group, indicated by larger mean changes and medium effect sizes, favouring the adjunct benefits of IHMs in management of IDA among reproductive-age women. Multi-centric, double-blinded, large-sampled studies are warranted to confirm these findings.

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ORIGINAL ARTICLE

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ABSTRACT

Background: Iron deficiency anaemia (IDA) is a major public health concern affecting women of reproductive age globally. If left untreated, it can cause various health issues including fatigue, shortness of breath, abnormal heart rhythms, chest pain, and complications during pregnancy. **Objectives:** To evaluate the efficacy of individualised homoeopathic medicines (IHMs) with iron and folic acid supplement (IFS) in treatment of iron deficiency among reproductive-aged women, in comparison with placebos with IFS. **Methods:** Single-blind, randomised, placebo-controlled clinical trial was conducted over total six months at the outpatient-department, of which participants received interventions and outcome assessments for three months. Reproductive women (15–49 years) with IDA were included based on haemoglobin (Hb) level ≤11.9 mg/dl to ≥7.1 mg/dl with serum ferritin <15 μg/l; randomised to receive either IHMs with IFS (IHMs-IFS, n = 30) or identical-looking placebos with IFS *(placebo-IFS, n = 30)* for 3 months. The outcomes included haemoglobin, Mean Corpuscular Volume (MCV), Mean Corpuscular Haemoglobin (MCH), serum ferritin (SF) levels measured at baseline and after three-months of intervention. **Results:** Of 110 screened participants, 60 were included after their consent and intervened; entered into intention-to-treat analysis. Inter-group differences shown Hb, MCV, SF values were statistically significant with medium effect size. Intra-group differences showed in Hb (IHMs-IFS: $p < 0.001$; placebos-IFS: $p < 0.01$), MCV (IHMs-IFS: $p < 0.001$; placebos-IFS: $p < 0.01$), MCH (IHMs-IFS: $p < 0.001$, placebos-IFS: $p < 0.01$), SF (IHMs-IFS: $p < 0.001$; placebos-IFS: $p < 0.001$) significant increases in both groups. **Conclusion:** Significant improvement was observed, within and between the groups. However, the magnitude of improvement was slightly greater in IHMs-IFS group compared with placebo-IFS group, indicated by larger mean changes and medium effect sizes, favouring the adjunct benefits of IHMs in management of IDA among reproductive-age women. Multi-centric, double-blinded, large-sampled studies are warranted to confirm these findings.

Keywords: Haemoglobin, Homoeopathy, Iron deficiency anaemia, RCT, Serum ferritin

Introduction

Anaemia is a public health concern that affects over 1.76 billion people worldwide.[1] It is a disorder where the red blood cell count is diminished and the body's capacity to fulfil the oxygen demands of tissues is hampered. Prevalence is estimated at 9% in countries with high development, in countries with low development the prevalence is 43%.[2] In India, according to National Family Health Survey-IV (2015–16), the

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prevalence of anaemia among women aged 15 to 49 years (reproductive age) was 53%,[3] and which has been increased by 4% in the next National Family Health Survey-V (2019–21).[4] Approximately 50% of cases are considered to be anaemia due to iron deficiency.[5] Iron deficiency anaemia (IDA) is defined as a haemoglobin concentration in blood below the lower limit of the normal range in individual age and sex. The threshold for diagnosing anaemia is 120 g/L for non-pregnant and 110 g/L for pregnant women of reproductive age (15-49 years).[5] In adults, serum ferritin level below 15 μg/L is diagnostic of IDA.[6] It is more common in women of reproductive age owing to inadequate intake of dietary iron or decreased absorption, increased requirement of it, and loss of blood. Untreated anaemia leads to several issues, including difficulties during pregnancy, fatigue, breathlessness, arrhythmia, chest pain etc.[7–9] To address this, the Government of India launched the National Iron+ Initiative under the National Health Mission, supplying Iron and Folic Acid Supplements (IFS) in 2013 to target populations.[10] Despite such efforts, anaemia prevalence remains high, suggesting the need for adjunctive strategies. Some preliminary evidence before starting of trial was limited, suggesting that homoeopathic remedies may enhance haematological parameters by stimulating physiological processes.[8,9] There is a paucity of randomised controlled trials evaluating the efficacy of individualised homoeopathic medicines (IHMs) as adjunctive therapy for IDA, particularly in reproductive-aged women. This study aims to evaluate the efficacy of IHMs as an adjunct to conventional IFS in improving haemoglobin levels in women of reproductive age diagnosed with IDA, and to assess their effects on mean corpuscular volume (MCV), mean corpuscular haemoglobin (MCH), and serum ferritin levels (SF). The rationale for using IHMs with IFS in IDA is to improve the body's iron metabolism and absorption capacity with adequate daily iron intake. This study aims to fill that gap by assessing whether the adjunctive use of individualised homoeopathic medicines with IFS (IHMs-IFS) offers greater improvement in haematological indices than placebo with IFS (placebos-IFS) alone.

Materials and methods

Study Design: This was a single-blind, randomised (1:1 allocation), placebo-controlled clinical trial.

Study Setting: This study was conducted in the outpatient department (OPD-3RA, Room no. H/7, Hospital building) of Metropolitan Homoeopathic Medical College and Hospital, Sodepur, Kolkata, West Bengal, India.

Participants: On preliminary screening, individuals with primary signs and symptoms of anaemia (i.e., pallor, fatigue, weakness, irregular heartbeat) were further evaluated. A total of 60 diagnosed anaemic females (haemoglobin level $\leq$11.9 mg/dl and $\geq$7.1 mg/dl; serum ferritin level $<$15 μg/L),[5,6] aged between 15 to 49 years were enrolled in this study. Informed Consent Form (available in three vernacular languages: Bengali, English, Hindi) was signed before participating in this study to confirm voluntary participation. In cases of minor participants ($>$7years to $<$18years), an informed assent form was signed by both participants and their parent/legal guardian.

Inclusion criteria

1. Women in reproductive age (15–49 years old). **2.** Women diagnosed on ICD-10 classification D50.9;[11] presented with primarily sign and symptoms of iron deficiency anaemia (i.e., pallor, fatigue, weakness, loss of appetite, irregular heartbeat) or already clinically diagnosed anaemic women (haemoglobin level $\leq$11.9 mg/dl to $\geq$7.1 mg/dl), and serum ferritin level $<$15 μg/L,[6] and MCV and MCH were assessed as outcome indicators. **3.** Literate patients willing to provide consent for treatment.

