# **Original Research Paper**



## **Community Medicine**

### NUTRITIONAL COUNSELING INCREASES THE NUTRITIONAL LEVEL IN CHILDREN AGED 6 TO 24 MONTHS IN UDUPI DISTRICT - A CLUSTER RANDOMIZED CONTROLLED TRIAL

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ABSTRACT OBJECTIVE: To promote the nutritional level of children aged 6 to 24 months through counseling on improved dietary quality and quantity.

METHODS: A community based cluster randomized controlled trial conducted in Udupi taluk. All the children aged 6 months were registered and followed until they completed 24 months of age.

RESULTS: Baseline characteristics of the subjects found to be similar in both the groups. The baseline knowledge assessed in both groups was very much similar. Mean measured weight increased significantly in the intervention group (0.794 kg, p < 0.002) at 24 months of age. Timely introduction of CF (68.6% vs 9.1% - < 0.001), mean age of introducing CF ( $5.2 \pm 1.1$  vs  $3.9 \pm 1.2 - < 0.001$ ) months, introducing family diet at 12 to 15 months (68.6% vs 23.5% - < 0.001). Cereals, pulses, milk and milk products, oil and fat, vegetables and total food consumption was significantly higher in intervention group. The energy and protein intake from complementary foods was significantly higher in intervention group (p < 0.01) at different follow up time points (12 months, 18 months and 24 months).

CONCLUSION: The study findings clearly shows promotion of child growth and complementary feeding practices in developing countries through nutritional counseling will improve the nutritional status of children less than 2 years of age.

KEYWORDS: Nutritional counseling, Complementary feeding, Randomized controlled trial, Child growth

#### INTRODUCTION

Under nutrition is defined as the outcome of insufficient food intake and repeated infectious diseases. It includes being underweight for one's age, too short for one's age (stunted), dangerously thin for one's height (wasted) and deficient in vitamins and minerals (micronutrient malnutrition)<sup>1</sup>. Inadequate nutrition during the first 2 years of life can lead to morbidity in childhood, and is one of the most important preventable risk factors for mortality<sup>2</sup>. Growth faltering occurs commonly among children in developing countries between the age of 6 and 24 months, when complementary foods introduced into their diets<sup>3</sup>. The primary explanations for children's poor growth during this period are insufficient or inappropriate dietary intakes and frequent infections<sup>4,5</sup>.

Complementary foods of appropriate energy and nutrient densities are needed in addition to breast milk to ensure adequate growth for infants aged > 6 months<sup>4</sup>. Protein- Energy -Malnutrition (PEM) remains a major public health problem in most of the developing countries. More than half of world's malnourished children live in India<sup>7</sup>. Sometimes, the lack of awareness and not poverty per se may be the likely cause of faulty infant feeding practices (IFP)<sup>8</sup>. Two controlled trials in (India and China)<sup>9</sup> shows that community-based culturally appropriate nutrition education can improve infant-feeding practices, dietary intake and growth 10. Recent studies have recognized the link between malnutrition and child-feeding practices<sup>11,8, 12</sup>. None of the study showed home based counseling with mothers, considering the age specific recommendations.

# MATERIALS AND METHODS

This study was conducted in the district of Udupi in coastal Karnataka, which is known for its high literacy rates and impressive health indicators comparable to western Developed Nations. Contrary to this situation, studies<sup>13</sup> from the area have reported the prevalence of more than 35% underweight for age among children in the age group of 0 to 24 months. In view of the findings, this cluster randomized controlled

trial was designed to look at how specific strategies could make a difference to the nutritional status of children in the age group of 0 to 24 months. The institutional Review Board approved the study and all the participants provided written informed consent. (Detailed methodology is given elsewhere 14.)

#### **Development of the Intervention Tool:**

A formative research, using qualitative techniques was conducted and<sup>15</sup> based on these findings a health education module was prepared incorporating the WHO, UNICEF recommendations<sup>16</sup> The module was converted into a flip chart for ease of use in the field.

