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ORIGINAL ARTICLE

Immunological, Biochemical, and Infant-Toddler Quality of Life Parameter-Based Study of *Swarna Prashana* (a Herbo-Mineral Ayurveda Preparation) in Infants

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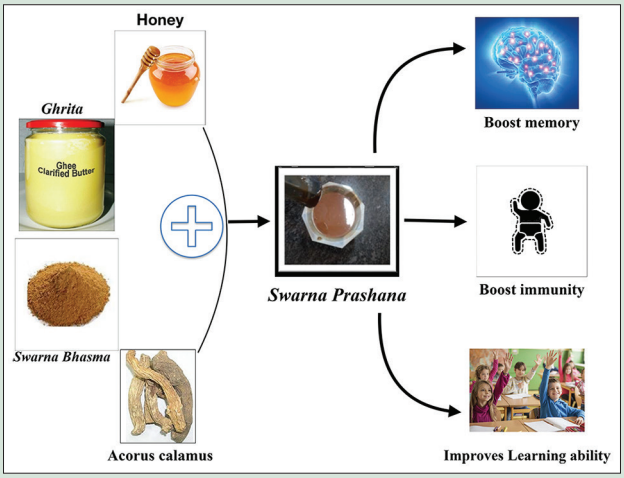
ABSTRACT

Background: Increasing rate of emergence of newer infection, resistance to antibiotics, reoccurrence of infections, and malnutrition have created a space for an effective and safe solution of above issues to mankind. *Swana Prashana* is a unique concept of Indian system of medicine for improving the generalized immunity consequently helping the child to resist and fight against various infection and diseases. **Aims:** Study was planned to evaluate the efficacy of Swarna Prashana and Swarna Vacha Prashana in infants. **Materials and Methods:** A randomized, controlled, single-blind clinical study was planned in healthy infants to study the effect of *Swarna Prashana* in anthropometry, hematological, biochemical, immunological, and infant-toddler quality of life (ITQOL) parameters in 3 differently categorized groups namely Group A: (*n* = 39, *Ghrita and Madhu)*. Group B: (*n* = 42, *Swarna Bhasma, Ghrita and Madhu*) Group C: (*n* = 38, *Swarna Bhasma, Ghrita, Madhu* and *Vacha Churna*). **Results:** The present clinical study showed statistically highly significant ($P < 0.001$) increase in all the anthropometrical measurements of infants all three groups. The drugs did not hamper normal growth of the infants and they did not have any additional effect on enhancing the anthropometrical values. Hematological and biological parameters did not show significant difference in comparison in all groups. The results of Renal function and liver function tests were in normal limits after completion of treatment and post treatment follow-up suggestive of safe to be administered in infants. Immunological parameters also did not show significant difference of comparison in all groups except in Group C where immunoglobulin G (IgG), IgM, albumin, globulin levels were increased. Group C significantly improved all the ITQOL parameters while on comparison significant difference was observed in improving the physical abilities only. **Conclusion:** Current study suggests *Swarna Prashana* as infants health promotive and morbidity preventive. Author advocates a large scale randomized double blind clinical trial for further validation of impact of *Swarna Prashan* as mass health-care initiative.

Key words: Ayurveda, immunomodulation, *Swarnaprashan*, Vyadhi kshamatva

SUMMARY

- *Swarna Prashana* is safe and effective in maintenance of health of infants. It can potentially contribute to malnutrition management through public health initiative in India.



Abbreviations Used: ITQOL - Infant-toddler Quality of Life: IgG - Immunoglobulin G; IgM - Immunoglobulin M; SGPT: Serum Glutamic Pyruvic Transaminase; SGOT: Serum Glutamic Oxaloacetic Transaminase; Hb: Hemoglobin; TLC: Total Leukocyte Count; TRBC: Total Red Blood Cell count; PLT count: Platelet Count; AIDS: Acquired Immune Deficiency Syndrome.

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INTRODUCTION

Swarna Prashana is a combination of two words – "*Swarna*" and "*Prashana*". *Swarna* refers to the noble metal Gold (Au).[1] *Prashana* is act of eating/consuming/ingesting. *Swarna Prashana* refers to the act of consuming or ingesting gold in the prescribed dose and quantity in the suggested manner, sometimes referred as *Swarna Bindu Prashana*. *Swarna Prashana* is a cultural practice in India and has included in *JatakarmaSamskara* which is one of the 16 essential *Samskars* described in Indian tradition.[2] Raw gold is rubbed on a stone with water while facing towards east chanting holy Mantras and is administered with honey and *ghrita* to a newborn just after birth (*Jaatmatra*).[3] With the time, raw gold has replaced by *Swarna Bhasma* while some drugs like *Vacha Churna* (*Acorus calamus*) and *Brahmi* (*Bacopa monnieri*) are now added as ingredient of *Swarna Prashana*. The word *Prashana* is also having a synonym as *Lehana*[4] and *Lehya* (lickable) indicates unctuous,

