Effectiveness of Salt Fortified with Iron and Iodine to Improve Iron status in a community settings in Sri Lanka

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EXECUTIVE SUMMARY

In Sri Lanka, prevalence of anaemia has remained an important public heath problem in spite of many improvements in other health status indicators. Recent studies show the prevalence of anaemia among women between 15 and 49 year of age, children under five years, pregnant women were 22%, 25% and 17% respectively. Several intervention programmes mainly supplementation for the target groups, educational activities have gone on for several decades.

Possibility of using fortification as a method of improving iron intake has been considered and in a country where there is a national programme for fortification of salt with iodine, feasibility of introducing salt, dual fortified with iodine and iron has been considered as an alternative approach.

This study aimed at testing the efficacy of consuming double fortified salt in Sri Lankan population using a Quasi experimental study design carried out at the community level. A cluster randomized community trial which included a baseline survey, follow up and end line survey was carried out. The impact of double fortified salt (DFS) on haemoglobin concentration and serum ferritin were assessed in children between the ages of 6 and 10 years resident in the selected households.

Gampaha district was selected to carry out the study. A Public Health Midwife (PHM) area was identified as a cluster and 16 PHM areas each from the urban and rural sectors (total of 32) were identified randomly. Within each cluster, households with 22 children in the selected age group were identified using a random selection method giving a total of 704 chidren. The 32 clusters were randomly allocated in equal numbers of the intervention group where the households received DFS and to the control group where salt fortified with iodine only was provided.

All individuals involved in the trial (parents, health workers, and research staff) were unaware of the assignment of the cluster to the intervention / control group until the code given in sealed envelopes was broken after the completion of the end survey.

Fresh batches of DFS and iodized salt were prepared every month, depending on the requirement. The salt packets were distributed by the staff of the MRI to selected households in the PHM areas as given in the label. Iodine was added at a level of 20-30 mg / kg of salt according to the country requirement for universal iodization. For the double fortified salt, iron was added to achieve 1000 ppm of elemental iron.

The salt provided was to be added to the food prepared at the household level, during the 9 month period, commencing from the time that the baseline assessment was completed. Mothers were advised to use only the provided salt during preparation of food for the 9 months period.

A pre-coded questionnaire was used to obtain basic information on health, use of vitamin/iron preparations. Information on the use of the salt was collected from the households. Mothers were considered as the key informants.

At baseline, information about demographic, nutrition, and health data of the children were gathered. Venous blood samples were collected for measurement of haemoglobin (Hb), serum Ferritin, and C-Reactive Protein. EDTA blood samples were taken to identify the presence of haemoglobinopathies. Urine samples were collected to assess the urine iodine level of children. Anthropometric measurements were made using standard procedures.

MRI staf visite homes at 4 weekly intervals throughout the 9 month period. Acceptance of DFS was assessed through a questionnaire, including questions that assessed whether salt changed colour, taste, or texture of the cooked food. Administration of salt was started as soon as the baseline assessment was completed. Mothers were advised to use only the provided salt during preparation of food for the 9 months period.

Salt samples send from the salt factory were stored in the laboratory and the keeping quality was checked every month to detect iron and iodine levels of the salt. Health personnel monitored the intake of salt and any shortages during the home visits.

At the end of 9 months, the questionnaire was reintroduced and venous blood, and urine samples were taken to measure Hb, serum Ferritin, C - reactive protein, and urine iodine. Anthropometric measurements were done using standard procedures.
Comparison of the 2 groups showed that housing conditions were better in the DFS group than iodine groups. There were no major differences between sectors, sex of the household heads and total number of people in the families between 2 groups.

Consumption of salt in DFS group was higher than iodine group, but there are no differences in factors considered in purchasing salt.

A low level of consumption of red meat, fish and poultry was seen in the DFS group than the iodine group. However, the frequency of consumption of roots, tubers were similar and the consumption of rice is almost universal.

Knowledge on anaemia was at a satisfactory level in both groups. Pattern of iron supplementation among children showed that only 6.9% of children in DFS group and 5.9% from iodine had ever taking iron.

Changes in colour of the salt were reported 5.7% in DFS group compared to 2.7% in iodine group. The main problem identified relevant to low acceptability of DFS was change in colour and this was identified as a decisive factor while purchasing salt.

There was an increase in the mean haemoglobin levels in the DFS group by 0.214g/dl which was statistically significant. However, a significant decline of the mean haemoglobin level was observed in iodine group.

Prevalence of anaemia was significantly redued by 11.5% in DFS group compared to the 9.5% increase in iodine group which was not statistically significant.

Mean ferritin levels were significantly increased by 0.43 µg/L in DFS group and reduced by 0.55µg/L in iodine group which was not statistically significant.

Prevalence of iron deficiency has reduced in both groups by 2.1% in DFS group and 4.3% in iodine group which is an observation contraty to the previous observation.

Iodine status has improved in both groups indicating the iodine sufficieny.

In conclusion, DFS has a high level of accepatbility. There is a impact of DFS in increasing mean haemoglobin, mean serum ferritin and reducing prevalence of anamia. Even though the reduction of the prevalence of iron deficiency is not very marked. There is no indication of any overdose levels during this 9 months period.

Use of the DFS as an alternative startegy to control anaemia in Sri Lanka could be considered in school mid day meal and poverty alleviation programmes. It is importnat to establish inbuilt monitoring and evaluation studies with a longer follow up period in a community setting prior to universal supplementation.

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ARI	Acute Respiratory Infections
BMI	Body Mass Index
CHDR	Child Health Development Record
CI	Confidence Interval
CMR	Crude Mortality Rate
GAM	Global Acute Malnutrition
DFS	Double Fortified Salt
GN	Grama Niladhari
GCE(OL)	General Certificate of Education (Ordinary Level)
IEC	Information, Education, Communication
IYCF	Infant and Young Child Feeding
LBW	Low Birth Weight
MAM	Moderate Acute Malnutrition
MRI	Medical Research Institute
MUAC	Mid Upper Arm Circumference
NGO	Non Governmental Organization
NRP	Nutrition Rehabilitation Programme
PHM	Public Health Midwife
RHA	Rural Health Assisstant
RHV	Rural Health Volunteer
SAM	Severe Acute Malnutrition
UNICEF	United Nations Education Fund
WFP	World Food Programme

1. INTRODUCTION

1.1. Background

The Democratic Socialist Republic of Sri Lanka lies east of the southern tip of the Indian Subcontinent. The Bay of Bengal is in its north and east with Arabian Sea to its west. Estimated total population of Sri Lanka is approximately 20 million. In terms of ethnicity 81.9% of the population is Sinhalese, 4.3% and 5.1% are Sri Lankan Tamil and Indian Tamil respectively (Census 2001). The majority (70.4%) of the population are Buddhists followed by the minorities of Hindus and Muslims. Sri Lanka has a low under 5 mortality rate (15/1000 live births) and low maternal mortality rate (14 per 100,000). The country reports 95% of antenatal care coverage with 97% of skilled assistance for deliveries. The adult literacy rate is 92% and the GNP per capita **is $930** (1).

For the past few decades Sri Lanka has reported improvements in many health indicators with a significant decline in mortality rates (Infant, child and maternal). However, malnutrition remains a persisting health problem. The Nutrition and Food Security Survey (NFSS), Sri Lanka 2009 reports that among the women aged 18-49 years 22% are malnourished. The prevalence of low birth weight (weight less than 2.5 kg) babies is 17% among all newborns (2). The Income and Expenditure Survey (2010) reports that nearly a 8.5% of the households in Sri Lanka are categorized as “poor households” in terms of adequacy in energy intake (3).

