NUTRITION FOUNDATION OF INDIA

COMBATING LOW BIRTH WEIGHT AND INTRA- UTERINE GROWTH RETARDATION

By

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CONTENTS

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Preface

In India, nearly one third of the newborns weigh less than 2500 grams. Low Birth Weight is associated with higher neonatal. Infant mortality and lower trajectory for growth during childhood and adolescence. Studies carried out in the last two decades have shown that low birth weight children may be at risk of developing non communicable diseases during adult life.

Maternal undernutrition, anemia and poor antenatal care are major factors associated with low birth weight. Research studies have shown that food supplementation and IFA supplementation result in reduction in low birth weight rate; hence these were taken up as National Programmes. However, the impact of these programs on birth weight is very merger.

Recent studies in Europe have shown that n-3 fatty acid supplementation during pregnancy improves birth weight. Department of family Welfare funded Nutrition Foundation of India to assess the impact of supplementation of 15 ml of soya oil along with 100 mg of elemental iron and 500 µg of folic acid in pregnant women from 22nd week of gestation till delivery. Data from this study showed that soya oil supplementation was associated with significant reduction in incidence of low birth weight deliveries.

This study was organized and conducted by the Nutrition Foundation of India with active collaboration from two MCD Maternity Centers. The Foundation is deeply appreciative of the support and contribution of the all the personnel involved in carrying out this project.

Prema Ramachandran
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The Nutrition Foundation of India gratefully acknowledge the support and participation of Dr Kamala Ganesh, former professor, Obstrenics and Gynaecology, Maulana Azad Medical College and, currently, Consultant in Obstrenics and Gynaecology. Dr Kamala Ganesh played a major part in bringing together all the investigators and field workers who were engaged in the study. The study was carried out in two Maternity Centers maintained by the Municipal Corporation of Delhi. The Foundation deeply appreciates the cooperation extended by Municipal Corporation of Delhi.

CHAPTER 1

INTRODUCTION

Low birth weight is a major public health problem in India. About 30% of all infants born in hospitals are reported to weigh less than 2.5 kg at birth. Studies carried out by ICMR in the late seventies showed that both in urban and rural areas in India women from low income group do not have ready access to antenatal care or food supplementation through ICDS. Maternal undernutrition, anemia and pregnancy induced hypertension were major factors responsible for-

- the high maternal morbidity and mortality and
- the high prevalence of low birth weight and high neonatal mortality .

Some research studies carried out in India have demonstrated that food supplementation and iron folate supplementation in pregnant women results in improvement in birth weight[1,2,3,4]. Antenatal care aimed at detection and treatment of maternal problems in pregnancy and detection and treatment of anaemia bring about substantial reduction in low birth weight. Essential antenatal care has been included as an important component of Reproductive and Child Health Programme in India[5]. Food supplementation to pregnant women has been one major component of Integrated Child Development Services. However because of poor coverage, content and quality of nutrition supplementation programmes and antenatal care, the low birth weight rates continue to be very high in India.

Data from NFHS I & II [6,7] indicates that over the last two decades there has been some improvement in maternal nutritional status as assessed by body weight. However data from NFHS (1998-99), as well as the District level Household Survey (DLHS) carried out by the Deptt of Family Welfare (2003)[8] have shown prevalence of anaemia in pregnant women to be over 80% and that anemia in pregnancy continues to be a major problem in all states in all segments of the population in all the states. DLHS has shown that even today, content amd quality f antenatal care is poor. Screening for and treatment of anaemia is not universal even in secondary and tertiary care institutions; primary health care institutions seldom screen women for anemia. Under National Anemia Control Programme, less than a third of the pregnant women receive 100 tablets of iron and folate during pregnancy and majority of women do not consume IFA tablets regularily [8]. It is therefore hardly surprising that anaemia still remains a major factor responsible for maternal morbidity and mortality and low birth weight.

It is source of concern that over the last three decades

- there has not been any significant reduction in low birth weight rate and neonatal mortality rate

- there has been a progressive increase in the contribution of neonatal deaths to infant deaths.

Department of Family Welfare has given a major impetus to a two-pronged effort aimed at reducing neonatal mortality rate; focus of one major approach to reduce neonatal mortality is through improvement in antenatal, intra-partum and neonatal care; the other is aimed at interventions to reduce low birth weight rates.