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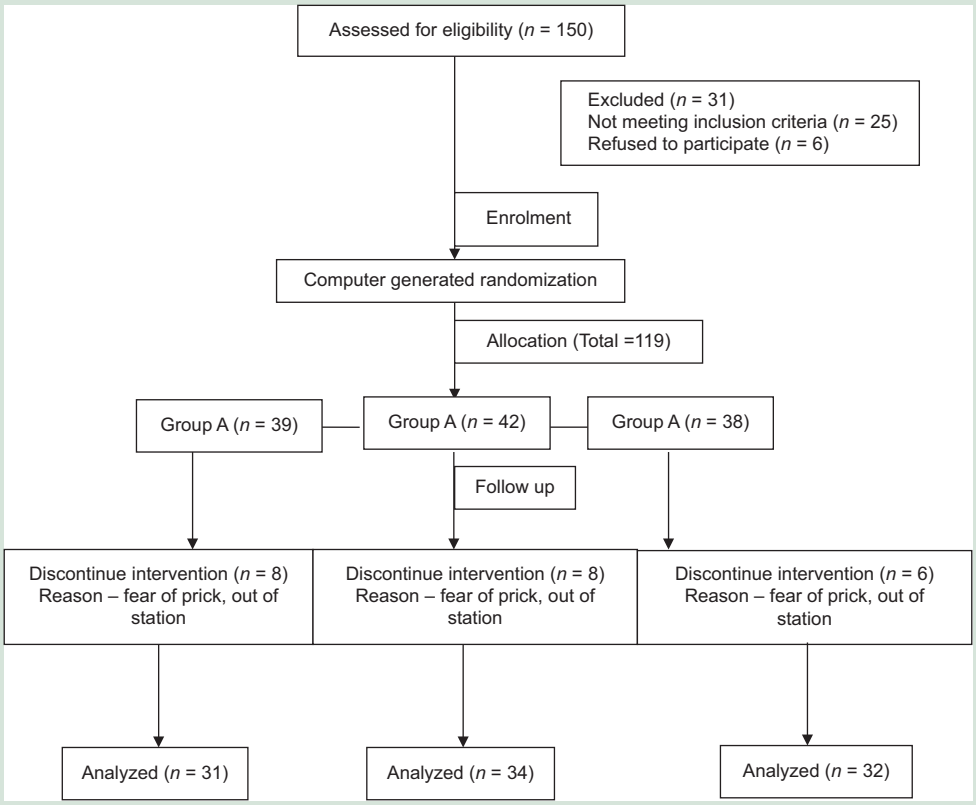

Chart 1: Detailed study design including dropout and its cause

sticky and semisolid variety of food/medicinal preparation. Oral administration by *Lehana* is considered to be convenient and safe way in pediatric age group. It enhances *Medha* (Intelligence), *Agni* (digestive power), *Bala* (strength), and *Ayu* (age). It is *Varnya* (complexion), *Pavitra* (pious), and *Mangalkaraka* (good will). Therapeutically used in *Grahabadha* and is *Vrishya*. If it is administered daily for a month, the child will become *Medhavi* (intelligent). If its administration continued for 6 months, the child will become *Smritivan* (increase memory), and *Shrutadhara* (remember everything which is heard).[5]

In Kashyapa Samhita, while describing the benefits of *Swarna Lehana*, Acharya Kashyapa opines that, by feeding the gold for 1 month, the child is not attacked by any disease. This classical description implicates that ingestion of *Swarna* modulates immune mechanism, so that morbidity is reduced. *Swarna Bhasma* has immunomodulatory,[6,7] free radical scavenging,[8] analgesic,[9] and anti-stress effect.[10] *In vitro*, *in vivo* and Clinical Studies done on *Swarna Prashan*/*Swarna Bindu Prashan* have suggested that it has a good immunomodulation,[11] growth promoter,[12-14] antitussive[15] and may support quality of life in cancer patients during anti-cancer[16] treatment.

Randomized clinical trial study is the essence of any research work. It reveals the promises and pitfalls of any hypothesis and improves its practical applicability. The concept of *Swarna Prashan* is an experience based-documented practice of disease prevention in the field of childcare since many decades. At this juncture, it becomes an essential to revalidate the hypothesis and observations according to the norms and practices of the present day clinical research. Hence, a systematic clinical study was planned to evaluate the immunomodulatory and growth promoting efficacy of *Swarna Prashana* given in healthy pediatric age group subjects.