#### Sample size and Randomization:

A two-arm cluster randomized controlled trial was designed in the ICDS (Integrated Child Development Services) project area. For power of 80% and 5% level of significance and an anticipated loss to follow up of 15% during each time point for seven repeated measurements with an intra- cluster correlation coefficient of 0.3 kg and a standard deviation (SD) of 1.09 the calculated sample size was 22. Taking into consideration a cluster design effect of 1.5, the minimum required sample size was 33 families in each group for the study 17,18.

There are 20 circles covering 514 anganwadi centers in the taluk. These were considered as the cluster. For logistic reasons 10 circles which were at a distance of more than 10 km. away from Manipal were excluded from the study. Another four circles were excluded as they were within the field practice area of Kasturba Medical College and this study specifically set outside this area. Of remaining six circles, two circles were included into the study following a simple random sampling procedure. Following this using a simple randomization technique one circle was assigned into the intervention arm and the other into the control area. This ensured the inclusion of seven anganwadis into each arm of the trial. Adequate precaution was taken during the allocation of the anganwadis within the designated circles to prevent contamination.

#### Recruitment of Participants:

All the pregnant mothers who were in last trimester of pregnancy and permanent residents of that area registered in the respective anganwadi were invited to participate in the study. The purpose and details of the study was explained and a written consent obtained from those willing to participate. Following a baseline knowledge assessment the family was recruited for the study within the 2<sup>nd</sup> week of delivery, provided the child fulfilled all inclusion criteria. Information pertaining to birth weight, feeding practices and socio- demographic data was obtained using a pre-tested proforma. Socio-economic status of family was assessed using the Revised Udai Parikh scale. All the children recruited into the study were followed from birth to 24 months of age.

#### Intervention:

A pre-tested questionnaire administered during the third trimester of pregnancy assessed the baseline knowledge of the mothers. The investigator also identified the feeding practices and feeding problems faced by them and focused the intervention on age specific appropriate feeding practices at regular intervals. The intervention counseling commenced during the third trimester of pregnancy and continued after delivery at intervals of 2, 5, 8, 11, 14, 16 and 20 months of age of the child. This was carried out in the local language that was acceptable to the population at large. A booklet was designed in the local language, which contained the nutritional recommendations and recommended feeding practices for children up to the age of two-years. Besides, a pictorial calendar with easily comprehensible and acceptable messages of recommended practices was distributed to all mothers in the intervention group.

#### **Anthropometric measurements:**

Weight was measured using a calibrated and standardized digital electronic weighing machine (with an acceptable error of 10 grams) and length with the help of a standardized infantometer.

#### Outcome measures:

The primary outcome measured was growth of the children in terms of weight, length/height of children.

The secondary outcomes were time of introducing complementary foods, optimal feeding (quality and quantity) practices and 24-hour recall diet survey.

#### Statistical analysis:

Data was entered and analyzed using SPSS version 16.0. We presented the socio-demographic details in the form of percentages and the anthropometric data in the form of mean values and Standard Deviation (SD) at different time points. A Linear Mixed Model was used to see the effect of intervention for repeated measures at unequal time points. Feeding practices are presented in the form of percentages and simple t-test has been performed to see the significance level. The significance levels for the independent variables were fixed at p < 0.05.

#### FLOW DIAGRAM OF STUDY DESIGN Fig. No. 1

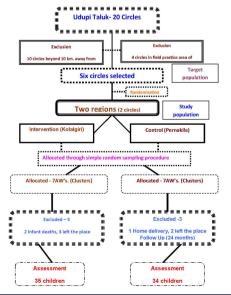


Figure – 1. (Flow diagram) shows the profile of the cluster randomized trial. 40 pregnant mothers in the intervention area and 37 pregnant mothers in control area were registered for the study. Five families in intervention area (2 infant deaths, 3 families migrated), and three families in control area (1 home delivery and 2 families migrated families) were excluded from the study. 35 families in intervention and 34 families in control area were followed up until the child is 2 years of age.