Text Box 1: Iron, folic acid and n-3 fatty acids- a final common pathway

Role of iron and folic acid in n-3 fatty acid metabolism	**Role of iron in n-6 fatty acid metabolism**
n-3 family	n-6 family
A- Linolenic (18:3) (ALNA)	Linolenic acid (18:2) (LA)
▼ ▲6- desturase (iron dependent)	▼ ▲6- desturase (iron dependent)
Octadecatetraenoic acid (18:4)	γ- Linolenic acid (18:3)
▼ elongase	▼ elongase
Eicosatetraenoic acid (20:4)	Dihomo- γ- Linolenic acid (20:3)
▼ ▲5-desaturase (folic acid dependent)	▼ ▲5-desaturase
Eicosatetraenoic acid (20:5)	Arachidonic acid (20:4) (AA)
▼ Cycloxygenase & Lipoxygenase (iron dependent)	▼
Eicosanoids 3 series	Eicosanoids 2 series
▼	▼
PGE_3	$PG\ E_2$ & $PGF_{2\alpha}$

In recent years there has been growing interest in the potential role of essential fatty acids in prevention of low birth weight and preterm births. Essential fatty acids and their derivatives, especially, arachidonic acid (AA) and long chain n-3 fatty acids like docosahexaenoic acid (DHA) have been shown to be related to foetal growth and development [9,10].

The ratio of linoleic to α- linolenic acid is significantly greater in the vegetarian as compared to non vegetarian diets. This higher ratio may lead to decrease the synthesis of EPA and DHA from α- linolenic acid and favour the synthesis of AA from linoleic acid, because essential fatty acids (both n-3 and n-6) have common enzymes in their metabolic pathway and n-3 fatty acids usually have higher affinity for the enzymes than the n-6 fatty acids. Prostaglandins and

metabolites of AA, in particular prostaglandins of $F_{2\alpha}$ are involved in uterine contraction and parturition. High circulating n-3 fatty acids may inhibit the production of the dienoic prostaglandins derived from AA, which stimulate uterine contraction, thus reduce preterm births (Text box 1)

Data from European countries have shown that fish oil (which important source of long chain n-3 fatty acid) supplementation during pregnancy improves birth weight [12,13]. The beneficial effect of fish oils supplementation is attributed to DHA (Docosahexaenoic acid) and EPA (Eicosapentaenoic acid). In India majority of the population may cannot afford fish oil which is expensive; many vegetarians will be averse to consuming fish oil. Mustard, soyabean and canola oil are some oils which are widely used inexpensive and rich in n-3 fatty acid (Table 1).

Table 1: Approximate ALNA content in oils (%)

	LA	ALNA	LA/ ALNA
Oils with low LA			20
Olive or palm oil	10	<0.5	
Oil with medium LA			
Rice bran	35	1.5	23
Groundnut	25	<0.5	50
Oils with high LA			
Seasame, corn, cottonseed, sunflower, safflower	40-70	0.5-1.0	40-140
Oils with high ALNA			
Mustard	12	10	1.2
Soyabean	50	5	10
Canola	20	8	2.5

LA- linolenic acid, ALNA- Alpha Linolenic acid
LA/ALNA Desirable ratio 5-10
Source: Ghafoorunissa, National Institute of Nutrition, 2001

There is an interrelationship between iron status and eicosanoid metabolism from essential fatty acids [14]. It has been reported that folic acid administration increases the n-3 PUFA in plasma lipid fractions, in platelet, erythrocytes and intestinal phospolipids. In population with very high prevalence of anaemia due iron and folate deficiency, it might be essential to provide iron folate supplements in order to promotes the utilization of essential fatty acids and derive optimal benefits from n3 fatty acid supplementation .

The Department of Family welfare funded Nutrition Founation of India to assess the impact of supervised supplementation with soya oil (a commonly used relatively inexpensive source of C: 18 n-3 fatty acid) along with iron and folic acid on low birth weight incidence among low-income group pregnant women.

CHAPTER 2

OBJECTIVE AND STUDY DESIGN

The objective of the study was to assess the effect of supplementation of 15 ml of soya oil containing 900 mg of alpha-linolenic acid (ALNA) in pregnant women from the 22nd week of gestation till delivery on the incidence of low birth weight .