MATERIALS AND METHODS

A written informed consent was obtained from the parents of infants (attained weight > 2.5 kg) approached before participation in the study from Out Patient Department and In Patient Department of Kaumarbhritya, IPGT and RA Jamnagar. Vaccination schedule was not interrupted during the study. The study protocol was approved from the ethical committee of IPGT and RA Jamnagar, India wide letter No. PGT/7-A/Ethics/2011-2012/2796 and the Research work has been registered in Clinical Trial Registry of India (CTRI)-CTRI/2012/03/002505 dated March 20, 2012.

Inclusion criteria

- Full term newborn and healthy infants (age between 0 and 12 months) of either sex
- Birth weight >2.5 kg (newborn).

Exclusion criteria

- Children more than 12 months
- Congenital anomalies and hereditary diseases
- Sick infants with infectious diseases, metabolic disorders.

Study design

This study is stage II clinical trial, in which the experimental study drug (Swarna Prashana) is given to a larger group (>100) to see the effective and safety purpose. A randomized, controlled, single-blind clinical study was planned and randomized sampling was followed to divide the patients in three different groups. Random sampling (Computer generated Random number table) was followed.

- Group A-*Madhu–Ghrita*[17] (Unequal-quantity)

Table 1: Dosage of *Swarna Prashana* for different age groups

Age (month)	Dosage in drops per day	Approximate quantity of ***Vacha Churna*** (mg)	Approximate quantity of ***Swarna Bhasma*** (mg)
1	1	3.33	0.2
2	2	6.66	0.4
3	3	9.99	0.6
4	4	13.32	0.8
5	5	16.65	1.0
6	6	19.98	1.2
7	7	23.31	1.4
8	8	26.64	1.6
9	9	29.97	1.8
10	10	33.30	2.0
11	11	36.63	2.2
12	12	39.96	2.4

Table 2: Distribution of total number of subjects enrolled in the study

Group	Registered	Completed	Drop out
A	39	31	8
B	42	34	8
C	38	32	6
Total	119	97	22

- Group B– *Swarna-Madhu–Ghrita*[18] (Unequal quantity)
- Group C– *Swarna-Vacha-Madhu-Ghrita*[19] (Unequal quantity)

Diagnostic criteria

Complete physical examination and detailed evaluation of the infants with respect to growth and development were done and documented the findings in a specially prepared proforma namely anthropometric changes such as length, head circumference, chest circumference, developmental milestones, gross motor, fine motor. The assessment of total effect of therapy was considered by the improvement in infant-toddler quality of life parameters (ITQOL). Routine investigation (hematological parameters) for monitoring changes were Hb gm%, total red blood cell count, total leucocyte count, differential leukocyte count, erythrocyte sedimentation rate, platelet counts, renal function test, liver function test, total serum protein, and serum immunoglobulin G (IgG) and IgM levels were carried out at the time of registration and subsequent follow ups.

Sample collection

Two milliliters blood of each patient was collected through the sterile syringe from a peripheral vein at first visit and on the subsequent follow-ups. All the samples were collected in between 10 and 12 AM to reduce diurnal variation.

Selection of drug

Swarna Bhasma

The selection of *Swarna Bhasma* was based on the textual indication. The drug *Swarna Bhasma* was provided by Rasshastra and Bhaishjya Kalpana Department, IPGT and RA, Jamnagar. The drug was prepared according to method as described in Ayurvedic formulary of India; 1976.[20]

Madhu (Honey) and Grita

Honey and *Grita* for the purpose of clinical study was taken from Khadi Gramoudhyog, Supermarket, Jamnagar. *Ghrita* was manufactured by Schreiber Dynamix Dairies Ltd., Maharastra and Honey was processed and marketed by Azad Kutir Udhyoga Sansthan, Uttar Pradesh. Patient's attendants were advised neither fridge nor to heat it.

Vacha

Vacha was procured from Ayurvedic pharmacy, IPGT and RA, Jamnagar.

Dose

As both ghee and honey were adjuvant drugs, only dosage of *Swarna Bhasma* was fixed according to the age of infants in months by following Fried's Rule. *Swarna Prashna* drops were administered orally once day in the morning for 4 weeks. Details of doses of *Vacha* and Gold according to age are shown in Table 1.

Follow-up

There were three follow-up to every registered patient-first on completion of 4th week and second and third post treatment follow-up on 8th week (post-treatment 4th week) second on 12th week (post treatment 8th week). The clinical and anthropometric parameter response of the treatment of each case was observed and recorded on follow-up on a prior designed pro forma for the study.

Statistical tools

t-test and one way ANOVA followed by Dunn's Method.