Exclusion criteria

1. Women with severe anaemia (Hb $<$ 7 mg/dl). **2.** Pregnant or puerperal women, lactating mothers. **3.** All others type of anaemia. **4.** Self-declared chronic illnesses like Thalassemia, Leukaemia and other haematological disorders. **5.** Self-declared and/or diagnosed immuno-compromised state and/or any acute and chronic inflammatory disorder, with any other complication. **6.** Early menopaused, hysterectomised patients. **7.** Patients who were unwilling to provide consent for treatment. **8.** Already undergone homoeopathic treatment for any others for six-months or more.

Intervention and duration

Verum Arm: IHMs (according to the patients' signs and symptoms) were administered mainly in centesimal potencies (6C, 30C, 200C or 1M; according to patients' susceptibility and by following the literature of homoeopathic posology),[12] one to seven doses, once or twice daily as required. Each dose comprised six to eight globules (no. 20) of cane sugar or distilled water, medicated with the indicated medicine (preserved in 90% v/v ethanol), taken orally on a clean tongue; repetition of dosage was dependent upon the requirement of each case. After taking medicine,

patients were advised not to eat, drink, or brush their teeth for 30 min, and in cases of globules, they were advised to suck the globules instead of swallowing. Homoeopathic medicines used in this trial were procured from a Good Manufacturing Practice (GMP)-certified company, Hahnemann Publishing Co. Private Ltd., Kolkata, West Bengal, India, and dispensed from hospital dispensaries. Identical-looking glass bottles were used to dispense the medicines and placebos were labelled properly. Based on symptom totality, history, and constitutional features for every occasion, a single medicine was prescribed. Repertorisation was performed using appropriate repertories whenever required and Materia Medica was consulted. Follow-ups were conducted at intervals of 14 days. Regarding advice on adherence, participants communicated weekly via phone calls and text messages. A register log-book was maintained for recording data of prescribed medicines, potencies etc.

Comparator arm: Placebo, identical in appearance to the IHMs, dispensed in an identical looking clean phial, was administered for 3 months. Each dose of placebo comprised six to eight globules (no.20) of cane sugar, moistened with rectified spirit to maintain similar smell, appearance and taste like verum groups, taken orally on a clean tongue. After taking medicine, patients were advised not to eat, drink, or brush their teeth for 30 min, and in cases of globules, they were advised to suck the globules instead of swallowing. Follow-up has been done after every 14 days.

Common care (both group): Iron and folic acid supplement tablets, each sugar coated, blue colour, containing dried *ferrous sulphate IP* - equivalent to 60 mg elementary iron, *folic acid IP* - 0.5 mg (i.e. 500 mcg), supplied by the government of West Bengal, were administered as per standard guidelines,[10] into every patient, once daily for three-months. IFS was used abiding govt. of India guidelines to treat mild to moderate IDA.[10]

Concomitant Care: At least 30 minutes of regular physical exercise, adequate water intake at regular intervals and avoidance of physical and mental stress, eating outside junk-food were advised as lifestyle management in same way to the participants of both groups. Patients were reminded of this at every scheduled visit. However, adherence to these recommendations was not objectively monitored or recorded during the study period.

Outcome measurements

Primary: Haemoglobin was measured as primary outcome at baseline and after 3 months.

Secondary: Other haematological parameters MCV, MCH, SF was measured at baseline and after 3 months.

Haematological parameters were measured using automated haematology analyser calibrated according to standard laboratory quality control procedures.

Randomisation

A permuted fixed block randomisation method was adopted using 6 permuted blocks, each of size 10; to reduce the predictability of group assignments and minimise imbalances in baseline characteristics. Random sequences were generated by an independent third-party random number generator, which was not allowed to influence the trial any time. An allocation ratio of 1:1 was maintained.

Blinding

Single-blind method was adopted-the participants were kept blinded about the intervention given to them throughout this trial period.

Sample size

Prior to the time of protocol development, due to absence of previously published studies with a similar design using IHMs and similar comparable outcome measures; formal sample size calculation from existing trials was not possible. As this study was exploratory, a target sample size 60 (30 in each arm) was considered.

Allocation concealment

A blinded (unaware about group allocation till study end), undergraduate student (A.H.) was involved in primary screening (presence of symptoms of IDA i.e., pallor, fatigue, weakness, loss of appetite, irregular heartbeat) followed by secondary screening (haematological tests i.e., Hb%, SF); then enrolment, and entering patients' identification data into a centralised computer software. This blinded, specially-designed, protected centralised computer software assigned patients randomly into either group as per randomisation chart, this after allocation data was only accessible by homoeopaths. Thereafter, screened patients were taken, examined, and prescribed by homoeopaths (T.S., D.D.), those who have post-doctoral degree with at least five-years of experience in clinical practice, by considering and viewing their allocated group from this software. Patients were totally blinded about their intervention; placebos were prescribed in some identical-looking

medicinal terms. Homoeopathic pharmacists, who were well-trained in this terminology to differentiate medicinal names and placebo terms were assigned for dispensing. Identical-looking amber-colored glass phials were used to dispense medicines and placebos. Strict confidentiality was maintained until the end of the study.

Statistical analysis

Data at baseline and after three-months were entered into the endpoint analysis; intention-to-treat (ITT) method was adopted. Missing values were replaced by predicted values from the equation of linear regression model. Histograms, Q-Q plots, Kolmogorov-Smirnov and Shapiro-Wilk tests were used to test distribution of data; no deviation was found, and normality were satisfied for outcome variables. Levene's test was performed, and no significant difference in variance was found on data. Unpaired t-test was applied, and continuous data presented as mean with standard deviation; categorical data presented as absolute values (percentages) and chi-squared test was applied for examining the baseline comparability of the confounders. Intra-group pre-post analysis was done by paired t-test for detection of within-groups differences; among baseline data and after 3 months data. Inter-group analysis between IHMs-IFS and placebos-IFS was done by unpaired t-test for detection of differences between groups; among baseline data and after 3 months data. Cohen's d represented the effect size (small effect, $\geq$ 0.2; medium effect, $\geq$ 0.5; large effect, $\geq$ 0.8). Findings were considered statistically significant with two-tailed p-value $<$ 0.05. SPSS-IBM, version-23 was used for statistical analysis.[13]

Study reporting adhered to the Consolidated Standards of Reporting Trials (CONSORT)[14] and Reporting Data on Homoeopathic Treatment (RedHot) guidelines.[15]

Results

Participant flow: A total of 110 patients were screened, 50 (illiterate: 02, denied consent: 4, not diagnosed with anaemia: 37, already under homoeopathic treatment: 7) were excluded, and 60 were enrolled by fulfilling pre-specified eligibility criteria and subsequently randomised and recruited with 1:1 allocation. Total study was run from April 11th to September 27th, 2023. 02 (two lost to follow-up for some reason) dropped out from the IHMs-IFS group, and 01 (one incomplete) from the placebos-IFS group (Fig. 1).