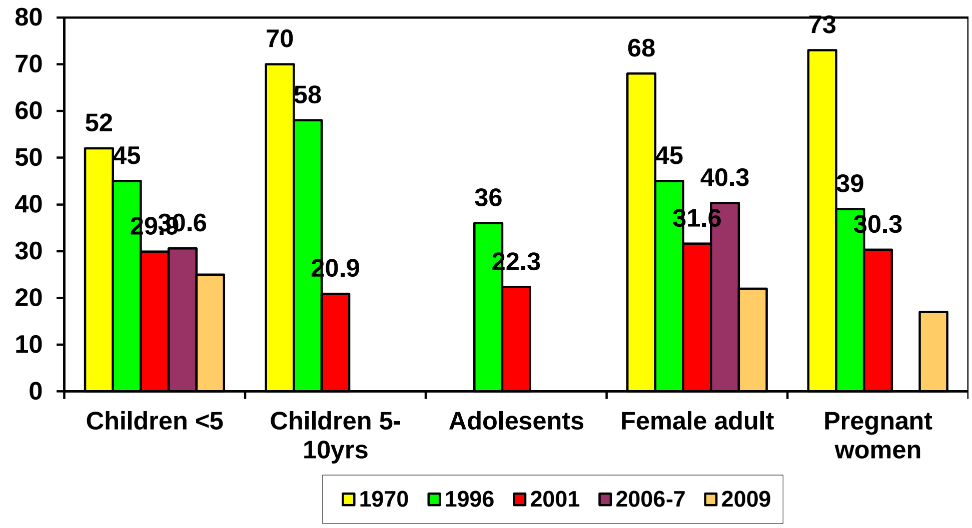
According to the NFSS, the prevalence of wasting among children under 5 years is 11.7%, underweight 21.6% and stunting 19.2 %(2). Over the past decades there has been slow but a steady decline in the rates of under-nutrition. Between 1993 and 2000, the prevalence of underweight has decreased from 37.7%t to 29.4%, a reduction by 8 percentage points while the prevalence of wasting showed a static figure, at 15.5 per cent. The prevalence of stunting has decreased from 23.8 % to 18 %..

While the above findings represent aggregate national level data, there are marked regional variations, which indicate the persistent pockets of underserved populations. In addition, micronutrient deficiencies notably anaemia, vitamin A deficiency and iodine deficiency disorders also constitute major public health problems in Sri Lanka.

Iron deficiency is the most prevalent nutritional deficiency in the world. The *Fourth Report of the World Nutrition Situation* issued by the United Nations estimates that 3.5 billion people in developing countries are iron deficient based on levels of hemoglobin (Hb) that reflect anemia (1). Women of reproductive age are among the most vulnerable to iron deficiency, with anemia prevalence estimates of 44% in developing countries. In Sri Lanka, the prevalence of anaemia among women between 15 and 49 year of age, children under five years, pregnant women were 22%, 25% and 17% respectively as shown in Figure 1 (2, 3).

In Sri Lanka, three strategies identified to improve iron nutritional status include public education to improve diets, iron supplementation, and iron fortification of the food supply. 3Public education and supplementation has been carried out in Sri Lanka for the last 30 years with the reduction of prevalence of anaemia in the population. However, these all have limitations that influence their effectiveness or long-term sustainability in countries in which resources are scarce.

Figure 1 : Trends in the prevalence of Anaemia in Sri Lanka



Sources: MRI 1970, Mudalige 1996, DHS 2006, MRI 2001, 2009

In Sri Lanka universal iodization of salt has been implemented since 1995. It was reported that after 10 years of iodization, iodine deficiency has been almost eliminated (MRI 2010). However, salt iodization has to be continued. Salt is likely to be an effective vehicle for fortification, as it is widely and regularly consumed at a level of 5–10 g/ day. Thus, dual fortification with iodine and iron is under consideration as a sustainable method to prevent both iodine and iron deficiencies. Availability of dual fortified salt that has significantly greater iron content provides the first opportunity to test the effect of consuming a bio fortified salt on the iron status of people. This study was designed to test the efficacy of consuming double fortified salt in a community setting in a Sri Lankan population who are at risk of iron deficiency.

1.2. Objective of the study:

1. To assess the effectiveness of DFS intake on hemoglobin and ferritin concentrations in school aged children (boys and girls 6 to 10 yrs of age) in a community setting in Sri Lanka.

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2. METHODOLOGY

This was a Quasi experimental study carried out at the community level. The study design was a cluster randomized community trial which included a baseline survey, follow up and end line survey.

2.1. Study population

The impact of double fortified salt (DFS) on haemoglobin concentration and serum ferritin were assessed in children between the ages of 6 and 10 years resident in the selected households. This specific age group was selected in order to avoid inclusion of adolescents who may be growing with more demand for iron.

a) Inclusion Criteria

A child between the ages of 6-10 years was identified as a study unit. The child was enrolled after obtaining written parental consent.

b) Exclusion Criteria

Any child whose mother did not give consent and children who were suffering from documented chronic health problems like heart disease, liver disease, kidney disease etc. were excluded.

2.2. Sample Size

The trial was expected to have 80% power to detect a difference in mean haemoglobin of 0.5 g/dl between the intervention arm (DFS) and the control arm (Iodine) with a significance level of 0.05, after 9 months of consumption of salt by children. A PHM area was defined as a cluster and approximately 20 children were included from each such area. In many previous studies, the intra-cluster correlation (ICC) for hemoglobin ranged from 0.04-0.08, and standard deviation from 1.1 to 1.4 g/dl in children. The corresponding values for preschool children in Colombo district were 0.05 and 1.1 g/dl respectively (NFSS, 2010).

Following assumptions were taken into account to calculate the sample size required for the baseline and end line survey:

Assumptions:

Outcome expected mean difference in Hb= 0.5, Standard deviation = 1.1
Cluster size (no. of study units per cluster) = 20, Power = 80%, P=0.05,

In a 2 arm trial;
Total number of clusters to be randomized = 16 clusters (8:8) with the ICC=0.04,
Total number of children = 20x16 = 320

Since 2 strata were included (Urban and non-urban) number equals 2x320 = 640

Allowing for a response rate 90%, number to be included is 20/0.9 = 22 per cluster
Total number to be enrolled in the trial = 22x16X2 = 704

Sample included 352 children in the intervention group and 352 in the control group.

The number of clusters to be randomized was calculated according the formula described by Donner & Klar (2000) using Sample size 10.2 software.

The total number of clusters to be randomized was 32 (16 interventions: 16 control), which would include a total of 704 children. Adjustment was made to allow a 10% loss-to-follow up or non-responses. The total number of children to be recruited is 704 or approximately 22 children from each of the 32 clusters.

2.3. Sampling procedure

a). Study Setting

Gampaha district was selected to carry out the study. This district included both urban and non urban areas and the prevalence of anaemia was 40.4% among children under five years (DHS 2006).

b). Identification of the sample

Study sites were Public Health Midwives (PHM areas), which is the smallest administrative unit in Ministry of Health, Sri Lanka. Each PHM area included approximately 3000 population and approximately 10% of this population is children aged 6-10 years. With the district being selected, the offices of the Medical Officers of Health (MOH) were approached for a list of PHM areas situated in the urban and rural sectors.

This enabled listing of all PHM areas in the Gampaha district by urban and rural sectors.

c). Selection of clusters

Sixteen clusters each from urban and rural sectors were selected randomly from the list of the PHM areas. The selected clusters were assigned either to intervention (DSF) or control (Iodine) group randomly. Approximately 22 children aged 6-10 years were selected from the households located around the starting point of each cluster as described below.

d). Selection of households

A household was defined as persons routinely sharing food from the same cooking pot and living in the same compound or physical location. Members of a household need not

necessarily be relatives by blood or marriage. Only one child was selected from a household. If there was more than one, a child was randomly selected.

In selecting the households within a PHM area, the survey team visited the center of the area. A random direction was picked by a spinning a bottle. The direction pointed by the neck of the bottle was considered as the direction in which the survey team travelled. The team traveled, from the centre to the border of the block, counting the number of households that they encountered. The first household to be visited was randomly selected from among these households by drawing a lot. The subsequent households were chosen by proximity. The next nearest household available was visited and this process continued until the required numbers of children in the specific age group were identified from the households.