RESULTS AND DISCUSSION

A randomized, controlled, single-blind clinical study was conducted to assess and compare the efficacy of (*Swarna Prashana Yoga*) with and without *Vacha* and combination of *Madhu* and *Ghrita* in infants aged 0–12 months.

In the present study, a total of 119 children were registered based on inclusion criteria; 39 in Group A, 42 in Group B and 38 in Group C, details of enrolled, completed and dropout subject are given in Table 2.

Total of 119 children were registered based on inclusion criteria; 39 in group A, 42 in group B and 38 in Group C, out of which 31in Group A, 34 in group B and 32in group C completed the treatment whereas 8 children in Group A, 8 in Group B, and 6 in Group C discontinued the treatment shown in Chart 1.

One hundred and eighteen (99.15%) mothers had underwent regular antenatal checkup and only 1 (0.85%) had irregular checkup while 117 (98.31%) of the mothers were vaccinated during pregnancy and 2 (1.68%) mothers were not vaccinated during pregnancy.

Total 4 (3.361%) subjects were preterm, 112 (94.11%) were term while 3 (2.52%) subjects were postterm. One hundred and nine (91.59%) subjects were cried soon after birth and 10 (8.41%) were did not cry soon after birth and only 1 (0.85%) subject had a history of neonatal intensive care unit admission. Exclusively breast fed were given to 39 (100%) Group A, 41 (97.62%) Group B and 36 (94.74%) in Group C. Total 16 (8.84%) subjects were suffered from illness in past time.

Anthropometry

All the three groups showed statistically highly significant ($P < 0.001$) increase in all the anthropometrical measurements of infants aged 0–1 month and 1–12 months. On comparison there was no statistically significant difference between all the groups. Drugs did not hamper normal growth of the infants, while maintaining the health of the infants. Details parameters of anthropometry and their means, standard deviation, intergroup comparison, and statistical significance are shown in Tables 3 and 4.

Hematological parameters

Group A showed statistically significant ($P < 0.001$) decrease in hemoglobin and significantly ($P < 0.05$) increase in lymphocyte counts. Group B showed statistically significant ($P < 0.05$) decrease in hemoglobin, neutrophil count, and increase platelets and lymphocyte counts. Group C showed statistically highly significant ($P < 0.001$) decrease in hemoglobin, neutrophil, statistically significant ($P < 0.05$) decrease in Total Red Blood Cell Count (TRBC), and statistically highly significant ($P < 0.001$) increase in lymphocyte counts. Hemoglobin, neutrophil, and TRBC decrease according to age of infants while lymphocytes increase respectively. All the above-mentioned changes were within normal limits showing that drugs did not interfere to the normal physiology of hematological parameters Table 5.

On comparison all three groups, drug did not show statistically significant difference on hematological parameters of infants aged 1–12 months. Detailed hematological parameters and their means, standard deviation, intergroup comparison, and statistical significance are shown in Table 6.

Biochemical parameters

Group A and Group B did not show any statistically significant difference on Biochemical parameters. Group C showed statistically significant ($P < 0.05$) decrease in Sr. Creatinine. The decreased Sr. Creatinine value was within the normal limits and so it might have occurred by chance. Some of these normal ranges change markedly when age drops below 2 years and especially below 1 year Table 7. On comparison all three groups, drug did not show any statistically significant difference on biochemical parameters of infants aged 1–12 months. Detailed biochemical parameters and their means, standard deviation, intergroup comparison, and statistical significance are shown in Table 8.

Immunological parameters

All three groups did not show any statistically significant difference on Immunological parameters. IgG volume marked increase after t/t in Group B and marked increases IgG, IgM, Globulin volume in Group C, but it was not statistically significant. These values should be decreased up to 1yr. Increased IgG mean a long-term (chronic) infection, such as AIDS, multiple myeloma, long-term hepatitis, and multiple sclerosis. Detailed immunological parameter and their means, standard deviation, intergroup comparison and statistical significance are shown in Tables 9 and 10.

Infant-toddler quality of life parameters

Group A showed statistically highly significant ($P < 0.001$) improvement on physical abilities, temperament and mood, general health, parent impact and statistically significant ($P < 0.05$) improvement on growth and development.

Group B showed statistically highly significant ($P < 0.001$) improvement on physical abilities, temperament and mood, general health, parent impact (Time), and statistically significant ($P < 0.05$) improvement on Growth and development and bodily pain/discomfort. Group C showed statistically highly significant ($P < 0.001$) improvement on bodily pain/discomfort, temperament and mood, general health, parent impact (Time) and statistically significant ($P < 0.05$) improvement on physical abilities, growth and development and parent impact (emotional), thus significant effect on all ITQOL parameters Table 11.