Numbers analysed: In total, 28 out of 30 completed in the IHMs-IFS and 29 out of 30 completed the trial in placebos-IFS groups; the others dropped out in both groups. All 60 participants (IHMs-IFS: 30; placebos-IFS: 30) entered into the final ITT analyses.

Baseline confounders: No significant difference in the distribution of the socio-demographic variables between the two groups could be identified. Continuous data was presented as mean ±standard deviation and unpaired t-tests were applied, and categorical data was presented as absolute values (percentages) and chi-square test was applied; also showing no significant differences (Table 1).

Outcomes and effect size

Haemoglobin: After three-months, Hb was increased by an average of 2.17 gram per decilitre (g/dL) in IHMs-IFS group and 1.34 g/dL in placebo-IFS group. Intra-group difference was statistically significant in both groups; IHMs-IFS [baseline–(follow-up) mean difference: –2.17 with 95% CI: –2.78 to –1.55, *p*-value $<$ 0.001, paired t-test] and placebos-IFS group [baseline–(follow-up) mean difference: –1.34 with 95% CI: –2.10 to –0.58, *p*-value $<$ 0.01, paired t-test). However, inter-group difference after three-months was statistically significant [(IHMs-IFS)–(Placebos-IFS) mean difference: 0.56, 95% CI: –0.01 to 1.12, *p*-value $<$ 0.05, unpaired t-test] with medium effect size (Cohen's d = 0.52), indicated that the improvement in Hb levels was slightly greater in IHMs–IFS group compared with placebo–IFS group (Tables 2 and 3).

Mean Corpuscular Volume (MCV): After three-months, MCV was increased by an average of 8.74 femtoliters (fL) in the IHMs-IFS group and 3.89 fL in the placebo-IFS group. Intra-group difference was statistically significant in both groups; IHMs-IFS group [baseline–(follow-up) mean difference: –8.74, 95% CI: –11.32 to –6.14, *p*-value $<$ 0.001, paired t-test] and placebos-IFS group [baseline–(follow-up) mean difference: –3.89 with 95% CI: –6.48 to –1.29, *p*-value $<$ 0.01, paired t-test]. Inter-group difference after 3 months was statistically significant [(IHMs-IFS)–(Placebos-IFS) mean difference: 3.67, 95% CI: 1.13 to 6.21, *p*-value $<$ 0.05, unpaired t-test) with medium effect size (Cohen's d = 0.75), indicated that the improvement in MCV levels was slightly greater in IHMs–IFS group compared with placebo–IFS group (Tables 2 and 3).

Mean Corpuscular Haemoglobin (MCH): After three-months, MCH was increased in both groups [IHMs-IFS: 1.55 picogram (pg); placebo-IFS: 1.33 pg]. Intra-group difference was statistically significant in

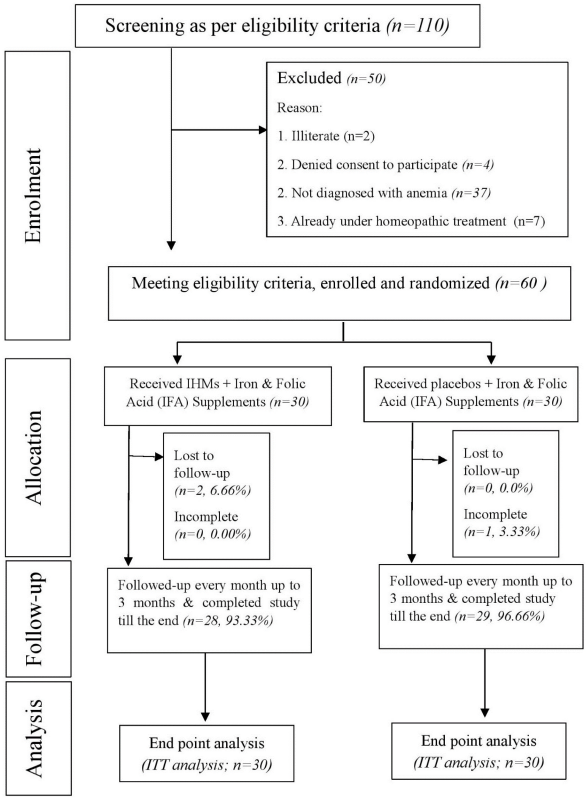

Fig. 1. CONSORT flow diagram. Abbreviations: CONSORT: Consolidated Standards of Reporting Trials; IHMs: Individualised homoeopathic medicines; IFA: Iron & folic Acid Supplement; LSM: Lifestyle modifications; ITT: Intention-to-treat.

both groups, IHMs-IFS group [baseline–(follow-up) mean difference: –1.55, 95% CI: –2.38 to –0.72, *p*-value < 0.001, paired t-test] and placebos-IFS group [baseline–(follow-up) mean difference: –1.33 with 95% CI: –2.12 to –0.53, *p*-value < 0.01, paired t-test]. But Inter-group differences after 3 months are not statistically significant [(IHMs-IFS)–(Placebos-IFS) mean difference: 0.65, 95% CI: –0.14 to 1.43, *p*-value > 0.05, unpaired t-test] with medium effect size (Cohen's d = 0.43). This indicated that there was no statistically significant difference in MCH level improvement between two groups; however, on within-group analysis, IHMs-IFS group showed slightly greater mean change than placebo-IFS group [(IHMs-IFS)–(Placebos-IFS): 0.22], which may have clinical relevance (Tables 2 and 3).

Serum Ferritin: After three-months, SF was increased markedly in both groups [IHMs-IFS: 25.48 micrograms per litter (μg/L); placebo-IFS: 18.48 μg/L]. Intra-group difference was statistically significant in both groups; IHMs-IFS group [baseline–(follow-up) mean difference: –25.48 with 95% CI: –29.83 to –21.14, *p*-value < 0.001, paired t-test] and Placebos-IFS group [baseline–(follow-up) mean difference: –18.48 with 95% CI: –21.59 to –15.36, *p*-value < 0.001, paired t-test]. But, inter-group differences between IHMs-IFS and placebos-IFS groups after three-months are statistically significant [(IHMs-IFS)–(Placebos-IFS) mean difference: 7.02, 95% CI: 1.73 to 12.31, *p*-value < 0.05, unpaired t-test] with medium effect size (Cohen's d = 0.68), indicated that the improvement in SF levels was slightly greater in IHMs–IFS group compared with placebo–IFS group (Tables 2 and 3).

Medicines used

Overall, in this study, 14 different medicines were prescribed with different potencies. The most frequently prescribed medicines were *Ferrum metallicum* (n = 4, 28.6%), *Ferrum sulphuricum* (n = 4, 28.6%), *Natrium muriaticum* (n = 3, 21.4%), and *Nitricum acidum* (n = 3, 21.4%) (Fig. 2).