Study population comprised of the children between 6-10 years of age. Consent was obtained from the parents prior to the inclusion in the study.

e). Allocation of intervention and control groups

All individuals involved in the trial (including parents, health workers, and research staff) was unaware of assignment of the PHM area to the intervention / control group until the code given in sealed envelopes was broken after the completion of the end survey.

Lanka Salt Company, the company that produced the iodized salt prepared fresh batches of DFS and iodized salt every month depending on the requirement. Double fortified salt and iodized salt, similar in crystal form, were packaged by Lanka Salt Company, Hambantota, labeling the PHM area name and transported to the MRI to be distributed by the MRI staff allocated to the PHM area. The salt packets were distributed by the staff of the MRI to selected households in the PHM areas as given in the label.

Iodine was added at a level of 20-30 mg / kg of salt according to the country requirement for universal iodization. For the double fortified salt, iron was added to achieve 1000 ppm of elemental iron. The salt made available was to be added to the food prepared on a daily basis at the household level, during the 9 month period.

2.4. Data Collection Tool

A pre-coded questionnaire was developed in English to obtain basic information on health, use of vitamin/iron preparations, food consumption pattern etc. . Information on the use of the salt distributed by the MRI staff, whether they have purchased and used any other forms of salt and other relevant information were collected from the households. Mothers were considered as the key informants from whom the information was obtained. The questionnaire was translated into Sinhalese. Pre-testing of the questionnaire was done in another area situated in Colombo district (Kolonnawa MOH area). After pre-testing, changes were incorporated as required.

2.5. Data Collection

a) Recruitment and training of interviewers

Firstly community awareness programmes explaining the purpose and conduct of the study were done in each selected PHM area through health staff, to get the maximum cooperation from the households. For data collection, three teams of 2 interviewers and a team leader per team were utilized. Data collection was done at household level - baseline, follow up and end line assessments. All teams were supervised.

The interviewers and team leaders were permanent staff of Medical Research Institute (MRI), including medical officers, technical staff and support staff. The interviewers were given 4-5 days training during which they were familiarized with the sampling procedure, detailed information on the recruitment of the sample at the community level and the method of completing the questionnaire. They were also trained to draw the blood samples, process and label the samples clearly. Action was taken to standardize these procedures between all observers.

The role of the team leader was to assist the field level data collectors in administering the questionnaire, taking anthropometric measurements and collecting blood samples and the management of the field activities. This decision was taken in order to minimize potential variability in measuring weight and height. The role of the supervisor was to assist in the management of the field activities. The supervisor also had the sole responsibility of transporting blood samples daily to the laboratory of Medical Research Institute.

Implementation of the study Administration of salt was started as soon as the baseline assessment was completed. Mothers were advised to use only the provided salt during preparation of food for the 9 months period.

b) Implementation at field level

Salt packets were distributed to mothers monthly by the MRI staff and were given as 1kg packets, a total of 2kg-3kg of salt powder taking into account the quantity necessary for the total number of household members per month and little extra salt to avoid any shortage during the month. Salt was packeted in a polyethylene packet. Lot number, PHM area name and an internal batch number was printed on the package. Administration of salt was started as soon as the baseline assessment was completed. Mothers were advised to use only the provided salt during preparation of food for the 9 months period.

c) Baseline assessment

At baseline, information about demographic, nutrition, and health data of the children were gathered. If worm treatment has not been given during the preceding 6 months, Mebendazole 500mg was provided for children on the day of interview.
Venous blood samples were collected for measurement of haemoglobin (Hb), serum Ferritin, and C - reactive protein. EDTA blood samples were taken to identify the

presence of haemoglobinopathies by using electrophoresis if the haemoglobin level was below 10g/dl. Urine samples were collected to assess the urine iodine level of children and transported to the laboratory. The same examiner using standard procedures were performed anthropometric measurements, including body weight and height, of all children using UNICEF uniscale and height measurement rods following the WHO standard procedure (WHO 1995).

d) Follow up

MRI staff visited children at home at 4 weekly intervals throughout the 9 month period starting from baseline survey. At each visit, mothers were interviewed about the health status of the child and any adverse events, including diarrhea, constipation, and discomfort. Acceptance of DFS was assessed through a standardized questionnaire, including questions that assessed whether salt changed colour, taste, or texture of the cooked food. Salt samples send from the salt factory were stored in the laboratory and the keeping quality was checked every month to detect iron and iodine levels of the salt. Health personnel monitored the intake of salt and any shortages during the home visits.

e) End line assessment

At the end of 9 months, the questionnaire was reintroduced and venous blood, and urine samples were taken to measure Hb, serum Ferritin, C - reactive protein, and urine iodine. The same examiner using standard procedures performed the anthropometric measurements, including body weight and height. On completion of the study, children who remained as anaemic were treated with oral Fe (30 mg Fe as ferrous sulfate daily for 12 weeks). Children diagnosed as Thalassaemia were provided with a diagnosis card for future use.

2.6 Data Analysis

Hard copies of the questionnaires were transferred to the Data Management Unit (DMU) at Nutrition Department, MRI, Colombo. All the collected forms were archived in Box files after allocation of unique ID. Prior to data entry, all forms were checked for completeness and consistency as well as coding of open- ended responses and area codes. In case of inconsistencies or missing responses, the editors 'flagged' the errors/omissions and consulted the interviewers for possible explanations

EPIINFO program was used for data entry with inbuilt checks. Data were cleaned further, by data entry manager who is a permanent staff member in the Nutrition unit.

For data entry, databases and entry screens were developed using EPI6. The entry screens employed range and consistency checks and skips to minimize entry of erroneous data. Special arrangements were made to enforce referential integrity of the database so that all data tables are related to each other without problems. Data were "double entered" to check the data entry errors. For data analysis SPSS version 15 and Anthro 2006 were used for data analysis.

Haemoglobin was measured by WHO recommended Cyanohaemoglobin method using venous blood with semiautomated chemistry analyzer (Ref).

Serum ferritin was analysed using semiautomated Enzyme Linked Immunoabsorbant Assay (ELISA) system. The ferritin assay kits were from DRG International, Inc. USA. The internal quality control (QC) samples from BIORAD USA (low, medium and high QC) were included with each assay.

C - reactive protein was measured by rapid latex agglutination test kit from omega diagnostics limited UK.

Haemoglobinopathies were detected by the HPLC methods.

All the test results were reviewed and technical validation was performed prior to the release of results.

Following cut-off values was used to define anaemia, iron depletion, acute phase of infection, wasting, stunting and overweight.

i. Anaemia: haemoglobin is less than 11.5 g/dl.
ii. Iron depletion: serum ferritin value is less than 15µg/L in the absence of acute infection and less than 30µg/l in the presence of acute infection.
iii. Acute phase of infection: c-reactive protein value is >6.0mg/L
iv. Wasting: BMI-for-age and sex is less than -2SD
v. Stunting: height-for-age is less than -2SD
vi. Overweight: BMI-for-age and sex is more than -2SD
vii. Iodine insufficiency: median urinary iodine value <100µg/L

Distribution of categorical variables was computed and frequencies and percentages reported. The mean and standard deviations of quantitative variables were calculated. For variables with multiple responses, a percentage ranking of the most frequent responses were assessed.. The data were analyzed using the software, Statistical Package for Social Sciences (SPSS version 15).

2.7. Ethical issues:

Prior to the commencement of the study, all aspects were discussed with the Provincial and Regional Director of Health Services and other relevant officials and their approval obtained. At the field level, the investigators obtained informed consent from the representatives of the communities involved in this study.

Informed written consent was obtained in respect of all the participants of the study. The consent form outlined the aims and objectives of the study along with the strict confidentiality of the participants.