On comparison all three groups, statistically highly significant ($P < 0.001$) improvement by bodily pain/discomfort, and statistically significant ($P < 0.05$) effect by general health and parent impact (Time), but did show statistically significant difference on rest of the parameters. ITQOL is an important subjective parameter, where improvement can be observed both by mothers and noted by the physicians. This shows that the drugs did not hamper the quality of life of Infants, of course increased it. Detailed ITQOL parameters and their means, standard deviation, intergroup comparison, and statistical significance are shown in Table 12.

Table 3: Effect on anthropometry parameters

Parameters	Group A								
	n	BT	AT	Mean difference	SD±	SE±	Change (%)	*t*	*P*
Weight	31	4.12	5.12	1.00	0.67	0.12	24.25↑	8.27	<0.001
Length	31	53.47	57.98	4.51	3.10	0.56	8.44↑	8.12	<0.001
HC	31	36.77	38.90	2.13	1.49	0.27	5.79↑	7.96	<0.001
CC	31	34.76	37.00	2.24	1.743	0.31	6.45↑	7.16	<0.001
Parameters	**Group B**								
	n	BT	AT	Mean difference	SD±	SE±	Change (%)	*t*	*P*
Weight	34	4.24	5.21	0.97	0.57	0.098	22.75↑	9.80	<0.001
Length	34	53.16	57.35	4.19	3.31	0.57	7.88↑	7.37	<0.001
HC	34	36.76	38.50	1.75	1.36	0.23	4.75↑	7.48	<0.001
CC	34	34.79	36.71	1.92	1.50	0.26	5.51↑	7.46	<0.001
Parameters	**Group C**								
	n	BT	AT	Mean difference	SD±	SE±	Change (%)	*t*	*P*
Weight	32	4.33	5.19	0.87	0.55	0.096	20.02↑	8.98	<0.001
Length	32	53.72	56.88	3.16	3.35	0.59	5.89↑	5.35	<0.001
HC	32	36.52	37.10	1.38	1.24	0.22	3.78↑	6.30	<0.001
CC	32	35.05	36.52	1.48	1.29	0.23	4.21↑	6.49	<0.001

HC: Head circumference; CC: Chest circumference; *n*: Number of subject; BT: Before treatment; AT: After treatment; SD: Standard deviation; SE: Standard error; *P*: Probability; *t*: Test statistic

Table 4: Comparison of effect on anthropometrical parameter

Parameters	Mean difference			*F*	*P*
	Group A	Group B	Group C		
Weight	1.00	0.97	0.87	0.53	>0.05
Length	4.51	4.19	3.16	2.21	>0.05
HC	2.13	1.75	1.38	3.04	>0.05
CC	2.24	1.92	1.48	1.93	>0.05

HC: Head circumference; CC: Chest circumference; *F*: Test statistic (Ronald fisher); *P*: Probability

Table 5: Effect on hematological parameters

Parameters	Group A								
	n	BT	AT	Mean difference	SD±	SE±	Change (%)	*t*	*P*
Hb %	31	13.14	10.98	−2.15	2.27	0.40	−17.07↓	−5.29	<0.001
TLC	31	11,306.45	11,290.32	−16.13	3529.88	633.99	−12.19↓	−0.03	>0.05
TRBC	31	21.17	18.60	−2.58	12.71	2.28	−10.21↓	−1.12	>0.05
PLT count	31	328.90	378.74	49.84	183.83	33.02	14.14↑	1.51	>0.05
Neutrophil	31	33.16	22.64	−10.52	16.46	2.96	−38.39↓	−3.56	<0.05
Lymphocyte	31	58.80	69.61	10.81	16.67	2.99	29.05↑	3.61	<0.05
Eosinophil	31	4.80	4.32	−0.48	3.04	0.55	4.00↓	−0.89	>0.05
Monocyte	31	3.12	3.06	−0.065	1.57	0.28	13.40↓	−0.23	>0.05
Parameters	**Group B**								
	n	BT	AT	Mean difference	SD±	SE±	Change (%)	*t*	*P*
Hb %	34	13.03	11.37	−1.67	3.05	0.52	−12.80↓	−3.19	<0.05
TLC	34	13,867.65	10,979.41	−2888.24	18,244.98	3128.99	−20.83↓	−0.92	>0.05
TRBC	34	4.15	3.93	−0.23	0.72	0.12	−5.49↓	−1.83	>0.05
PLT count	34	360.09	446.79	86.71	217.61	37.32	24.08↑	2.32	<0.05
Neutrophil	34	37.62	27.44	−10.18	16.94	2.91	−27.05↓	−3.50	<0.05
Lymphocyte	34	53.21	62.09	8.88	17.57	3.01	16.69↑	2.95	<0.05
Eosinophil	34	3.27	3.88	0.62	2.09	0.36	18.93↑	1.72	>0.05
Monocyte	34	2.82	2.71	−0.12	1.47	0.25	18.93↑	−0.47	>0.05
Parameters	**Group C**								
	n	BT	AT	Mean difference	SD±	SE±	Change (%)	*t*	*P*
Hb %	32	12.89	10.69	−2.20	2.51	0.44	−17.07↓	−4.96	<0.001
TLC	32	10,796.87	9481.25	−1315.62	5060.35	894.55	−12.19↓	−1.47	>0.05
TRBC	32	4.21	3.78	−0.43	0.69	0.12	−10.21↓	−3.54	<0.05
PLT count	32	339.37	387.37	48.00	196.48	34.73	14.14↑	1.382	>0.05
Neutrophil	32	39.31	24.21	−15.09	14.80	2.61	−38.39↓	−5.767	<0.001
Lymphocyte	32	50.87	65.65	14.78	14.23	2.51	29.05↑	5.87	<0.001
Eosinophil	32	3.75	3.90	0.15	2.93	0.51	4.00↑	0.30	>0.05
Monocyte	32	3.21	2.78	0.43	1.50	0.27	13.40↓	1.64	>0.05