Adverse events

Participants were actively monitored for adverse events (AEs) throughout the study. Monitoring protocols included scheduled visits every 14 days and telephonic follow-ups, during which participants were queried about any new or worsening symptoms

Table 1. Comparison of socio-demographic characteristics between two groups at baseline (n = 60).

Feature	IHMs group (n = 30)	Placebo group (n = 30)	*p*-Value
Age (Years)[a]	27.67 ± 8.47	29.33 ± 8.06	0.44
Blood Pressure[a]			
• Systolic (mm/Hg)	113.93 ± 12.24	113.40 ± 12.83	0.87
• Diastolic (mm/Hg)	78.60 ± 4.87	78.20 ± 6.75	0.79
Residence[b]			
• Rural	07 (23.3)	06 (20.0)	0.32
• Semi-Urban	21 (70.0)	24 (80.0)	
• Urban	02 (6.7)	00 (0)	
Marital Status[b]			
• Single	12 (40.0)	10 (33.3)	0.59
• Married	18 (60.0)	20 (66.6)	
Education Status[b]			
• 8th standard or below	05 (16.6)	06 (20.0)	0.16
• 9th - 12th standard	14 (46.6)	07 (23.3)	
• Higher than 12th standard	11 (36.6)	17 (56.6)	
Employment Status[b]			
• Business	03 (10.0)	03 (10.0)	0.60
• Service	04 (13.3)	07 (23.3)	
• Dependent or others	23 (76.6)	20 (66.6)	
Socio-economic status[b]			
• Poor	05 (16.6)	05 (16.6)	0.14
• Middle	17 (56.6)	10 (33.3)	
• Affluent	08 (26.6)	15 (50.0)	

Abbreviation: IHMs, Individualised homoeopathic medicines.

[a]Continuous data presented as mean ± standard deviation and unpaired t-tests applied.

[b]Categorical data presented as absolute values (percentages) and chi-squared test applied; *p-value* less than 0.05 (two-tailed) considered as statistically significant.

Table 2. Comparison of outcomes measured within two groups at baseline and after 3 months (n = 60).

Haematological Details	Baseline: Mean ± SD	After 3months: Mean ± SD	df	Mean difference ± SD (95% CI)	t_{29}	*p*-Value
Haemoglobin (Hb%)						
• IHMs-IFS group (n = 30)	8.9 ± 1.21	11.02 ± 0.99	29	–2.17 ± 1.64 (–2.78, –1.55)	–7.22	***0.001******
• Placebo-IFS group (n = 30)	9.1 ± 1.24	10.46 ± 1.16	29	–1.34 ± 2.03 (–2.10, –0.58)	–3.62	***0.01****
Mean Corpuscular Volume (MCV)						
• IHMs-IFS group (n = 30)	80.01 ± 4.64	88.75 ± 4.48	29	–8.74 ± 6.96 (–11.32, –6.14)	–6.88	***0.001******
• Placebo-IFS group (n = 30)	81.19 ± 4.86	85.08 ± 5.32	29	–3.89 ± 6.95 (–6.48, –1.29)	–3.06	***0.01****
Mean Corpuscular Haemoglobin (MCH)						
• IHMs-IFS group (n = 30)	27.77 ± 1.43	29.32 ± 1.49	29	–1.55 ± 2.23 (–2.38, –0.72)	–3.81	***0.001******
• Placebo-IFS group (n = 30)	27.35 ± 1.48	28.67 ± 1.55	29	–1.33 ± 2.13 (–2.12, –0.53)	–3.42	***0.01****
Serum Ferritin (SF)						
• IHMs-IFS group (n = 30)	9.81 ± 1.12	35.29 ± 11.89	29	–25.48 ± 11.63 (–29.83, –21.14)	–11.99	***0.001******
• Placebo-IFS group (n = 30)	9.79 ± 0.84	28.27 ± 8.26	29	–18.48 ± 8.33 (–21.59, –15.36)	–12.14	***0.001******

Abbreviations: IHMs-IFS, Individualised homoeopathic medicines with iron and folic acid supplement; Placebo-IFS, placebos with iron and folic acid supplement; CI, confidence interval; SD, standard deviation; t_{29}: *t* score at 29 degrees of freedom.

p-Value: intra-group differences detected by paired t-tests; *$p < 0.05$; **$p < 0.01$; ***$p < 0.001$.

using a standardised AE reporting form designed for AYUSH interventions.[16] Each reported event was evaluated for onset, duration, severity, and potential causality by AYUSH Pharmacovigilance Committee, if required. No serious adverse events were observed and reported from both groups during the study and may be any minor AEs were self-limiting and unknowingly resolved without additional intervention.

Table 3. Comparison of outcomes measured between two groups at baseline and after 3 months (n = 60).

Haematological Details	IHMs-IFS group (n = 30)	Placebo-IFS group (n = 30)	Mean group difference ± SE	95% CI	t_{58}	*Effect size (Cohen's d)*	*p*-Value
Haemoglobin (Hb%)							
Baseline: Mean ± SD	8.9 ± 1.21	9.1 ± 1.24	–0.27 ± 0.32	–0.90, 0.36	–0.84	–	0.402
• After 3 months: Mean ± SD	11.02 ± 0.99	10.46 ± 1.16	0.56 ± 0.28	–0.01, 1.12	1.99	0.52	***0.05****
Mean Corpuscular Volume (MCV)							
Baseline: Mean ± SD	80.01 ± 4.64	81.19 ± 4.86	–1.19 ± 1.23	–3.64, 1.27	–0.97	–	0.34
After 3 months: Mean ± SD	88.75 ± 4.48	85.08 ± 5.32	3.67 ± 1.27	1.13, 6.21	2.89	0.75	***0.05****
Mean Corpuscular Haemoglobin (MCH)							
Baseline: Mean ± SD	27.77 ± 1.43	27.35 ± 1.48	0.42 ± 0.37	–0.33, 1.17	1.13	–	0.263
After 3 months: Mean ± SD	29.32 ± 1.49	28.67 ± 1.55	0.65 ± 0.39	–0.14, 1.43	1.65	0.43	0.105
Serum Ferritin (SF)							
Baseline: Mean ± SD	9.81 ± 1.12	9.79 ± 0.84	0.10 ± 0.25	–0.49, 0.52	0.041	–	0.13
After 3 months: Mean ± SD	35.29 ± 11.89	28.27 ± 8.26	7.02 ± 2.64	1.73, 12.31	2.65	0.68	***0.05****

Abbreviations: IHMs-IFS, Individualised homoeopathic medicines with iron and folic acid supplement; Placebo-IFS, placebos with iron and folic acid supplement; CI, confidence interval; SD, standard deviation; SE, standard error difference; t_{58}: *t* score at 58 degrees of freedom. *p-Value*: inter-group differences detected by unpaired t-tests; *$p < 0.05$; **$p < 0.01$; ***$p < 0.001$.