STUDY DESIGN

A Task Force consisting of obstetricians, paediatricians, nutritionists and statisticians was constituted to assist NFI

- Study Design
- Monitoring of progress and advise midcourse corrections as and when required
- Interpretation of the results

Study Centers: The subjects were recruited from two Maternity Homes in Delhi- Defence Colony Maternity Home (DCMH) and Kamala Nehru Maternity Home (KNMH). These two maternity homes were chosen they adequate number of pregnant women seeking antenatal care who lived in neighboring areas and couls be followed easily, matained good records and medical officers (MO's) were willing to participate in the study.

Twelve Mahila Karyakarta's (MKK's), six for each center, were recruited for giving the supplements to women daily. All of them were local residents, who stated that they will be available in that area for the next three years could read and write Hindi and had social commitment. MKK's were selected by MO's of maternity homes. MO's of the respective Maternity Homes gave training to the MKK regarding counseling of pregnant women and proving supplements daily under supervision.

Study Groups: In India, under the National Nutritional Anemia Control Programme, all pregnant women visiting antenatal clinics receive routine antenatal care along with 100 mg elemental iron and 500 µg folic acid in the last 100 days of pregnancy. However, regularity of intake of iron-folic acid tablets under programme conditions is low. Following detailed discussion between members of the Task Force, the study was conducted in three groups namely:-

a) **IFA Group:** A single tablet containing 100 mg of elemental iron and 500 µg folic acid was administered at home daily by MKK from the 20th week gestation till delivery. An effort was made in the beginning to have adequate 'stock' of IFA tablets for the entire study. This enabled the centers to overcome irregular supply of IFA for the study except for a very short period.

b) **IFA + Soya Oil Group:** A daily supplement of a single tablet containing 100 mg elemental iron and 500 µg folic acid and 15 ml of soya oil (containg 900 mg of alpha linolenic acid) from the 22nd week of gestation till delivery were administered to women daily by MKK at home.

Table 2: Fatty acid composition of Soya Oil	
Fatty acid	**Brand-Fortune**
16:0 (Palmitic)	11.6
18:0 (Stearic)	4.6
18:1 (Oleic)	20.0
18:2 (Linoleic)	57.0
18:3 (α- Linolenic acid)	6.6
SFA%	16.2
MUFA%	20
PUFA%	63.6
P/S	3.9
n-6/n-3	8.6
Source: Dr Ghafoorunissa, NIN, Hyderabad	

The supplement was an emulsion of 15 ml of soya oil in 5 ml of sugar syrup containing 3.75 gm sugar + orange essence (for palatability). This supplement provided 138 kcal and on analysis was found to contain 900 mg of alpha- linolenic acid (ALNA) with n-6/ n-3 ratio of 8.6 (Table 2)

c) **Control Group (C):** Consisted of women from the neighborhood who received routine antenatal care including access to iron and folic acid supplementation in these maternity homes. The purpose of recruitment of control group was to obtain information on low birth weight rates in women who received antenatal care and delivered in the Maternity home but did not have supervised supplementation.

Sample Size: It was estimated that the incidence of low birth weight in these two hospitals as 25%. The sample size required for demonstrating 10% point reduction in low birth weight rate with 95% confidence limits and a power of 80% as compared to control group was estimated to be 270; assuming that there will be dropout rate of 10% from the 20th week of gestation till delivery, the sample size was calculated to be 300.

CHAPTER 3

RESULTS

The study was carried out between May 2001 and December 2003 in Delhi- Defence Colony Maternity Home (DCMH, Maternity Centre 1) and Kamala Nehru Maternity Home (KNMH, Maternity Centre. The profile of the two maternity homes is given in Text Box 2

Women coming to the antenatal clinic between 13-20 weeks of pregnancy were screened by the MO's. Apparently healthy women with no systemic or obstetric problem were informed about the proposed supplementation, and that they will receive either FA or IFA + Soya oil. Those who were willing to participate in the study were given either IFA or IFA + Soya daily at home by MKK in the area for one week. Women who did not complain of gestational side effects and were able and willing to take supplements daily under supervision for one week were enrolled in the study.