Ethical committee approval was obtained from the Ethical Review Committee of the Medical Research Institute.

3. RESULTS

A total of 704 households each with a child in the selected age group were identified and were allocated randomly to two groups - the intervention group (n=352) and the control group (n=352). In the intervention group and the control group, there were one and two non respondents and thus limiting the sample to 351 and 350 respectively. Intervention group was given the double fortified salt (DFS) and other 350, the control group where the households were given salt fortified with iodine only.

The results are presented as Part I and Part II.

Part I - Description of the study groups based on the information collected in the baseline survey and end line survey
Part II - Information related to the nutritional status including data collected at the baseline survey and at the end of 9 months

PART I

At the beginning of the study, all baseline information relevant to the two groups was collected. This information is presented in tables 1 to 9.

3.1. Information on households

3.1.1. Basic Information

Table 1 presents the **basic information on the two groups of households.** The distribution of households by sector was almost the same in the two groups with nearly half of them being in the urban and the rural sectors. Nearly 95% of the heads of the households in each group were males with the proportion of males being marginally higher in the intervention group. None of othe variables studied such as total number of members in the family, mother's education and monthly household income were statistically significant between the two groups.

Table 1: Basic Information of households in DFS and Iodine groups

Characteristics	DFS	Iodine	chi square	P value
Total	N=351	N=350		
Sector				
Urban	173(49.3%)	176(50.3%)	0.07	0.82
Rural	178(50.7%)	174(49.7%)		
Sex of the household head				
Male	334 (95.2%)	330 (94.3%)	0.266	0.62
Female	17(4.8%)	20(5.7%)		

Total number of members in family				
1-3	53(15.1%)	47(13.4%)	0.895	0.64
4-6	291(82.9%)	293(83.7%)		
≥7	7(2.0%)	10(2.9%)		
Mothers education in years				
Primary	10(2.8%)	23(6.6%)		
Secondary	252(71.8%)	249(71.1%)	6.05	0.11
Passed O’ Level	83(23.6%)	74(21.1%)		
Higher	6(1.7%)	4(1.1%)		
Monthly household income				
< 9,000	24(6.8%)	29(8.3%)	2.196	0.70
9,000 – 13,999	67(19.1%)	56(16.0%)		
14,000 – 19,999	88(25.1%)	95(27.1%)		
20,000 – 31,999	130(37.0%)	123(35.1%)		
≥ 32,000	42(12.0%)	47(13.4%)		
Not mentioned	3(0.9%)	4(1.1%)		

3.1. 2. Characteristics related to housing

As shown in table 2, a majority of the houses had walls made of brick or cabook this proportion being higher in the DFS group (60.4%) than in the iodine group (56.0%) . About one third of the houses had walls made of cement blocks. A significantly higher proportion of houses in the DFS group had tiled roofs compared to the higher proportions of asbestos roofing and those with roofs of corrugated sheets, among the iodine group. There were no significant differences in the material used for flooring.

Table 2: Housing Characteristics and wealth quintile

Type of housing	DFS	Iodine	Statistical significance	
Total	**n=351**	**n=350**		
Walls exterior			6.529	0.258
Brick/ Cabok	212(60.4%)	196(56.0%)		
Cement block	111(31.6%)	124(35.4%)		
Wood	13(3.7%)	6 (1.7%)		
Other	15 (4.4%)	24(6.9%)		
Roof				
Tiles	228(65.0%)	192(54.9%)	22.934	0.000
Asbestos	79(22.5%)	114(33.9%)		
Concrete	22(6.3%)	6(1.8%)		
Corrugated sheet	17(4.8%)	26(7.7%)		
Cadjan	5(1.4%)	6(1.7%)	3.205	0.524
Floor				
Cement	261(74.4%)	271(77.4%)		
Tile or Terrazzo	70(19.9%)	62(17.7%)		
Other	20(5.7%)	17(4.9%)		

3.1.3. Sources of water supply and toilet facilities

The source of water differed between the two groups with piped water being available in more of the households in the iodine group. However, the main source of water for both groups was a protected well. About 98% of households in the DFS group had flush toilets with significant differences between the two groups.(Table 3)

Table 3: Main source of drinking water and availability of toilet facilities

Characteristics	DFS	Iodine	Chi	P
Type of water	N=351	N=350	37.699	0.000
Piped water	62(17.7%)	105(30.0%)		
Public taps	12(3.4%)	27(7.7%)		
Tube well	29(8.3%)	29(8.3%)		
Protected well	147(41.9%)	133(38.0%)		
Unprotected well	101(28.8%)	53(15.2%)		
Toilet facility				
Flush toilet	344(98.0%)	328(93.7%)	17.865	0.000
Pit latrine	5(1.4%)	2(0.6%)		
Communal latrine	2(0.6%)	20 (5.7%)		

3. 2. Information on the children included in the study.

From the above households, a total of 351 children were identified to be included in the DFS (intervention) group and 350 children for the Iodine (control) The sex distribution of the children did not show any major differences between the two groups and there was a marginal predominance of males in both groups.(Table 4). However, the age distribution showed a significantly higher proportion of children in the iodine group being in the older age group, 9 – 10.9 year (22.1%) compared to the DFS group (14.0%).

Table 4: Basic Information of the child in DFS and Iodine groups

Characteristics	DFS	Iodine	chi	p
Sex of the child	351	350		
Male	182(51.9%)	187(53.3%)	0.175	0.705
Female	169(48.1%)	163(46.6%)		
Age of the child				
5.0-6.9	157(44.7%)	137(39.1%)	7.87	0.02
7.0-8.9	145(41.3%)	136(38.9%)		
9.0-10.9	49(14.0%)	78(22.0%)		

3.3. Information on the pattern of consumption of salt

As shown in table 5, the number of persons living in the household varied with about 75% of them having 1 – 5 persons and only 3% having more than 10 persons in both groups. Type of salt used varied with about half of them in each group consuming both crystal and powdered salt, and approximately one fifth, consuming crystal salt only. In almost all households (more than 90%) salt was added during cooking while adding salt while eating was an uncommon practice, reported among only about 0.6% in the iodine group. None of these variables were significantly different between the two groups. However, a significantly higher proportion of households in the DFS group (91.5.4%) were aware of iodized sale compared to the iodine group (84.9%)

Frequency of buying salt varied significantly between the two groups with more of the iodine group purchasing salt 1-4 times a month (90.3%) compared to the DFS group (82.9%).

Different factors that were considered when purchasing salt were inquired into. None of these factors, taste, price, colour, brand, health effects, availability 'were significantly different between the two groups. Information on the brand of salt purchased varied with the number of brands approximating to 40. .Place of purchase was from the small shops or from shops where products are sold on a wholesale 'basis. About one fourth of the households purchased the same brand of salt. Quality of the salt and the availability of the product in the locality are the two main factors that influenced the purchase of a given brand.

More than 70% of the households in each group, mother was the person responsible for buying salt. Nearly all households expressed their willingness to purchase DHF salt irrespective of the cost (higher or the same) . The mean amount of salt purchased per month did not differ significantly between the two groups and averaged to 1.4 kg.