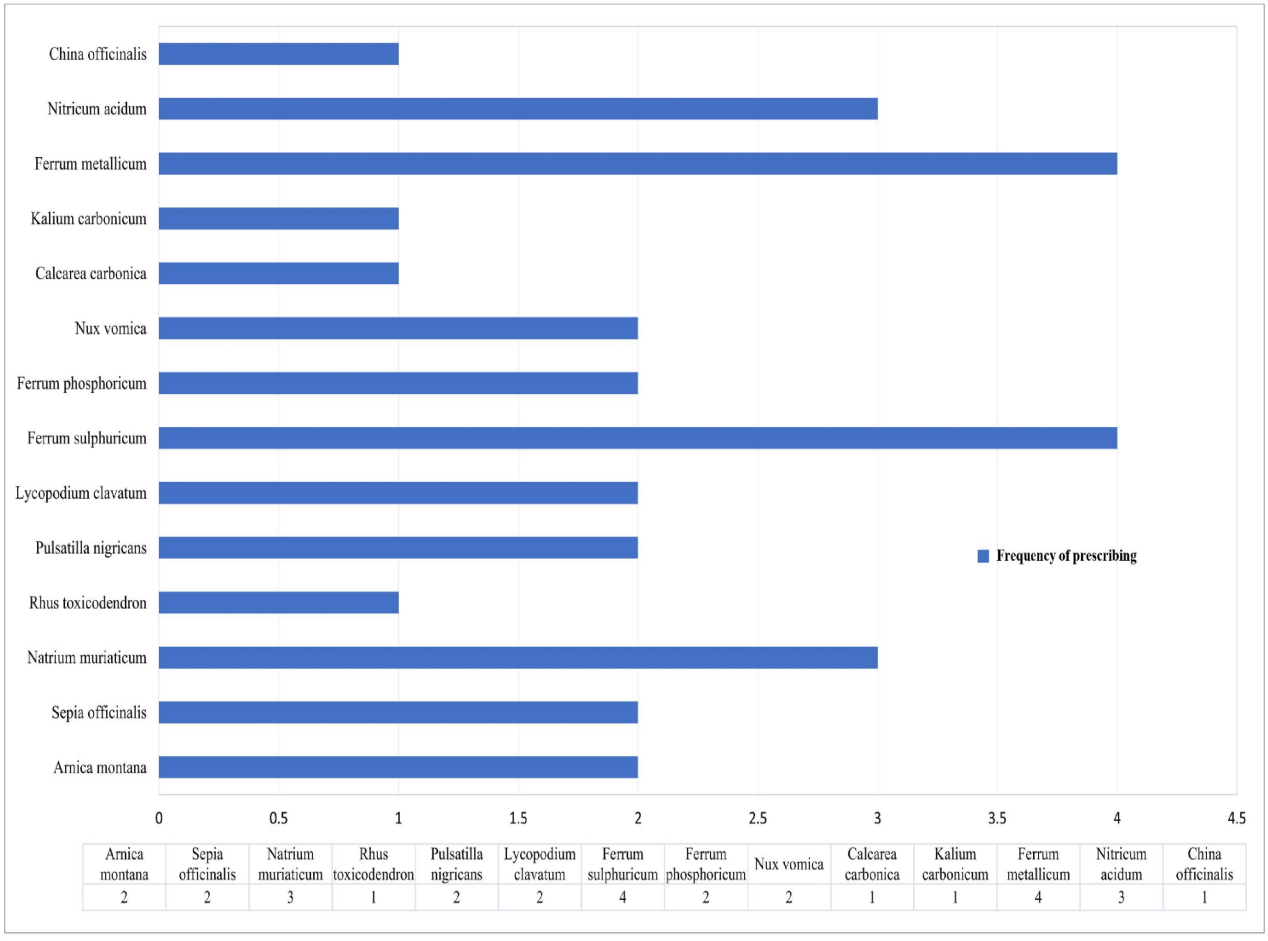

Fig. 2. Frequency of prescribed medicines.

Discussion

Anaemia, particularly IDA, continues to be a global health burden, especially in low- and middle-income countries where nutritional deficiencies are prevalent. IDA is characterised by reduced haemoglobin concentration, often accompanied by microcytosis and hypochromia, due to insufficient

iron stores. Its clinical presentation includes pallor, fatigue, dizziness, breathlessness, and cognitive impairment, all of which can significantly impact the quality of life. Among women of reproductive age, the prevalence of IDA is alarmingly high due to menstrual blood loss, inadequate dietary intake, and frequent pregnancies, making this demographic particularly vulnerable.

Female patients of reproductive age (typically between 18–45 years) diagnosed with iron deficiency anaemia, with laboratory confirmation of low haemoglobin (Hb < 12 g/dL), and decreased serum ferritin levels were included into this study. The selection of this age group was guided by earlier research highlights of studies like Balarajan *et al.*,[7] Owais *et al.*,[8] Bansal *et al.*[17] Participants who were severe anaemic (Hb < 7 mg/dl), pregnant, suffering from chronic diseases, or receiving ongoing conventional anaemia treatments were excluded to reduce confounding variables.

This single-blind, randomised, placebo-controlled trial evaluated the adjunctive efficacy of individualised homoeopathic medicines with standard iron and folic acid supplementation in sixty reproductive-aged women with iron deficiency anaemia. Sixty participants were entered into end-point analysis.

Inter-group analysis after three-months of intervention revealed that IHMs-IFS group showed statistically significant improvements in Hb (mean difference: 0.56, $p < 0.05$), MCV (mean difference: 3.67, $p < 0.05$), and serum ferritin (mean difference: 7.02, $p < 0.05$) compared to the placebo-IFS group with medium effect sizes. Although both groups showed significant intra-group improvements over three months, the magnitude of mean changes was consistently greater in the IHMs-IFS arm.

These findings align with early published studies for instance, *Lecithinum* 6C significantly improved haemoglobin, MCV, MCH, and serum ferritin in reproductive-aged anaemic females align with study conducted by Sarkar *et al.*,[18] while *Ferrum phosphoricum* 3X and *Ferrum metallicum* 3X increased haemoglobin, serum ferritin in moderately anaemic children align with study conducted by Khurana *et al.*[19] Notably, the placebo arm demonstrated an approximate haemoglobin increase of 1.3 g/dL and a serum ferritin rise of about 18.5 μg/L, closely matching improvements reported in comparable studies conducted by Bansal *et al.*,[17] and Handiso *et al.*[20]

This supports the internal validity of the trial and suggests that IHMs may offer additional benefits when used alongside standard care. Single medicines were prescribed in this trial. 14 different homoeopathic medicines were used; *Ferrum sulphuricum, Ferrum metallicum, Natrium muriaticum, Nitricum acidum* being most common.