# RESULTS Table – 1 Baseline Characteristics of children in the intervention and control groups

Characteristics	Intervention (No.35)	Control (No. 34)	
Mothers			
Religion / Hindus	34 (97.1)	29 (85.3)	
Socio- Economic Status / Low	11 (31.4)	09 (26.5)	
Middle	23 (65.7)	24 (70.6)	
Mode of Delivery / Vaginal	21 (60.0)	25 (73.5)	
Primegravida	23 (65.7)	23 (67.6)	
Children			
Sex of the child /Male	18 (51.4)	20 (58.8)	
Female	17 (48.6)	14 (41.2)	
Mean birth weight	2858±304	2916±444	
Hospital stay (Mean days)	$6.1\pm2.2$	5.0±1.8	
Base line knowledge of mothers (15 point scale)	7.51 ±3.5	7.38 ±2.9	

The base line characteristics (Table-1) show religion, socio-economic status, mode of delivery and gravida, more or less similar in both the groups. Genders, mean birth weight, hospital stay in days were also show similar in both the groups. Mother's knowledge assessed using a 15 point scale as per the WHO recommended feeding practices was  $7.51\pm3.5$  in intervention were as  $7.38\pm2.9$  in control group very much similar.

Fig. No. 2 Mean Weight (g) of the children at birth to 24 months of age intervention and control groups (P-value < 0.002)



**Fig: no. 2 shows mean weight of children** at different time points. Birth to 6th month children in control group showing better weight gain were as intervention children were showing a study weight gain throughout birth to 2 years. At one year, the mean weight gain was 44 grams, at 18 months 669 grams and at 2 years 736 grams more in intervention group than children in control group. The mean weight gain measured from birth to 2 years, the children in intervention group gained 794 grams more than control group (p-value < 0.002) which is statistically significant.

The mean length of the children at birth was 48.7 cm in intervention group vs. 48.8 cm in control group. At 24 months, both the groups attained 84.2 and 84.3 cm of height respectively. There was no statistically significant difference noted in height gain between the groups.

Table No. 2 Introduction of complementary foods in intervention group compared to control group

Types of complementary foods at different ages	Intervention (n=35) no. (%)	Control (n=34) no. (%)	P – value
Complementary foods			
< 6 months of age	11 (31.4)	30 (90.9)	< 0.0001
At 6 months of age	24 (68.6)		< 0.0001

Mean age of introduction Complementary foods (in months, mean SD)	5.2 ± 1.1	3.9 ± 1.2	0.001
Family diet			
13 to 15 months	24 (68.6)	08 (23.5)	0.001
16 to 18 months	34 (97.1)	23 (67.1)	0.746

#### Chi-Square test used -< 0.05 was considered as significant

**Table No. 2** shows introduction of complementary foods by mothers in intervention and control groups. Timely introduction of complementary foods provides adequate nutrition to the infants for their optimal growth. Among the study subjects 31.4% of mothers in intervention group and 90.9% of mothers in control group introduced the complementary foods before completing 6 months of age (p < 0.001). In intervention and control group 68.6% and 9.1% of children respectively were introduced complementary foods at  $\geq$  6 months of age (p < 0.001).

The mean age of introducing complementary foods in our study was  $5.2\pm1.1$  months in intervention group as compared to  $3.9\pm1.2$  months in control group and the difference between the groups was statistically significant (p < 0.001).

The introduction of family diet, for children after completion of one year (13 to 15 months) in intervention group was 68.6% as compared to 23.5% in control group (p < 0.001). During 16 to 18 months, all most all children (97.1%) in intervention and only 67.1% children in control group were fed from family pot but the difference was not statistically significant.