Table 5: Information on consumption of salt

Characteristics	DFS	Iodine	chi	p
Number of persons living in the household	N=351	N=350		
1-5	264(75.2%)	264(75.4%)	0.005	0.998
6-10	84(23.9%)	83(23.7%)		
>10	3(0.9%)	3(0.9%)		
Time of adding salt				
During cooking	332(94.6%)	328(93.7%)	4.282	0.233
After cooking and before serving	8(2.3%)	4(1.1%)		
While eating	0(0%)	2(0.6%)		
Both cooking and eating	11(3.1%)	16(4.6%)		
Type of salt used				
Crystal	75(21.4%)	78(22.3%)	0.416	0.812
Powder	89(25.4%)	94(26.9%)		
Both	187(53.4%)	178(50.9%)		
Awareness on iodised salt				
Yes	321(91.5%)	297(84.9%)	7.304	0.007
No	30(8.5%)	53(15.1%)		
Frequency of buying salt				
>3 times a week	1(0.3%)	2(0.6%)	13.104	0.004
1-4 times a month	291(82.9%)	316(90.3%)		
Once a month	51(14.5%)	22(6.3%)		
Not remember	8(2.3%)	10(2.9%)		
Factors considered during purchasing				
Taste	5(1.4%)	6(1.7%)	0.95	0.772
Price	12(3.4%)	9(2.6%)	0.433	0.659
Colour	135(38.6%)	154(43.6%)	1.855	0.193
Brand	20(5.7%)	17(4.9%)	0.248	0.736
Health	139(39.6%)	126(36.0%)	0.967	0.35
Availability of product	89(25.4%)	93(26.6%)	0.135	0.731
Other (exp. Date, clean, size of pkt)	55(15.7%)	60(16.9%)	0.256	0.21
Place of buying salt				
Supermarket	24(6.8%)	34(9.7%)	5.836	0.120
Wholesale	118(33.6%)	130(37.1%)		

Small shop	191(54.4%)	177(50.6%)		
Other	18(5.1%)	9(2.6%)		
Buying the same brand				
Yes	85(24.2%)	91(26.0%)	0.296	0.602
No	266(75.8%)	259(74.0%)		
Reason for buying these brands				
Quality	55(15.7%)	58(16.3%)	2.634	0.621
Price	0(0%)	1(0.3%)		
Only available in the locality	288(82.1%)	288(82.3%)		
Other	7(2.0%)	3(0.9%)		
Person decide on purchasing of brand				
Mother	252(71.8%)	253(72.3%)	5.925	0.205
Father	37(10.5%)	30(8.6%)		
Parents	1(0.3%)	1(0.3%)		
Depends upon who buys	61(17.4)	66(18.8%)		
Willingness to purchase DFS salt				
Even at a higher cost than iodised salt	348(99.1%)	348(99.4%)	0.343	0.842
At a same cost of iodised salt	348 (99.1%)	350 (100.0%)	3.039	0.219
Mean quantity of salt purchase at one time (SD) in Kg	1.44(0.78)	1.39(0.73	F=0.71	0.398
Mean quantity of salt used per month (SD) in kg	1.93(0.76)	2.02(0.89)	F=2.3	0.13

3.4. Knowledge on anaemia

In nearly two thirds of the households, the respondents indicated that they knew about anaemia. However, 39.3% in the DFS group and in 42.6% in the iodine group were not aware of the reasons for anaemia, even though the difference was not statistically significant (Table 6) The responses between the two groups on the 'foods to be taken to prevent anaemia' were not significantly different except for a higher proportion in the DFS group (24.2%) saying that eggs can be taken to prevent anaemia, compared to the18% in the iodine group.

Table 6: Knowledge on anaemia

Characteristics	DFS	Iodine	chi	p
Knowledge on anaemia	N=351	N=350		
Yes	263(74.9%)	257(73.4%)	0.206	0.650
No	88(25.1%)	93(26.6%)		
Reasons for anaemia				
Lack of food	178(50.7%)	178(50.9%)	9.298	0.158
Illness	9(2.6%)	5(1.4%)		
Bleeding	8(2.3%)	11(3.1%)		
Heavy work	0(0%)	1(0.3%)		
Do not know	138(39.3%)	149(42.6%)		
Other	17(4.8%)	6(1.7%)		
Foods to be taken to prevent anaemia				
Meat or Fish	213(60.7%)	196(56.0%)	1.582	0.208
Eggs	85(24.2%)	63(18.0%)	4.066	0.044
Leafy green vegetables	249(70.9%)	257(73.4%)	0.54	0.462
Legumes and Vitamin A rich foods	100(28.5%)	92(26.3%)	0.428	0.513
Do not know	76(21.7%)	65(18.4%)	2.919	0.265

3.5. Information on the pattern of iron consumption

Iron consumption was studied using information on the pattern of iron supplementation among children and from food consumption patterns. More than 93 % of the children responded negatively to the question ‘ever taken iron tablets or syrup’ in both groups. Among those who had taken an iron supplement, 50 – 60 % had taken such supplements for a period of less than one month and the frequency of taking the supplement daily ranged between 83% in the DFS group and 75% in the iodine group. However, none of these differences were statistically significant between the two groups (Table 7).

No reasons were given by a significantly lower proportion of respondents (25%) in the DFS group compared to the 80% in the iodine group, to the question on the reasons for not taking iron as prescribed . Though not significant statistically, the proportions giving the reasons for giving iron varied between the two groups, with 46.1% in the DFS group indicating the reason to be ‘to prevent anaemia’ compared to the 43.7% in the iodine group.

Table 7: Pattern of iron supplementation among children

Characteristics	DFS	Iodine	chi	p
Ever taken iron tablets or syrup	N=351	N=350		
Yes	23(6.6%)	20(5.7%)	0.251	0.616
No	328(93.4%)	330(94.3%)		
Period of taking iron				
< 1 month	13(56.5%)	14(70.0%)	4.650	0.325
1-4 months	10(43.5%)	4(20.0%)		
5-9 months	0(0%)	1(5.0%)		
>9 months	0(0%)	1(5.0%)		
Frequency of taking iron				
Daily	19(82.6%)	15(75.0%)	0.623	0.732
Irregular	4(17.4%)	5(25.0%)		
Reason for not taking iron as prescribed				
Child got sick	1(25.0%)	1(20.0%)	8.858	0.031
Bad taste or smell	1(25.0%)	4(80.0%)		
Other	7(50.0%)	0(0%)		
Reason for giving iron for children				
Increase strength	52(14.8%)	56(16.0%)	0.514	0.774
Prevent anaemia	162(46.1%)	153(43.7%)		
Do not know	137(39.1%)	141(40.3%)		

3.6. Food consumption pattern

3.6.1. Food consumption pattern of the child

Responses to the questions on the food consumption during the week preceding the interview was used to study the food consumption pattern. Data are presented in Table 8.

In general, consumption of red meat was low with more than 80% not consuming such products at all. However, among those who consumed red meat, there was a higher proportion (18.9%) among the iodine group compared to the 15.1% in the DFS group. The pattern was significantly different between the two groups.

Consumption of poultry was comparatively more frequent with only 39% in the DFS group and 30% in the iodine group having indicated that they have not consumed such items. The consumption pattern was significantly different between the two groups with an 'improved' intake among the iodine group. The pattern showed a similarity with the consumption of fish with the proportion of non consumers being much lower, less than 12% in each group.

Table 8: Food consumption pattern of the child during the last one week

Characteristics	DFS	Iodine	chi	p
Consumption of food items during the last week	**N=351**	**N=350**		
Red meat			11.310	0.046
2 times a day	11(3.1%)	4(1.1%)		
Once a day	0(0%)	1(0.3%)		
5 days a week	1(0.3%)	0(0%)		
3-4 days a week	4(1.1%)	2(0.6%)		
1-2 days a week	37 (10.5%)	59 (16.9%)		
None	298(84.9%)	284(81.1%)		
Poultry				
<2 times a day	2(0.6%)	5 (1.4%)	14.532	0.024
2 times a day	5(1.4%)	1(0.3%)		
Once a day	0(0.0%)	1(0.3%)		
5 days a week	1(0.3%)	0(0.0%)		
3-4 days a week	27(7.7%)	28(8.0%)		
1-2 days a week	179(51.0%)	214(61.1%)		
None	137(39.0%)	101(28.9%)		
Fish			10.916	0.091
<2 times a day	3(0.9%)	4(1.1%)		
2 times a day	11(3.1%)	10(2.9%)		
Once a day	36 (10.3%)	34(9.7%)		
5 days a week	32(9.1%)	60(17.1%)		
3-4 days a week	97 (27.7%)	96 (27.4%)		
1-2 days a week	133 (37.9%)	112(32.0%)		
None	39(11.1%)	34(9.7%)		
Yellow fruits			3.610	0.729
<2 times a day	4(1.1%)	2(0.6%)		
2 times a day	3(0.9%)	4(1.1%)		
Once a day	53(15.1%)	55(15.7%)		
5 days a week	45(12.8%)	33(9.4%)		
3-4 days a week	135(38.5%)	150(42.9%)		
1-2 days a week	94(28.2%)	94(26.9%)		
None	12(3.4%)	12(3.4%)		
Dark leafy greens			6.816	0.338
<2 times a day	2(0.6%)	1(0.3%)		
2 times a day	8(2.3%)	4(1.1%)		
Once a day	65(18.5%)	44(12.6%)		
5 days a week	45(12.8%)	48(13.7%)		
3-4 days a week	132(37.6%)	144(41.1%)		
1-2 days a week	94(23.1%)	94(26.9%)		
None	18(5.1%)	16(4.5%)		
Roots and tubers			9.256	0.160