Strengths of the study include rigorous randomisation, adherence to homoeopathic principles with individualisation, minimal-dose prescriptions and the use of identical-looking placebos. Randomisation helped reduce allocation bias, and the alignment of placebo arm data with published literature supports the internal consistency of the trial.

However, several limitations must be acknowledged like single-blind design may introduce potential detection bias, performance bias could arise since treating homoeopaths knew the group allocations. Small sample size and single-center setting limit generalisability and statistical power with short-term follow-up (three-months) does not capture long-term effects. Lifestyle and dietary adherence were not quantitatively assessed during follow-up. Since nutritional intake and daily activity may influence haemoglobin recovery, residual confounding cannot be ruled out. Measurement of some iron metabolism indicators was not feasible due to infrastructural constraints.

Despite these limitations, the observed results align with prior evidence suggesting possible benefits of Homoeopathy in IDA. Future research should focus on multi-center, double-blind randomised controlled trials with larger sample sizes to confirm these findings and improve both internal and external validity. Additionally, long-term studies are warranted to explore the sustained benefits and underlying mechanisms of adjunctive homoeopathic treatment in managing iron deficiency anaemia.

Conclusion

In this single-blind, placebo-controlled randomised trial on 60 reproductive aged women suffering from iron deficiency anaemia, within-group improvements on Hb%, MCV, MCH, SF were seen in both IHMs-IFS and placebos-IFS groups and significant between-groups differences at end-point in Hb%, MCV, SF value were seen statistically significant with medium effect size. where the magnitude of improvement was slightly greater in IHMs-IFS group compared with placebo-IFS group, indicated by larger mean changes and medium effect sizes, which overall favouring adjunctive benefits of IHMs with IFS against placebos with IFS.

Statement of ethics

Approval was obtained from the Institutional Ethics Committee, and this trial was prospectively

registered in the Clinical Trials Registry—India (CTRI/2023/04/051327), before starting this trial, with a secondary identifier of Universal Trial Number (U1111-1298-4208). The study protocol followed the latest revised Declaration of Helsinki on Human Experimentation.[21] Before enrolment, each participant was provided with an information sheet in the local language detailing objectives, methods, risks and benefits of participating, and confidentiality issues. Written informed consent or assent was obtained from all patients.

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Conflict of interest statement

The authors declare no conflict of interest. The trial was performed under the Short-Term Studentship in Homoeopathy scheme, 2022 of the Central Council for Research in Homoeopathy, India with student incentive, solely to encourage research activities.

Author's contribution

Avidipta Hazra: Concept, Design, Literature search, Clinical study, Data acquisition, Data analysis, Statistical analysis, Manuscript preparation, Manuscript editing, Guarantor. **Tanmay Sarkar:** Concept, Design, Literature search, Clinical study, Data acquisition, Manuscript review, Manuscript editing, Guarantor. All the authors reviewed and approved the final paper. **Debarsi Das:** Concept, Design, Literature search, Manuscript review, Guarantor. **Rakesh Ghosh:** Concept, Literature search, Data acquisition, Manuscript review, Guarantor. **Chandrani Ghosh:** Concept, Literature search, Data acquisition, Manuscript review, Guarantor.

Data availability statement

The data of this study are available from the corresponding author upon reasonable request.

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Efficacité de médicaments homéopathiques individualisés en complément d'une supplémentation conventionnelle en fer et en acide folique dans l'anémie ferriprive chez les femmes en âge de procréer : essai randomisé, contrôlé par placebo, en simple aveugle.

Contexte : L'anémie ferriprive (AFI) est un problème de santé publique majeur qui touche les femmes en âge de procréer dans le monde entier. Non traitée, elle peut entraîner divers problèmes de santé, notamment fatigue, essoufflement, troubles du rythme cardiaque, douleurs thoraciques et complications pendant la grossesse. **Objectifs :** Évaluer l'efficacité de médicaments homéopathiques individualisés (MII) associés à une supplémentation en fer et en acide folique (SAF) dans le traitement de la carence en fer chez les femmes en âge de procréer, comparativement à un placebo associé à une SAF. **Méthodes :** Un essai clinique randomisé, contrôlé par placebo et en simple aveugle a été mené sur six mois en consultation externe. Les participantes ont reçu les interventions et les évaluations des résultats pendant trois mois. Les femmes en âge de procréer (15-49 ans) présentant une anémie ferriprive (AF) ont été incluses sur la base d'un taux d'hémoglobine (Hb) compris entre 7,1 et 11,9 mg/dl et d'une ferritine sérique inférieure à 15 µg/l. Elles ont été randomisées pour recevoir soit des MII associés à une SAF (MII-SAF, n = 30), soit un placebo d'apparence identique associé à une SAF (placebo-SAF, n = 30) pendant trois mois. Les résultats comprenaient l'hémoglobine, le volume globulaire moyen (VGM) et le volume globulaire moyen.
Les taux d'hémoglobine (TCMH) et de ferritine sérique (FS) ont été mesurés à l'inclusion et après trois mois d'intervention. **Résultats :** Sur 110 participants présélectionnés, 60 ont été inclus après avoir donné leur consentement et ont participé à l'intervention ; ils ont été analysés selon le principe de l'intention de traiter. Les différences intergroupes ont montré des valeurs d'Hb, de VGM et de FS statistiquement significatives, avec une taille d'effet moyenne. Les différences intragroupes ont montré des augmentations significatives de l'Hb (IHMS - IFS : $p < 0,001$; placebos - IFS : $p < 0,01$), du VGM (IHMS - IFS : $p < 0,00$; placebos - IFS : $p < 0,01$), de la TCMH (IHMS - IFS : $p < 0,001$; placebos - IFS : $p < 0,01$) et de la FS (IHMS - IFS : $p < 0,001$; placebos - IFS : $p < 0,001$) dans les deux groupes. **Conclusion :** Des améliorations significatives ont été observées dans les deux groupes, tant au sein de chaque groupe qu'entre eux. Cependant, l'ampleur de l'amélioration était légèrement supérieure dans le groupe IHMS-IFS par rapport au groupe placebo-IFS, comme l'indiquent les variations moyennes plus importantes et les tailles d'effet moyennes, ce qui plaide en faveur des bénéfices adjuvants des IHMS dans la prise en charge de l'anémie ferriprive chez les femmes en âge de procréer. Des études multicentriques, en double aveugle et à grande échelle sont nécessaires pour confirmer ces résultats.