Text box 2

STUDY CENTERS

Defence Colony Maternity Home (functioning under IPP-VIII)	**Kamala Nehru Maternity Home** (Functioning under MCD New Delhi)
Pregnant women came from: Kalkaji, Kotla, Prem Nagar, Jal VIhar, Dayananda Colony, Aliganj, Pillanji, Sewa Nagar, Mahawat Nagar, Gandhi Camp, Kher pur, Babu Path, Bhola Nagar, Defence Colony	**Pregnant women came from:** Padam Nagar, Moti Nagar, E. Moti Bagh, Railway Colony, Ambha Nagar, SDN Colony, Pratap Nagar, Vasudev Nagar, Chuna Bhatti, Swami Dayananda Colony, Krishan Ganj, West Moti Bagh, Ambha Nagar, Vivekananda Puri
Facilities	
• OPD- 6 days a week • ANC- 2 days (Monday and Thursay) • OT- 2 days (Tuesday and Friday) • Vaccination- 2 days (Wednesday and fri) • Labour room- 24 hours • Lab investigations- Hemoglobin, blood sugar, blood group, urine routine microscopic, urine pregnancy test • Number if beds- 16 • Family planning services including sterilization available • MTP facilities available • Over 600 deliveries/ year	• OPD- 6 days a week • ANC- 2 days (Tueday and Thursay) • No OT available • Antenatal registeration- Mon to Sat • Immunization (Well baby clinic) Wednesday and Friday • Labour room- 24 hours • No Lab investigations • Number if beds- 15 • OC, Copper T available, no sterilization, no MTP facilities available • Distribution of medicines is by ANM • Over 600 deliveries/ year

The MKK who resided in the area gave the pregnant women supplements every day and ensured that they consumed it under supervision. Each MKK was given a defined area (based on where she lived). Each MKK was given either IFA or IFA + soya oil. The woman were given either IFA or IFA + soya oil depending on the fact that whether the MKK was giving IFA or IFA + soya oil in the area where she was living. This study design was followed in order to ensure that the MKK's did not make mistakes in administering the supplements. If the woman was going out of the station for the short period, the supplements for consumption during this period were given to her and she was requested to consume it regularly. On her return, the regularity of consumption was ascertained from the history and also by assessing the remaining amount of supplements. Any women who had discontinued supplements for longer than ten days for whatever reasons were treated as dropout. Dropouts also included those who developed complications, those who were detected as having twin pregnancy, those who changed place for seeking antenatal care and those shifted residence. No special effort was made to ensure that women seek antenatal care at specified periods of pregnancy or that they follow advice including referrals.

Women from all the three groups received antenatal care in the respective Maternity Homes. The MO's in the maternity homes recorded details regarding the socio-economic background, family size, mean age at marriage and parity, LMP and Obstetric history examined the women and recorded the findings. All women were requested to come to hospital for delivery. Details of deliveries were recorded. Birth weight was taken in an accurate balance (Digital Table Top Weighing machine). In women who delivered at home, the details of delivery were provided by the MKK who also took the birth weight. All the MKK's labour room staff were trained in accurately recording birth weight.

TABLE 3: RECRUITMENT, FOLLOW-UP AND DROPOUTS

Total Enrolment	**Defence Colony Maternity Home**			**Kamala Nehru Maternity Home**			**Total**		
	566			556			1122		
Groups	C	IFA	IFA+ Soya Oil	C	IFA	IFA+ Soya Oil	C	IFA	IFA+ Soya Oil
Recruitment	172	195	199	166	187	203	338	382	402
Dropouts	10	30	36	11	34	47	21	64	83
Data on birth weight	162	165	163	155	153	156	317	318	319
Total	490			464			954		

A total of 1122 pregnant women were recruited at both the Centres. The number of women recruited, followed- up and dropped out in the two maternity homes is

indicated in Table 3. During the course of the study there were 168 dropouts (15 %) and in the final analysis, data on birth weight on 954 singleton deliveries were available (490 singleton deliveries at DCMH and 464 singleton at KNMH).

Recruitment of women in different groups in DCMH and KNMH began in August 2001; recruitment between Aug 2001- Dec 2003 in the two maternity homes and overall is shown in Table 4.