Hb: Hemoglobin; TLC: Total leucocyte count; TRBC: Total red blood cell count; PLT count: Platelet count; BT: Before treatment; AT: After treatment; SD: Standard deviation; SE: Standard error

Table 6: Comparison of effect on hematological parameters

Parameters	Mean difference			*F*	*P*
	Group A	Group B	Group C		
Hb %	−2.15	−1.67	−2.20	0.81	>0.05
TLC	−16.13	−2888.24	−1315.62	0.53	>0.05
TRBC	−2.58	−0.23	−0.43	0.69	>0.05
PLT count	49.84	86.71	48.00	0.51	>0.05
Neutrophil	−10.52	−10.18	−15.09	1.61	>0.05
Lymphocyte	10.81	8.88	14.78	1.76	>0.05
Eosinophil	−0.48	0.62	0.15	1.25	>0.05
Monocyte	−0.065	−0.12	0.43	0.52	>0.05

Hb: Hemoglobin; TLC: Total leukocyte count; TRBC: Total red blood cell count; PLT count: Platelet count

Table 7: Effect on biochemical parameters

Parameters	Group A								
	n	BT	AT	Mean difference	SD±	SE±	Change (%)	*t*	*P*
SGPT	31	21.93	26	4.06	17.30	3.10	18.51↓	1.31	>0.05
SGOT	31	42.24	45.26	3.02	24.41	4.386	7.15↑	0.69	>0.05
Total bilirubin	31	1.52	1.21	−0.31	1.40	0.253	−20.39↓	−1.25	>0.05
Direct bilirubin	31	1.35	1.06	−0.28	2.02	0.362	−20.74↓	−0.79	>0.05
Blood urea	31	16.58	17.60	1.01	9.92	1.782	6.11↑	0.57	>0.05
Serum creatinine	31	0.65	0.58	−0.077	0.287	0.051	−11.85↓	−1.501	>0.05
Serum uric acid	31	3.23	2.70	−0.53	2.10	0.70	−16.49↓	−0.76	>0.05
Parameters	**Group B**								
	n	BT	AT	Mean difference	SD±	SE±	Change (%)	*t*	*P*
SGPT	34	36.47	27.91	−8.55	51.41	8.81	−23.44↓	−0.97	>0.05
SGOT	34	66.26	45.52	−20.73	68.91	11.81	−31.29↓	−1.75	>0.05
Total bilirubin	34	1.69	1.41	−0.27	1.04	0.18	−15.98↓	−1.55	>0.05
Direct bilirubin	34	0.71	0.47	−0.24	0.72	0.12	33.80↓	−1.98	>0.05
Blood urea	34	18.23	17.05	−1.18	6.69	1.15	−6.45↓	−1.03	>0.05
Serum creatinine	34	0.53	0.46	−0.07	0.24	0.04	−12.64↓	−1.67	>0.05
Serum uric acid	34	3.23	2.70	−0.53	2.10	0.70	16.49↓	−0.76	>0.05
Parameters	**Group C**								
	n	BT	AT	Mean difference	SD±	SE±	Change (%)	*t*	*P*
SGPT	28.68	21.03	−7.65	26.55	4.69	−26.67↓	−1.63	>0.05	<0.001
SGOT	49.09	38.56	−10.53	33.66	5.95	21.45↓	−1.77	>0.05	>0.05
Total bilirubin	1.83	1.30	−0.52	2.16	0.38	28.42↓	−1.37	>0.05	<0.05
Direct bilirubin	0.55	0.55	0.00	0.00	0.00	0.00	0.00	>0.05	>0.05
Blood urea	16.25	15.96	−0.28	5.82	1.03	−1.72↓	−0.27	>0.05	<0.001
Serum creatinine	0.47	0.40	−0.07	0.19	0.03	−15.11↓	−2.13	<0.05	<0.001
Serum uric acid	3.233	2.700	−0.53	2.10	0.70	−16.49↓	−0.76	>0.05	>0.05