Wirksamkeit individualisierter homöopathischer Arzneimittel als Ergänzung zur konventionellen Eisen- und Folsäuresupplementierung bei Eisenmangelanämie bei Frauen im gebärfähigen Alter: Einfachblinde, randomisierte, placebokontrollierte Studie.

Hintergrund: Eisenmangelanämie (IDA) ist ein bedeutendes Gesundheitsproblem, das weltweit Frauen im gebärfähigen Alter betrifft. Unbehandelt kann sie verschiedene gesundheitliche Probleme verursachen, darunter Müdigkeit, Kurzatmigkeit, Herzrhythmusstörungen, Brustschmerzen und Komplikationen in der Schwangerschaft. **Zielsetzung:** Bewertung der Wirksamkeit individualisierter homöopathischer Arzneimittel (IHMS) mit Eisen- und Folsäuresupplementierung (IFS) zur Behandlung von Eisenmangel bei Frauen im gebärfähigen Alter im Vergleich zu Placebo mit IFS. **Methoden:** Eine einfachblinde, randomisierte, placebokontrollierte klinische Studie wurde über sechs Monate ambulant durchgeführt. Die Teilnehmerinnen erhielten drei Monate lang Interventionen und wurden hinsichtlich ihrer Behandlungsergebnisse untersucht. Eingeschlossen wurden Frauen im gebärfähigen Alter (15–49 Jahre) mit Eisenmangelanämie (IDA) anhand eines Hämoglobinwerts (Hb) von ≤ 11,9 mg/dl bis ≥ 7,1 mg/dl und eines Serumferritins < 15 µg/l. Sie wurden randomisiert entweder IHMS mit IFS (IHMS-IFS, n = 30) oder ein identisch aussehendes Placebo mit IFS (Placebo-IFS, n = 30) über drei Monate erhalten. Zu den Ergebnissen gehörten Hämoglobin, mittleres korpuskuläres Volumen (MCV), mittleres korpuskuläres Volumen
Hämoglobin (MCH) und Serumferritin (SF) wurden zu Studienbeginn und nach dreimonatiger Intervention gemessen. **Ergebnisse:** Von 110 gescreenten Teilnehmern wurden 60 nach Einwilligung in die Studie aufgenommen und in die Intention-to-Treat-Analyse einbezogen. Die Unterschiede zwischen den Gruppen waren für Hb, MCV und SF statistisch signifikant (mittlere Effektstärke). Innerhalb der Gruppen zeigten sich signifikante Anstiege der Werte für Hb (IHMS – IFS: $p < 0,001$; Placebo – IFS: $p < 0,01$), MCV (IHMS – IFS: $p < 0,00$; Placebo – IFS: $p < 0,01$), MCH (IHMS – IFS: $p < 0,001$; Placebo – IFS: $p < 0,01$) und SF (IHMS – IFS: $p < 0,001$; Placebo – IFS: $p < 0,001$) in beiden Gruppen. **Schlussfolgerung:** In beiden Gruppen, sowohl innerhalb als auch zwischen ihnen, wurden signifikante Verbesserungen beobachtet. Das Ausmaß der Verbesserung war jedoch in der IHMS-IFS-Gruppe im Vergleich zur Placebo-IFS-Gruppe etwas größer, was sich in größeren mittleren Veränderungen und mittleren Effektstärken zeigte und die zusätzlichen Vorteile von IHMs bei der Behandlung von Eisenmangelanämie bei Frauen

im gebärfähigen Alter unterstreicht. Multizentrische, doppelblinde Studien mit großen Stichproben sind erforderlich, um diese Ergebnisse zu bestätigen.

प्रजनन आयु की महिलाओं में आयरन की कमी से होने वाले एनीमियाके उपचार में पारंपरिक आयरन और फोलिक एसिड सप्लीमेंट के साथ सहायक के रूप में व्यक्तिगत होम्योपैथिक दवाओं की प्रभावकारिता: एक सिंगल ब्लाइंड, यादृच्छिक, प्लेसीबो-नियंत्रित परीक्षण।

पृष्ठभूमि: आयरन की कमी से होने वाला एनीमिया (आईडीए) विश्व स्तर पर प्रजनन आयु की महिलाओं को प्रभावित करने वाली एक प्रमुख सार्वजनिक स्वास्थ्य समस्या है। यदि इसका इलाज न किया जाए, तो यह थकान, सांस लेने में तकलीफ, असामान्य हृदय गति, सीने में दर्द और गर्भावस्था के दौरान जटिलताओं सहित विभिन्न स्वास्थ्य समस्याओं का कारण बन सकता है। **उद्देश्य:** इस अध्ययन के उद्देश्य प्रजनन आयु की महिलाओं में आयरन की कमी के उपचार में आयरन और फोलिक एसिड सप्लीमेंट (आईएफएस) के साथ व्यक्तिगत होम्योपैथिक दवाओं (आईएचएमएस) की प्रभावकारिता का मूल्यांकन करना था, तथा इसकी तुलना IFS के साथ प्लेसिबो से करना था। **विधि:** छह महीने की अवधि के लिए बाह्य रोगी विभाग एक सिंगल ब्लाइंड, यादृच्छिक, प्लेसीबो नियंत्रित नैदानिक परीक्षण किया गया, जिसमें प्रतिभागियों को तीन महीने तक हस्तक्षेप और परिणाम मूल्यांकन प्राप्त हुए। हीमोग्लोबिन (Hb) स्तर ≤11.9 mg/dl से ≥7.1 mg/dl और सीरम फेरिटिन <15 µg/l के आधार पर प्रजनन आयु की महिलाओं (15-49 वर्ष) को शामिल किया गया; उन्हें तीन महीने के लिए या तो IHMs के साथ IFS (IHMs-IFS, n = 30) या समान दिखने वाले प्लेसीबो के साथ IFS (प्लेसीबो-IFS, n = 30) प्राप्त करने के लिए यादृच्छिक रूप से दो समूहों में विभाजित किया गया। परिणामों में हीमोग्लोबिन, मीन कॉर्पस्कुलर वॉल्यूम (MCV), मीन कॉर्पस्कुलर हीमोग्लोबिन (MCH) और सीरम फेरिटिन (एसएफ) के स्तर शामिल थे, जिन्हे प्रारंभिक अवस्था में और हस्तक्षेप के तीन महीने बाद मापा गया। **परिणाम:** 110 जांचे गए प्रतिभागियों में से, 60 को उनकी सहमति के बाद अध्ययन में शामिल कर दिया गया; उन्हें इंटेंशन-टू-ट्रीट विश्लेषण में शामिल किया गया। अंतर समूह विशलेषण से पता चला कि हीमोग्लोबिन, एमसीवी और एसएफ के मान सांख्यिकीय रूप से महत्वपूर्ण थे और इसमें मध्यम प्रभाव आकार देखा गया| समूह के भीतर के अंतरों में Hb (IHMs - IFS: $p < 0.001$; प्लेसीबो - IFS: $p < 0.01$), MCV (IHMs - IFS: $p < 0.00$; प्लेसीबो - IFS: $p < 0.01$), MCH (IHMS - IFS: $p < 0.001$, प्लेसीबो - IFS: $p < 0.01$), SF (IHMs - IFS: $p < 0.00$; प्लेसीबो - IFS: $p < 0.01$) में दोनों समूहों में महत्वपूर्ण वृद्धि देखी गई। **निष्कर्ष:** समूहों के भीतर और समूहों के बीच दोनों में महत्वपूर्ण सुधार देखे गए। हालांकि, प्लेसीबो - IFS समूह की तुलना में IHMS - IFS समूह में सुधार की मात्रा थोड़ी अधिक थी, जो बड़े औसत परिवर्तनों और मध्यम प्रभाव आकारों द्वारा इंगित की गई, जो प्रजनन आयु की महिलाओं में IDA के प्रबंधन में IHMs के सहायक लाभों का समर्थन करती है। इन निष्कर्षों की पुष्टि के लिए बहु-केंद्रित, डबल ब्लाइंड और बड़े नमूने वाले अध्ययनों की आवश्यकता है।