Table 4: Recruitment in both the centers

Groups	Defence Colony Matenity Home			Kamala Nehru Maternity Home			Total		
	IFA	IFA + Soya oil	C	IFA	IFA + Soya oil	C	IFA	IFA + Soya oil	C
Aug-Sep 01	15	13	0	30	35	0	45	48	0
Oct-Dec 01	22	17	0	28	25	17	50	42	17
Jan-Mar 02	13	24	12	36	20	17	49	44	29
Apr-Jun 02	26	25	3	23	16	17	49	41	20
Jul-Sep 02	23	35	0	26	37	13	49	72	13
Oct-Dec 02	15	27	0	10	23	34	25	50	34
Jan-Mar 03	31	20	0	0	0	40	31	20	40
Apr-Jun 03	20	2	36	0	0	16	20	2	52
Jul-Sep 03	0	0	85	0	0	1	0	0	86
Oct-Dec 03	0	0	26	0	0	0	0	0	26

Dropout rate in the two Maternity Homes in different groups is shown in Table 5. Maximum dropouts were seen in IFA + Soya group followed by the IFA group in both the centres. The control group had the least dropout rate.

Reasons for dropout are shown in Table 6. It was obvious that in majority of women the reason for dropping out was unrelated to side effects of the supplements.

Table 5: Dropouts (%)									
Groups	**Defence Colony Matenity Home**			**Kamala Nehru Maternity Home**			**Total**		
	IFA	**IFA + Soya oil**	**C**	**IFA**	**IFA + Soya oil**	**C**	**IFA**	**IFA + Soya oil**	**C**
Dropouts (%)	15.4	18.1	5.8	18.2	23.2	6.6	16.8	20.6	6.2

Table 6: Reasons for Dropouts										
Dropout reasons	**Defence Colony Matenity Home**			**Kamala Nehru Maternity Home**			**Total**			**Grand total**
	IFA	**IFA + Soya oil**	**C**	**IFA**	**IFA + Soya oil**	**C**	**IFA**	**IFA + Soya oil**	**C**	
Obstetric problem	4	5	-	4	2	-	8	7	-	15
Twins	2	2	-	1	2	1	3	4	1	8
Maternal deaths	-	-	1	-	-	-	-	-	1	1
Neonatal deaths	-	-	2	-	-	-	-	-	2	2
Shifted residence	20	20	7	15	30	10	35	50	17	102
Gone to village	4	3	-	11	6	-	15	9	-	24
Home delivery	-	-	-	1	2	-	1	2	-	3
IUD	-	-	-	2	-	-	2	-	-	2
Personal reasons	-	6	-	-	5	-	-	11	-	11
Dropouts	30	36	10	34	47	11	64	83	21	168

The profile of pregnant women enrolled in the study in the maternity homes is given in Table 7. There were some differences between the profile of women attending DCMH and KNMH. Women recruited for the study in DCMH were younger than those recruited from KNMH. Majority of women recruited in DCMH came from smaller nuclear families. Majority of women from KNMH came from larger joint families.

Table 7: Characteristics of pregnant women at the time of registration

Groups		Defence Colony Maternity Home			Kamala Nehru Maternity Home			Total		
		IFA	IFA + Soya oil	C	IFA	IFA + Soya oil	C	IFA	IFA + Soya oil	C
Age		24.7 ± 3.69	24.2 ± 4.3	24.5 ± 4.1	25.5 ± 4.2	25.3 ± 4.2	25.1 ± 4.37	25.1 ± 3.95	24.8 ± 4.25	25.1 ± 4.36
Religion (%)	Hindu	89.2	84.2	95.5	94.4	96.4	94.7	91.8	90.3	94.7
	Muslim	5.1	10.8	2.8	-	-	2.3	2.6	5.4	2.3
	Others	5.7	5.0	1.7	5.6	3.6	3.0	5.6	4.3	3.0
Type of family (%)	Nuclear	80.1	76.4	94.9	46.8	45.6	70.8	63.5	60.9	70.8
	Joint	19.9	23.6	5.1	53.2	54.4	29.2	36.5	39.1	29.2
Family size		3.5 ± 1.73	3.6 ± 1.83	2.9 ± 0.88	4.6 ± 2.2	4.9 ± 2.4	3.6 ± 1.54	4.0 ± 2.02	4.2 ± 2.22	3.6 ± 1.54
Family income (%)	< Rs 500	1.1	1.0	2.3	11.3	8.5	8.5	6.2	4.7	8.5
	Rs 2000-5000	79.5	86.9	90.7	63.7	69.7	78.3	71.6	78.3	78.4
	Rs 5000-10000	10.2	9.1	5.2	21.4	17.0	10.6	15.8	13.1	10.6
	> Rs 10000	9.2	3.0	1.7	3.6	4.8	2.5	6.4	3.9	2.5
Age at Menarche		13.4 ± 0.77	13.4 ± 0.98	13.4 ± 1.40	13.3 ± 1.33	13.7 ± 1.50	13.2 ± 2.90	13.4 1.00	13.6 ± 1.26	13.3 ± 1.30
Age at Marriage		18.0 ± 2.7	18.2 ± 2.7	18.5 ± 2.6	19.5 ± 3	19.5 ± 2.9	19.2 ± 2.7	18.7 ± 2.8	18.9 ± 2.9	18.8 ± 2.7
Parity	0 %	40.7	44.44	26.32	53	37.6	52.5	46.8	41.05	39.04
	1-3 %	58.7	51.23	73.6	47	62.4	43.2	52.9	56.79	58.86
	> 3 %	0.6	4.33	-	-	-	4.3	0.3	2.16	2.1
	Mean Parity	0.89	0.97	1.11	0.83	1.04	0.99	0.86	1.00	1.02
Mean Gestational Age at recruitment (in weeks)		20.5 ± 1.67	21.2 ± 1.02	20.05 ± 5.95	19.7 ± 1.23	23.1 ± 1.57	19.8 ± 9.82	20.1 ± 1.06	22.1 ± 1.32	19.9 ± 7.42
Mean body weight of pregnant women at recruitment		48.7 ± 7.61	46.7 ± 6.32	51.0 ± 5.40	52.0 ± 8.87	51.6 ± 7.82	51.4 ± 5.38	50.4 ± 8.31	49.2 ± 7.51	51.2 ± 5.35