SGPT: Serum glutamic pyruvic transaminase; SGOT: Serum glutamic oxaloacetic transaminase; BT: Before treatment; AT: After treatment; SD: Standard deviation; SE: Standard error

Table 8: Comparison of effect on biochemical parameter

Parameters	Mean difference			*F*	*P*
	Group A	Group B	Group C		
SGPT	4.06	−8.55	−7.65	1.20	>0.05
SGOT	3.02	−20.73	−10.53	1.93	>0.05
Total bilirubin	−0.31	−0.27	−0.52	0.18	>0.05
Direct bilirubin	−0.28	−0.24	0.00	0.26	>0.05
Blood urea	1.01	−1.18	−0.28	0.41	>0.05
Serum creatinine	−0.08	−0.07	−0.07	0.03	>0.05
Serum uric acid	−0.53	−0.53	−0.53	0	>0.05

SGPT: Serum glutamic pyruvic transaminase; SGOT: Serum glutamic oxaloacetic transaminase

Table 9: Effect on immunological parameters

Parameters	Group A								
	n	BT	AT	Mean difference	SD±	SE±	Change (%)	*t*	*P*
Total protein	31	5.61	5.37	−0.24	1.82	0.327	−4.28↓	−0.74	>0.05
Albumin	31	3.37	3.27	−0.10	0.92	0.165	−2.97↓	−1.056	>0.05
Globulin	31	2.24	2.10	−0.14	1.13	0.20	−6.34↓	−0.70	>0.05
AG ratio	31	1.58	1.35	−0.23	0.77	0.14	−14.56↓	−1.68	>0.05
Serum IgG	9	1949.25	1949.25	0.00	0.00	0.00	0.00	0.00	>0.05
Serum IgM	9	57.11	43.22	−13.88	44.57	14.85	−24.30↓	−0.94	>0.05
Parameters	**Group B**								
	n	BT	AT	Mean difference	SD±	SE±	Change (%)	*t*	*P*
Total protein	34	5.87	5.55	−0.31	1.88	0.32	−5.28↓	−0.97	>0.05
Albumin	34	3.36	3.22	−0.16	1.078	0.185	−4.76↓	−0.84	>0.05
Globulin	34	2.51	2.33	−0.15	1.055	0.181	−5.98↓	−0.85	>0.05
AG ratio	34	1.32	1.26	−0.061	0.750	0.129	−4.62↓	−0.48	>0.05
Serum IgG	15	1605.42	1897.58	292.16	826.37	261.32	18.20↑	1.12	>0.05
Serum IgM		74.70	56.30	−18.40	96.90	30.64	−24.63↓	−0.60	>0.05

Contd...

Table 9: Contd...

Parameters	Group C								
	n	BT	AT	Mean difference	SD±±	SE±	Change (%)	*t*	*P*
Total protein	32	4.95	5.26	0.30	0.929	0.164	6.06↑	1.884	>0.05
Albumin	32	3.01	3.07	0.06	0.419	0.074	1.76↑	0.591	>0.05
Globulin	32	1.94	2.19	0.25	0.793	0.140	12.89↑	1.784	>0.05
AG ratio	32	1.43	1.49	0.06	0.895	0.158	3.76↑	0.356	>0.05
Serum IgG	11	2029.18	3430.90	1401.71	3820.25	1559.61	69.08↑	0.899	>0.05
Serum IgM		53.83	62.00	8.167	49.66	20.27	15.17↑	0.403	>0.05

AG ratio: Albumin: Globulin ratio; BT: Before treatment; AT: After treatment; SD: Standard deviation; SE: Standard error

Table 10: Comparison of effect on immunological parameters

Parameters	Mean difference			*F*	*P*
	Group A	Group B	Group C		
Total protein	−0.24	−0.31	0.30	1.56	>0.05
Albumin	−0.10	−0.16	0.05	0.78	>0.05
Globulin	−0.14	−0.15	0.25	1.78	>0.05
AG ratio	−0.23	−0.06	0.06	0.46	>0.05
Serum IgG	0.00	292.16	1401.71	0.97	>0.05
Serum IgM	−13.88	−18.40	8.167	0.29	>0.05