<2 times a day	3(0.9%)	1(0.3%)		
2 times a day	5(1.4%)	0(0%)		
Once a day	22(6.3%)	14(4.0%)		
5 days a week	40(11.4%)	35(10.0%)		
3-4 days a week	120(34.2%)	137(39.1%)		
1-2 days a week	134(38.2%)	135(38.6%)		
None	27(7.7%)	28(8.0%)		
Rice			10.875	0.028
<2 times a day	204(58.1%)	181(51.7%)		
2 times a day	119(33.9%)	153(43.7%)		
Once a day	10(2.8%)	9(2.6%)		
5 days a week	15(4.3%)	5(1.9%)		
3-4 days a week	3(0.9%)	2(0.6%)		
Milk and milk products			5.395	0.494
<2 times a day	23(6.6%)	25(7.1%)		
2times a day	102(29.1%)	102(29.1%)		
Once a day	158(45.0%)	169(48.3%)		
5 days a week	16(4.6%)	10(2.9%)		
3-4 days a week	16(4.6%)	7(2.0%)		
1-2 days a week	13(3.7%)	14(4.0%)		
None	23(6.6%)	23(6.5%)		
Eggs			4.267	0.641
<2 times a day	5(1.4%)	2(0.6%)		
2 times a day	6(1.7%)	2(0.6%)		
Once a day	3(0.9%)	5(1.4%)		
5 days a week	11(3.1%)	12 (3.4%)		
3-4 days a week	94(26.9%)	90(25.7%)		
1-2 days a week	166(47.3%)	166(47.4%)		
None	66(18.8%)	73(20.9%)		
Nuts and legumes			5.370	0.497
<2 times a day	2(0.6)	0(0.0%)		
2 times a day	3(0.9%)	1(0.3%)		
Once a day	30(8.5%)	31(8.9%)		
5 days a week	39(11.1%)	40(11.4%)		
3-4 days a week	96(27.4%)	86(24.6%)		
1-2 days a week	101(28.8%)	119(34.0%)		
None	80(22.8%)	73 (20.9%)		

Frequency of consumption of yellow fruits, dark green leaves , roots and tubers were fairly similar with a majority of the children having consumed such products on 1 – 4 days a week. The minor differences in the frequency seen among the two groups were not statistically significant.

Consumption of rice was almost universal with a higher proportion in the DFS group consuming rice (58%) more frequently compared to the iodine group (51.7%). This difference was statistically significant. Approximately 70% in each group consumed milk once or twice or more than twice a day. Nearly 79-81% of the children had consumed nuts and legumes once or twice a week.

3.6.2. Information on consumption of tea and coffee

As shown in table 9, nearly a third of the children consumed tea or coffee, two or more times a day. Drinking tea or coffee within two hours of a meal was not a frequent occurrence with 8 – 11% of the children doing so compared to the high proportions (Approximately 53 %,) consuming tea / coffee between meals.

Eating fruits after main meals was practiced by approximately 40% in each group with a small percentage drinking milk after the main meal. None of these practices were significantly different between the two groups.

Table 9: Information on the consumption of tea and coffee

Variable	DFS	Iodine	Chi square	P value
Tea or coffee	N=351	N=350		
<2 times a day	66(18.8%)	64(18.3%)	12.228	0.057
2 times a day	149(42.5%)	150(42.1%)		
Once a day	69(19.7%)	81(23.1%)		
5 days a week	21(6.0%)	6(1.7%)		
3-4 days a week	7(2.0%)	14(4.0%)		
1-2 days a week	13(3.7%)	14(4.0%)		
None	26(7.4%)	21(6.0%)		
Drinking tea or coffee				
Just after meal within 2 hours	30 (8.6%)	39(11.1%)	5.451	0.363
Just before meals	59(16.8%)	69(19.7%)		
In between meals	193(54.9%)	186(53.1%)		
Not drinking	69(19.7%)	56(16.0%)		
Eating fruits after main meals				
Yes	131 (37.3%)	148(42.3%)	2.843	0.2
No	220(62.7%)	202(57.7%)		
Drinking milk soon after main meals				
Yes	19(5.4%)	12 (3.4%)	2.644	0.267
No	332(94.6%)	338(96.6%)		

3.7 Acceptability

Problems encountered with the salt and acceptability of the DFS was assessed at the end of the 9 months.

Table 10: **End line assessment on acceptability of DFS**

	DFS	Iodine	chi	p
Problem identified with salt during 6 months	**N=350**	**N=346**		
Yes with colour	20(5.9%)	9(2.6%)	4.292	0.038
Yes with taste	12(3.6%)	13(3.8%)		
No	318(94.1%)	324(93.6%)		
Changes during cooking with the salt				
Colour	27(8.0%)	26(7.7%)	0.015	0.904
Taste	10(3.0%)	10(3.0%)	0.000	0.989
Smell	2(0.6%)	0(0%)	1.994	0.158
None	311(92.0%)	310(92.3%)	4.498	0.213
Colour change during rainy reason			0.119	0.730
Yes	17(4.9%)	15(4.3%)		
No	333(95.1%)	331(95.7%)		
Observed any change with the child				
Activity	5(1.4%)	21(6.2%)	10.340	0.001
Allergy	2(0.6%)	10(3.0%)	5.479	0.019
None	343(98.0%)	315(93.8%)		
Liking to continue with this salt			**3.487**	**0.327**
Yes	334(95.4%)	325(93.9%)		
No	16(4.6%)	21(6.1%)		
Decisive factor while purchasing salt				
Taste	8(2.4%)	3(0.9%)	4.284	0.232
Price	12(3.6%)	9(2.7%)	0.424	0.515
Colour	107(31.7%)	83(24.7%)	4.026	0.045
Brand	25(7.4%)	15(4.5%)	2.595	0.107
Health	188(55.6%)	167(49.7%)	2.368	0.124
Availability of product	47(13.9%)	56(16.7%)	0.992	0.319
Willingness to purchase DFS salt if the cost is:				
Even higher than iodised salt	329(97.1%)	324(96.4%)	6.025	0.197
Same as iodised salt	335(99.1%)	333(99.1%)	1.200	0.549
Do not know	3(0.9%)	3(0.9%)		
Affordable price difference than the iodised salt				
Rs. 5 more	159(45.4%)	142(41.0%)	3.751	0.441
Rs 5-10	136(38.8%)	147(42.4%)		
>Rs. 10	33(9.4%)	34(9.8%)		
No response	22 (6.3%)	23 (6.6%)		

More than 90% of the households in each group did not identify any problems with the salt, such as changes in colour, taste or smell. However, a marginally higher proportion of households in the DHS group (5.9%) said that there was a problem with the colour of the salt, compared to 2.6% in the iodince group. However, these differences were not statistically significant.