Eficacia de los medicamentos homeopáticos individualizados como complemento de la suplementación convencional con hierro y ácido fólico en la anemia por deficiencia de hierro en mujeres en edad reproductiva: Ensayo simple ciego, aleatorizado y controlado con placebo.

Antecedentes: La anemia por deficiencia de hierro (ADH) es un importante problema de salud pública que afecta a las mujeres en edad reproductiva a nivel mundial. Si no se trata, puede causar diversos problemas de salud, como fatiga, dificultad para respirar, arritmias cardíacas, dolor torácico y complicaciones durante el embarazo. **Objetivos:** Evaluar la eficacia de los medicamentos homeopáticos individualizados (MHI) con suplementos de hierro y ácido fólico (SIF) en el tratamiento de la deficiencia de hierro en mujeres en edad reproductiva, en comparación con placebos con SIF**. Métodos:** Se realizó un ensayo clínico aleatorizado, controlado con placebo y a simple ciego durante un total de seis meses en el departamento de pacientes ambulatorios, de los cuales los participantes recibieron intervenciones y evaluaciones de resultados durante tres meses. Se incluyeron mujeres en edad reproductiva (15-49

años) con anemia por deficiencia de hierro (IDA) según un nivel de hemoglobina (Hb) ≤11,9 mg/dl a ≥7,1 mg/dl con ferritina sérica < 15 µg/l; aleatorizadas para recibir IHM con IFS (IHM-IFS, n = 30) o placebos de apariencia idéntica con IFS (placebo-IFS, n = 30) durante 3 meses. Los resultados incluyeron hemoglobina, volumen corpuscular medio (VCM), volumen corpuscular medio
Niveles de hemoglobina (MCH), ferritina sérica (SF) medidos al inicio y después de tres meses de intervención. **Resultados:** De 110 participantes evaluados, 60 fueron incluidos después de su consentimiento e intervención; ingresaron al análisis por intención de tratar. Las diferencias entre grupos mostraron que los valores de Hb, VCM, SF fueron estadísticamente significativos con un tamaño del efecto medio. Las diferencias intragrupo mostraron en Hb (IHMS - IFS: p < 0,001; placebos - IFS: p < 0,01), VCM (IHMS - IFS: p < 0,00; placebos - IFS: p < 0,01), MCH (IHMS - IFS: p < 0,001, placebos - IFS: p < 0,01), SF (IHMS - IFS: p < 0,001; placebos - IFS: p < 0,001) aumentos significativos en ambos grupos. **Conclusión:** Se observaron mejoras significativas tanto dentro como entre los grupos. Sin embargo, la magnitud de la mejora fue ligeramente mayor en el grupo IHMS-IFS en comparación con el grupo placebo-IFS, lo que se evidencia en cambios promedio mayores y tamaños del efecto moderados, favoreciendo los beneficios coadyuvantes de los IHM en el manejo de la anemia por deficiencia de hierro en mujeres en edad reproductiva. Se justifican estudios multicéntricos, doble ciego y con muestras grandes para confirmar estos hallazgos.

個人化順勢療法藥物作為常規鐵劑和葉酸補充劑的輔助療法治療育齡婦女缺鐵性貧血的療效：單盲、隨機、安慰劑對照試驗。

背景：缺鐵性貧血（IDA）是影響全球育齡婦女的重大公共衛生議題。如不及時治療，可導致多種健康問題，包括疲勞、呼吸困難、心律不整、胸痛以及懷孕併發症。**目的：**評估個體化順勢療法藥物（IHMS）合併鐵和葉酸補充劑（IFS）治療育齡期女性缺鐵性貧血的療效，並與安慰劑合併IFS進行比較。方法：在門診進行為期六個月的單盲、隨機、安慰劑對照臨床試驗，受試者接受介入和結果評估三個月。**納入標準為：**年齡在15至49歲之間、血紅蛋白（Hb）水平≤11.9 mg/dl至≥7.1 mg/dl且血清鐵蛋白<15 µg/l的育齡期女性缺鐵性貧血患者；隨機分為兩組，分別接受IHMS聯合IFS（IHMs-IFS組，n=30）組，n=30）或相同三個月的安慰劑組，SIFS-IFS組，n=30）或合療程。結果包括血紅素、平均紅血球體積（MCV）、平均紅血球在基線和介入三個月後測量血紅蛋白（MCH）和血清鐵蛋白（SF）水平。**結果：**在110名篩選的參與者中，60名在獲得知情同意後納入研究並接受介入；納入意向性治療分析。組間差異顯示，Hb、MCV和SF值具有統計意義，效應量為中等。組內差異顯示，Hb（IHMS-IFS組：p < 0.001；安慰劑-IFS組：p < 0.01）、MCV（IHMS-IFS組：p < 0.00；安慰劑-IFS組：p < 0.01）、MCH（IHMS-IFS <p <HMS-IFS 0.01）和SF（IHMS-IFS組：p < 0.001；安慰劑-IFS組：p < 0.001）在兩組中均顯著增加。**結論：**組內和組間均觀察到顯著改善。然而，與安慰劑-IFS組相比，IHMS-IFS組的改善幅度略大，表現為平均變化值更大、效應量中等，這表明IHMs在育齡婦女缺鐵性貧血的治療中具有輔助療效。需要進行多中心、雙盲、大樣本研究來證實這些發現。