AG ratio: Albumin: Globulin ratio

Table 11: Effect on Infant-Toddler Quality of life parameters

Parameters	Group A								
	n	BT	AT	Mean difference	SD±	SE±	Change (%)	*t*	*P*
Physical abilities	31	6.94	7.71	0.77	0.99	0.18	11.16↑	4.35	<0.001
Growth and development	31	10.19	10.61	0.42	0.85	0.15	4.11↑	2.76	<0.05
Bodily pain/discomfort	31	17.97	17.81	−0.16	0.78	0.14	−0.90↓	−1.15	>0.05
Temperament and mood	31	17.90	19.77	−1.87	1.73	0.31	−10.45↑	−6.03	<0.001
General health	31	9.00	12.39	3.39	2.51	0.45	37.63↑	7.51	<0.001
Parent impact (emotional)	31	12.42	12.68	0.26	0.89	0.16	2.08↑	1.61	>0.05
Parent impact (time)	31	2.07	2.81	0.74	0.86	0.15	35.93↑	4.83	<0.001
Parameters	**Group B**								
	n	BT	AT	Mean difference	SD±	SE±	Change (%)	*t*	*P*
Physical abilities	34	7.03	8.41	1.38	0.92	0.16	19.66↑	8.75	<0.001
Growth and development	34	10.53	10.77	0.24	0.65	0.11	2.23↑	2.10	<0.05
Bodily pain/discomfort	34	17.85	17.44	−0.41	0.96	0.16	−2.31↓	−2.51	<0.05
Temperament and mood	34	17.97	20.03	2.06	1.48	0.25	11.46↑	8.13	<0.001
General health	15	11.24	14.71	3.47	2.47	0.42	30.89↑	8.21	<0.001
Parent impact (emotional)		12.35	12.35	0.00	0.00	0.00	0.00	0.00	>0.05
Parent impact (time)		2.06	2.24	0.17	0.46	0.079	8.55↑	2.24	<0.05
Parameters	**Group C**								
	n	BT	AT	Mean difference	SD±	SE±	Change (%)	*t*	*P*
Physical abilities	32	7.22	7.75	0.51	0.88	0.16	7.11↑	3.42	<0.05
Growth and development	32	10.56	10.84	0.28	0.68	0.12	2.66↑	2.33	<0.05
Bodily pain/discomfort	32	15.66	17.84	2.19	1.20	0.21	13.98↑	10.29	<0.001
Temperament and mood	32	17.56	18.88	1.31	1.47	0.26	7.48↑	5.06	<0.001
General health	11	9.69	12.91	3.22	1.74	0.31	33.23↑	10.49	<0.001
Parent impact (emotional)		11.34	11.47	0.13	0.34	0.06	1.10↑	2.10	<0.05
Parent impact (time)		2.16	2.69	0.53	0.57	0.10	24.63↑	5.60	<0.001

BT: Before treatment; AT: After treatment; SD: Standard deviation; SE: Standard error

Table 12: Comparison of effect on Infant-Toddler Quality of life parameters

Parameters	Mean difference			*F*	*P*
	Group A	Group B	Group C		
Physical abilities	0.77	1.38	0.53	7.22	<0.05
Growth and development	0.42	0.24	0.28	0.59	>0.05
Bodily pain/discomfort	0.16	0.41	2.19	64.66	<0.001
Temperament and mood	1.87	2.06	1.31	2.96	>0.05
General health	3.39	3.50	3.22	0.31	>0.05
Parent impact (emotional)	0.26	0.00	0.13	1.65	>0.05
Parent impact (time)	0.74	0.18	0.53	6.03	<0.05

CONCLUSION

The present clinical study showed statistically highly significant ($P < 0.001$) increase in all the anthropometrical measurements of infants all three groups. The drugs did not hamper normal growth of the infants and they did not have any additional effect on enhancing the anthropometrical values. Hematological and biological parameters did not show significant difference in comparison in all groups, but were in normal limits. The results of Renal function and liver function tests were in normal limits even after completion of treatment which suggests that the drug was safe to be administered in infants. Immunological parameters also did not show significant difference of comparison in all groups except in Group C IgG, IgM, Albumin, Globulin levels were increased.

Group C significantly improved all the ITQOL parameters. But on comparison, it showed significant difference, only in improving the physical abilities. On the rest of the parameters there was no difference between three groups. Hence it could be concluded that *Swarna Prashana* can be safely administered for infant for a supportive care for attaining a normal growth and development. Author advocates a large scale randomized double blind clinical trial for further validation of impact of *Swarna Prashan* as mass health-care initiative.

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Conflicts of interest

There are no conflicts of interest.

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