No changes were observed in 98% of the children in the DFS group and 94% in the iodine group. However, some children reported changes in the activity pattern of the child and also reported allergic reactions. Even though the numbers were small, the percentage of children who reported such changes were significantly higher among the iodine group (Changes in activity in 1.4% in the DFS and 6, 2% inte iodine group, allergy in 0.6% in the DFS group and 3.0% in the iodine group).

A large % of households, 95.4% in the DFS group and 93.9% in the iodine group said that they would like to continue with this salt. The common decisive factors that influence the purchase of salt were ‘health reasons’ and the colour of the salt. None of the observations described were significantly different between the two groups.

Cost did not seem to be an important factor in purchasing salt as indicated by more than 96% of the households of their willingness to purchase salt even if the cost is higher. However, approximately 10% of the households indicated that the affordable difference in the price is less than Rs. 10 per kg.

During the field visits, it was observed that the practice of proper mixing of the food item was not a universial practice which may have inflcuneced the avaioalbility of iron form the DFS through its addition to food.

PART II

3.8. Nutritional status indicators at the baseline survey

3.8.1. Anthropometric indicators

At the baseline level, there were no major differences between the two groups with the prevalence of thinness, being approximately 27% in each group and the prevalence of stunting of approximately 6% (Table 11).

Table 11: Nutritional status of children at the beginning

Indicators	DFS No. (%)	Iodine No. (%)	
0 months	**(n=349)**	**(n=350)**	
Thinness (wasting)	95 (27.2%)	96 (27.5)%	X^2=0.007, P=1.00
Normal	70.8%	72.5%	
Overweight	2.0%	0.0%	
Stunting	22 (6.3%)	21 (6.0%)	X^2=0.28, P=0.88

3.8.2. Biochemical indicators

The **biochemical indicators** studied included haemoglobin, serum ferritin and median urinary iodine levels.

3.8.2.1. Acute phase of infections

At the time of commencement of the study, the **prevalence of the indicator C reactive protein of ≥6 mg/l** indicating an acute phase of infection was present among 2.3% and 2.6% of children in the DFS and iodine groups respectively. This difference is not statistically significant.

3.8.2.2.. Haemoglobinopathies

In the total sample, only 9 children (1.3%) of the children were identified as having beta thalassaemia.

3.8.2.3.. Anaemia

As shown in Table 11, at the beginning of the study, the mean Hb levels were significantly higher in the iodine group.

Table 12: Anaemia, iron deficiency and iodine status among children at the beginning

Indicators	DFS No. (%)	Iodine(%)	chi	p
Haemoglobin	**N=351**	**N=350**		
Prevalence of anaemia (<11.5)	111 (31.5%)	48 (13.7%)	31.18	0.000
Mild (10.5-11.4)	89.2%	97.9%		
Moderate (7.5-10.4)	10.8%	12.2%		
Severe (<7.5)	0%	0%		
Mean Haemoglobin (SD) g/L (SD)	12.04(1.21)	12.52(0. 99)	F=33.42	0.000
Serum Ferritin	**N=346**	**N=346**		
Mean Serum Ferritin (SD) µg/L	36.19(25.24)	28.35(22.89)	F=18.33	0.000
Prevalence of iron deficiency (<15 µg/L)	62 (17.9%)	102 (29.5%)	12.79	0.000
Urinary iodine	**N=339**	**N=344**		
Median urinary iodine (range) µg/L	101.1 (14.3-447.3)	98.4 (16.3-512.0)	0.742	0.389
C-Reactive protein				
Prevalence of acute infections	8 (2.3%)	9 (2.6%)	0.60	1.00

Prevalence of anaemia was significantly higher in the DFS group, 31.5% compared to the iodine group, and 13.7%. Among the children 2.3% in the DFS group and 2.6% in the iodine group had high level of C reactive protein indicating the acute phase of infection.

3.8.2.4. Iron deficiency

The mean serum ferritin level was significantly higher among the DFS group (Table 12). The prevalence of iron deficiency was significantly higher in the iodine group (29.5%) than DFS group (17.9%).

3.8.2.5. Iodine status

Median urinary iodine levels were marginally higher in the DFS group than Iodine group. However, this difference was not statistically significant (Table 12). It indicates that DFS group had adequate intake of iodine and the iodine group had insufficient intake of iodine.

3.9. Findings from the end line survey (after 9 months)

The nutritional status using anthropometric indicators and selected biochemical parameters related to acute infections, anaemia, iron status and iodine status were assessed at the beginning and at the end of the study, at 0 months and after 9 months.

All households that participated in the baseline assessment were followed up for 9 months by providing salt supplies every month. However, only 338 children from DFS

group and 336 children from iodine group participated in the end line assessment. Thus, the drop outs rates in the DFS and Iodine group are 3.7% and 4.0% respectively. Reasons for drop out were moving the child to other locations and doctor's advice due to sickness.

Biochemical assessments were done in 335 children from DFS group and 333 children from iodine group due to refusal of some children to allow drawing blood.

The changes in the indicators were assessed both at a group level and at individual level where the difference within each individual was assessed and comparisons made.

Tables 13 to 18 present the data from the assessments of the two groups at baseline, after 9 months and difference between 0 – 9months at individual level as a mean difference.

3.9.1. Anthropometric indicators

At the baseline level, there were no major differences between the two groups with the prevalence of thinness, being approximately 27% in each group and the prevalence of stunting of approximately 6% (Table 13).

However, assessment at the end of 9 months showed a marginal increase in the prevalence of thinness in the DFS group from 27.4% to 29.3% with the comparable proportion increasing from 27.5% to 29.7% in the iodine group.

However, the prevalence of stunting which were comparable between the two groups at the commencement of the study shows an increase in the DFS group from 6.3% to 9.0% with a reduction in the iodine group from 6.0% to 4.8% during the 9 month period. Both these reductions were statistically not significant.

Table 13: Nutritional status of children: baseline and end of the study period

Indicator	Thinness (wasting)			Stunting		
	DFS	**Iodine**	**Test statistics**	**DFS**	**Iodine**	**Test statistics**
0 months	27.2% (n=351)	27.5% (n=350)	X^2=0.007 P=1.000	6.3% (n=349)	6.0% (n=350)	X^2=0.28 P=0.88
9 months	29.3% (n=335)	29.7% (n=333)	X^2=0.407 P=0.82	9.0% (n=334)	4.8% (n=333)	X^2=4.53 P=0.046
	X^2=2.38 P=0.304	X^2=2.34 P=0.89		X^2=0.74 P=0.42	X^2=1.25 P=0.25	

3.9.2. . Prevalence of acute infections

At the end of 9 months, the **prevalence of the indicator C reactive protein of > 6 mg/L** indicating an acute phase of infection shows a higher percentage than the baseline. However, this increase is not statistically significant. The difference in the percentages

was wider with 5.4% in the DFS group and 2.7% in the iodine group, which is not significant.

Table 14: Acute infections of children – baseline and end of the study period

Indicator	Acute phase of infection		
	DFS	**Iodine**	**Test statistics**
0 months	8 (2.3%) (N=351)	9 (2.6%) (N=350)	$X^{2=}0.06$ P=1.00
9 months	18 (5.4%) (N=332)	9 (2.7%) (N=335)	X^2=3.212 P=0.08
Test statistics	X^2=0.80 P=0.36		

Effectiveness of an intervention programme to improve iron deficiency anaemia could be indicated through changes in the mean haemoglobin levels, prevalence of anaemia and mean serum ferritin levels. These changes were assessed before and after the intervention in each group.

3.9.3. Mean haemoglobin levels

After 9 months, the mean Hb level shows a marginal increase in the DFS group (12.03 to 12.19) with a significant decline in the values seen among the iodine group, from 12.52 to 12.08. However, the changes in the both groups were statistically significant (Table 15).