In both the maternity homes, majority of the recruited women were Hindus from low/ low middle-income groups. There was no significant difference in the age at menarche between the women recruited in the two maternity homes. Women attending KNMH got married at later age but there were no significant differences in parity as compared to those attending DCMH. There was however no significant differences in the profile of women recruited in different groups in each of the maternity homes.

At birth, infants were weighed by labour room staff in hospital deliveries and by MKK's in home deliveries. Crosschecking and verification showed that the weighment was accurate in both hospital and home settings. Data on incidence of low birth weight and mean birth weight are given in Table 8. Only singleton live births were included for analysis.

Mean birth weight of babies born to mothers in IFA + Soya group in both maternity homes was significantly higher as compared to control group ($p<0.05$). There was a significant reduction in the overall incidence of low birth weight deliveries (total) in Soya +IFA group as compared to both control group ($p <0.05$) and IFA group ($p <0.05$), but no significant difference is seen between control group and IFA group.

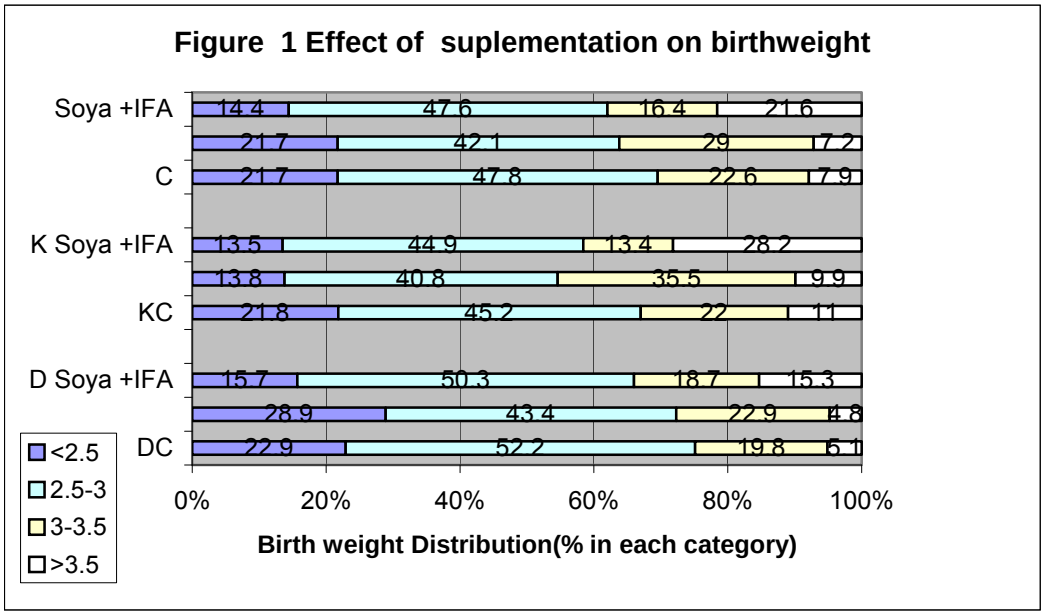
TABLE 8: Effect of supplementation on birth weight

	DCMH			**KNMH**			**Total**		
Groups	**C**	**IFA**	**IFA + Soya oil**	**C**	**IFA**	**IFA + Soya oil**	**C**	**IFA**	**IFA + Soya oil**
Mean Birth Weight (Kg ± SD)	2.71^{a} ±301	2.69^{a} ±463	2.82^{b} ±444	2.76^{a} ±457	2.82^{a} ±409	2.97^{b} ±488	2.73^{a} ±386	2.76^{a} ±456	2.89^{b} ±471
LBW (<2.5 Kg)	36^{a} 23%	48^{b} 29%	25^{a} 15.7%	33^{a} 21.3%	21^{b} 13.8%	21^{b} 13.5%	69^{a} 22.1%	69^{a} 21.7%	46^{b} 14.5%

Significance between groups	DCMH		KNMH		Overall	
	LBW	Mean BW	LBW	Mean BW	LBW	Mean BW
Control vs IFA	P< 0.05	NS	P< 0.05	NS	NS	NS
Control vs IFA + Soya	NS	P<0.02	P<0.05	NS	NS	NS
IFA vs IFA + Soya	P<0.05	P<0.01	NS	P< 0.01	P< 0.05	p< 0.01

Chi-Square Test was used for estimating the significance with relation to LBW and Standard Normal Test for estimating the significance with relation to Mean Birth Weight and Mean Gestational Age. Variation in superscripts (within a row) for a given variable in each center indicates significance of difference between groups.

The birth weight distribution (Figure 1) shows that there is a shift towards the right in IFA + Soya group. The findings in the present study indicates that nutritional interventions with an inexpensive supplement such as soya oil (15 ml) along with 100 mg of iron and 500 µg of folic acid from the 22nd week of gestation till delivery can bring about a significant reduction in incidence of low birth weight.



Initially, all the labour room staff were trained in taking weight, the length, head circumference, chest circumference and mid upper arm circumferences in the neonates. It was envisaged that at birth, in addition to weight, length, head circumference, chest circumference and mid upper arm circumference were to be measured in all infants. Random check on these measurements taken by the ANM/ MKK showed that they were not accurate. Analysis of data collected by the ANM/ MKK on these measurements showed that the correlation between length, chest circumference, head circumferences and mid upper arm circumference was very low. In the view of this, the data on these measurements was not analysed and included in the report.

At the beginning of the study, it was proposed that all the infants in each of the three groups will be followed up for the growth and development during the next three years. However efforts at follow up of infants was not very successful; the drop out rate at three, six and twelve months was unacceptably high. The Task Force reviewed the data and recommended that as the number of infants followed up to two years in each group will be too small and self selected, it will not be responsible to draw meaningful conclusion from the follow up study. In view of this they recommended that the follow up study may not be continued.

CHAPTER 5

DISCUSSION AND CONCLUSION

The study was taken up in two Maternity Homes because it would not be possible to enroll within two years adequate number of women from a single Maternity Home, who are living in the vicinity and willing to participate in the study. Care was taken to choose two Maternity homes, which appeared to cater to a similar population. However, data from the study showed that there were some differences between the two centres in the profile of the women enrolled for the study. There were differences in some factors that influence birth weight, such as parity and maternal body weight; these might to some extent be responsible for the inter centre differences in birth weight was higher and incidence of low birth weight was lower in the group that received soya and IFA supplements.

One of the major problems encountered while conducting supplementation studies in pregnancy is to ensure compliance for a period of 20 weeks. This problem was overcome in the present study by ensuring that supplements were administered everyday by women volunteers who resided in the same area; these volunteers were recruited and trained for this task by medical officer in these two centres. Yet another problem in undertaking such studies is the high dropout rate in the initial period of supplementation, either due to side effects or because the women did not like daily home visits by MKK for giving the supplements. As only those women were able to consume taking them under supervision daily for a period of 20 weeks were recruited for the study, the dropout rate was low-less than 15%.