Table 15: Comparison of mean haemoglobin levels: baseline and end of the study period

Indicator	Mean haemoglobin		
	DFS	**Iodine**	**Test statistics**
0 months	12.03 (1.21)	12.52 (0.99)	F=40.64; P=0.000
9 months	12.19 (0.92)	12.08 (0.87)	F=1.53; P=0.17
Test statistics	F=2.12; P=0.000	F=2.08; P=0.000	
Mean difference	0.214 (1.18)	-0.444 (1.10)	F=50.19; P=0.000

3.9.4. Prevalence of anaemia

Table 16 shows that there is a reduction in the overall prevalence of anaemia in the DFS and the increase in the iodine group, the reduction in the DFS group was statistically significant but not in the iodine group.

Table 16 : Prevalence of anaemia: baseline and end of the study period

Indicator	Prevalence of anaemia		
	DFS	**Iodine**	**Test statistics**
0 months	110 (31.3%)	48 (13.7%)	X^2=31.18 P=0.000
9 months	60 (20.1%)	65 (21.2%)	X^2=0.175 P=0.688
Test statistics	X^2=14.39; P=0.000	X^2=2.79; P=0.07	
Difference between period	-11.5%	+9.5%	

However, among those children who were anaemic, the proportion of mild to moderate anaemia was 89.2% and 10.8% respectively among the DFS group while the prevalence of mild to moderate anaemia was 97.9% and 2.2% in the iodine group at the baseline level. At the end of the study period, the prevalence of mild anaemia has increased among the iodine group from 97.9% to 98.3% with a significant reduction of moderate anaemia from 10.8% to 10.0% among the DFS group (Table 17).

Table 17 : Degree of anaemia: baseline and end of the study period

Indicator	DFS			Iodine			
	Mild (10.5-11.4)	**Moderate (7.5-10.4)**	**Severe (<7.5)**	**Mild (10.5-11.4)**	**Moderate (7.5-10.4)**	**Severe (<7.5)**	**Test Statistics**
0 months	89.2%	10.8%	0.0%	97.9%	2.2%	0.0%	X^2=9.26 P=0.002
9 months	90.0%	10.0%	0.0%	98.5%	1.5%	0.0%	X^2=2.08 P=0.16
Test statistics	X^2=34.64; P=0.000			X^2=6.09; P=0.19			

None of the children in any of the groups were severely anaemic at any of the assessments.

3.9.5. Mean serum ferritin: baseline and end of the study period

Serum ferritin levels show statistically significant changes during the 9 months among the DFS group with an increase from 36.19µg/l to 37.14 µg/l with the comparable change among the iodine group being a marginal decline from 28.35µg/l to 27.18 µg/l, which is not statistically significant (Table 18).

However, the serum ferrtin levels are far below 100µg/l indicating the possibility that iron deficiency is a problem in this population.

Table 18 : Comparison of mean serum ferritin levels: baseline and end of the study period

Indicator	Mean serum ferritin (SD)		
	DFS	**Iodine**	**Test statistics**
0 months	36.19 (25.24)	28.35 (22.89)	F=18.33; P=0.000
9 months	37.14 (29.29)	27.18 (22.25)	F=18.39; P=0.000
Test statistics	F=1.47; P=0.009	F=0.89; P=0.73	
Mean Difference between period	+0.43 (3.42)	-0.55 (2.78)	F=0.034; P=0.855

3.9.6. Prevalence of iron deficiency

The proportion with iron deficiency at the baseline survey was 17.9% in the DFS group and 29.5% in the iodine group. This difference was statistically significant. At the end of 9 months, the prevalence in both groups showed a decline, which was more marked in the iodine group (Table 19). But the reductions in both groups were not statistically significant.

Table 19 : Comparison of prevalence of iron depletion: baseline and end of the study period

Indicator	Prevalence of iron deficiency		
	DFS	**Iodine**	**Test statistics**
0 months	62 (17.9%)	102 (29.5%)	12.79 P=0.000
9 months	49 (15.8%)	57 (25.2%)	7.40 P=0.008
Test statistics	X^2=0.27 P=0.37	X^2=0.86 P=0.44	
Mean Difference between period	-2.1%	-4.3%	

3.9.7. Iodine status after 9 months

After 9 months, the median urinary iodine level shows an increase in the DFS group (101.1-164.1) as well as in the iodine group (98.4-133.9). The increase in the DFS group is statistically significant. Both groups show an adequate intake of iodine (Table 20).

Table 20 : Comparison of median iodine level: baseline and end of the study period

Indicator	**Median urinary Iodine levels μg/L**		
	DFS	**Iodine**	**Test statistics**
0 months	101.1 (14.3-447.3)	98.4 (16.3-512.0)	F=0.742; P=0.389
9 months	164.1 (3.8-627.7)	134.0 (5.6-474.5)	F=20.9; P=0.000
Test statistics	F=2.72; P=0.004	F=1.77; P=0.083	

4. Conclusions

1. Comparison of the 2 groups showed that housing conditions were better in the DFS group than iodine groups.
2. There are no major differences between sectors, sex of the household heads and total number of people in the families between 2 groups.
3. Consumption of salt in DFS is higher than iodine group, but there is no differences in factors considering in purchasing salt
4. More than 90% of households were added salt during cooking while adding salt during eating was an uncommon practice. Encapsulated iron in salt tends to get deposited at the bottom of the utensils and the importance in mixing the food prior to the consumption has been observed as an important practice.
5. Food consumption pattern showed a significantly low level of consumption of red meat, fish and poultry in the DFS group than the iodine group. However, the frequency of consumption of roots, tubers were similar and the consumption of rice is almost universal. Approximately 70% consume milk and 65-70% consumes nuts in both groups.
6. Knowledge on anaemia was generally at a satisfactory level in both groups.
7. Pattern of iron supplementation among children showed that only 6.9% of children in DFS group and 5.9% from iodine had ever taken iron.
8. Changes in colour of the salt were reported 5.7% in DFS group compared to 2.7% in iodine group.
9. The main problem identified related to the acceptability of DFS being negative, was the change in colour which was identified as a consideration while purchasing salt.
10. Mean haemoglobin levels were increased by 0.214/dl in DFS group which was statistically significant. However, a significant decline of the mean haemoglobin level was observed in the iodine group.
11. There was a reduction in the overall prevalence of anaemia in the DFS and the increase in the iodine group; both the reduction and the increase were statistically significant.
12. Serum ferritin levels among the DFS group showed a marginal increase from 36.19µg/l to 37.1 µg/l4 with the comparable change among the iodine group being a marginal decline from 28.35µg/l to 27.13 µg/l . However, the serum ferrtin levels are

far below 100µg/l indicating the possibility that iron deficiency is a problem in this population.

13. The median urinary iodine level showed an increase in both groups, the iodine group (98.4-133.9). Both groups showing an adequate intake of iodine.

14. Iron overdose was not seen as a problem in the community trial even after continuing for 9months. None of the children had serum ferritin level above 250µg/l indicating iron overdose.

5. Recommendations

1. DFS is an effective iron-fortification strategy to reduce the burden of anaemia in a community.

2. The prevalence of anaemia with a high prevalence of mild anaemia indicates the need for a concerted effort to increase availability of iron through dietary sources. In this context, introduction of DFS in selected populations has to be considered as a key intervention.

3. It is a potential intervention to be implemented in replacing iodide salt with DFS in existing feeding programs and poverty alleviation programmes in Sri Lanka such as school midday meal programs, poshan malla for pregnant women, and public food distribution systems (samurdhi beneficiaries programme) in high anaemic areas. It may be a cost-effective way to reach anaemic population groups.

4. A community based trial of a longer term with a rigorous in built monitoring and evaluation system has to be considered prior to undertaking universal supplementation by using DFS.

5. Colour changes of DFS is a factor which, was seen to have a negative influence on the utilization of DFS. Hence attempts to be taken to reduce colour changes of the product that has to be used at the community level in order to increase consumption.

6. It is necessary to enhance the consumption pattern of iron rich food items among this group.

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