In most of the studies on food supplementation, close monitoring by medical officers was carried out in order to ensure careful recording of the events during pregnancy and delivery. This inevitably resulted in high quality antenatal care and the women had benefits due to earlier detection and prompt and effective treatment of obstetric complications. At times, it is difficult to assess the relative contributions of supplements and antenatal care with regard to the observed benefit.

In the present study, women were requested to visit the Maternity Home for antenatal care but the MKK did not ensure that they in fact went to the Maternity Home. As and when they visited the Maternity Home, whoever was present in the antenatal OPD provided the antenatal care. The women receiving supplements therefore received antenatal care, which was similar to the antenatal care received by the control group. Thus in this study the potential confounding effect of the antenatal care by specific doctors involved in the study was eliminated. The observed beneficial effect on birth weight in the study is therefore clearly due to the supplements provided.

In the study women received antenatal care whenever they visited Maternity Homes for antenatal checkup. They were examined by Medical officers who were present on that day. At times, the MO's were busy with emergencies and examination was done by paramedical personnel in the OPD. It was not possible to ensure standardization of measurements and recording of findings during the antenatal visits by all the personnel involved in providing care in the antenatal OPD. In view of this, it was not possible to analyse the data on antenatal events in the three groups and assess the effect of supplements on the course of pregnancy.

One of the major unanswered questions in the study is the impact of supplements on incidence of preterm delivery. As the antenatal clinic practices were not in any way altered during the study, LMP recording was done by who ever was available in the OPD. No attempt was made to probe the recollection of the woman and accurately record the LMP. The clinical assessment of gestational age and matching it with the gestational age as assessed from LMP was done by the medical officers but they were not always present in the antenatal OPD to examine every woman. In many women an ultrasound examination was performed at some point during the pregnancy for various reasons. However, the examination was done in different clinics and not all of them clearly indicated the ultrasound assessment of gestational age. Majority of women delivered in the Maternity Home but not all neonates were seen by the paediatrician who accurately assessed gestational age at birth. In view of all these, it was not possible to assess the gestational age in all the the neonates in all the three groups in both the maternity homes. Therefore in this study, it was not possible to assess the impact of the maternal supplementation on gestational age. Labour room personnel measured head circumference, chest circumference mid arm circumference and length of the neonate soon after birth. In spite of the fact that they had received training in taking these measurements, quality control studies indicated their measurements were not accurate. In view of this, the data on these indices are not presented in this report.

CONCLUSION

The study shows that supplementation of soys oil along with iron and folic acid results in significant improvement in mean birth weight, a shift to the right in the frequency distribution of birth weight and reduction in the incidence of low birth weight. The study has provided a lead regarding the potential benefits of soya oil (containing alpha linolenic acid) supplementation in combating the problem of low birth weight, which is a major public health problem in India. The results of this study need to be confirmed by other independent studies conducted in different parts of the country. If other studies confirm the findings of the NFI study, possible mechanisms by which soya oil exerts its beneficial effect should be ascertained. Simultaneously, operational research studies on soya oil and IFA supplementation in the primary health care setting may have to be taken up to

assess feasibility and effectiveness of this supplementation under programme conditions.

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LIST OF ABBREVIATIONS

AA	**Arachidonic Acid**
ALNA	**Alpha-Linolenic Acid**
ANC	**Antenatal Care**
ANM	**Auxillary Nurse Midwife**
C	**Control Group**
DCMH	**Defence Colony Maternity Home**
DHA	**Docosahexaenoic Acid**
DLHS	**District Level Household Survey**
EPA	**Eicosapentaenoic Acid**
ICDS	**Integrated Child Health Services**
ICMR	**Indian Council of Medical Research**
IFA	**Iron and Folic Acid**
IPP VIII	**Indian Population Project VIII**
IUD	**Intra-uterine Dealth**
KNMH	**Kamala Nehru Maternity Home**
LA	**Linolenic Acid**
LBW	**Low Birth Weight**
LMP	**Last Menstrual Period**
MCD	**Municipal Corporation of Delhi**
MKK	**Mahila Karyakarta**
MO	**Medical officer**
NFHS	**National Family Health Survey**
NS	**Not significant**
OPD	**Out Patient Department**
OT	**Operation Theatre**
PIH	**Pregnancy Induced Hypertention**
PUFA	**Polyunsaturated Fatty Acids**

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