Table No. 3: Quantity of different types of foods consumed by children at 12 months, 18 months and 24 months of age in intervention group and control group

Age of child and types of	Intervention		Control		P-
foods consumed	`	=35)	(n=34)		value
		n grams	Mean in		
	(5	SD)	grams (SD)		
<b>12 months of age</b> $(n = 35,34)$					
Cereals and millets		(41.9)	78.6	(26.1)	0.100
Pulses	6.6	(7.8)	2.1	(3.8)	0.004
Milk and milk products	340.4	(152.3)	250.3	(143.9)	0.015
Fruits and Vegetables	24.7	(25.1)	15.0	(30.6)	0.155
Fish and meat	3.7	(15.3)		0	
Oil and fats	9.2	(10.4)	2.2	(4.4)	0.001
Other foods	58.5	(54.8)	51.6	(30.4)	0.525
Total food consumed	521.9	(156.6)	399.9	(147.7)	0.002
<b>18 months of age</b> (n 34, 33)					
Cereals and millets	115.50	(36.29)	97.2	(27.2)	0.023
Pulses	9.8	(8.6)	4.5	(6.1)	0.006
Milk and milk products	407.2	(132.29)	330.8	(126.6)	0.019
Fruits and Vegetables	85.2	(63.49)	50.1	(45.9)	0.012
Fish and meat	27.09	(34.84)	14.5	(24.6)	0.001
Oil and fats	14.3	(12.02)	4.4	(7.4)	0.001
Other foods	96.56	(99.94)	63.1	(50.9)	0.036
Total food consumed	738.40	(168.61)	563.1	(136.9)	0.001
<b>24 months of age</b> (n 35, 34)					
Cereals and millets	120.1	(28.4)	111.7	(21.7)	0.175
Pulses	11.7	(9.2)	5.4	(6.1)	0.002
Milk and milk products	452.8	(112.6)	355.7	(133.3)	0.002
Fruits and Vegetables	96.9	(70.7)	73.4	(49.7)	0.116
Fish and meat	51.1	(36.6)	34.1	(40.8)	0.073
Oil and fats	23.7	(23.8)	10.4	(10.6)	0.004
Other foods	108.6	(58.2)	72.8		0.010
Total food consumed	865.2	(159.9)	663.8	(144.7)	0.001

**Table No.3** shows that the total food consumption during second year of life. Intake of pulses, milk and milk products, and oil and fats were significantly higher in children in intervention group as compared to control group at 12 months, 18 months and 24 months of age respectively. Intake of fruits and vegetables, fish, meat and other foods at 18 months of age was also significantly higher in intervention group children (p < 0.01). Total food consumption was higher at 12 months, 18 months and 24 months of age in intervention group of children as compared to control group. The difference was found to be statistically significant (p < 0.001). (The difference between groups was statistically significant, cereals and millets p < 0.015, pulses p < 0.015

and milk and milk products < 0.026 - Mixed ANOVA)

Table No. 4: Dietary intake (calories and proteins) of the children in intervention group and control group

Age of child	Calories (Kcal)		Protein	ıs (g)
	Intervention	Control	Intervention	Control
	(n=35)	(n=34)	(n=35)	(n=34)
	Mean (SD)	Mean (SD)	Mean (SD)	Mean (SD)
At 6 months	276.3 (639)	227.4 (117)	5.1 (3.3)	6.9 (4.3)
At 9 months	640.3 (243)	549.2 (225)	16.1 (5.7)	13.8 (5.2)
At 12 months	841.2 (169) *	644.8 (183)	22.9 (7.2) *	16.8 (5.8)
At 18 months	1107.3 (324) *	807.4 (200)	32.2 (10.5) *	24.3 (7.6)
At 24 months	1196.8 (195) *	932.2 (177)	40.1 (7.8) *	30.9 (8.3)

<sup>\*</sup>p value = < 0.001 (Analysis using Mixed ANOVA)

**Table No.4** shows the mean intake of calories and proteins during the previous 24 hours from non- breast-milk foods consumed by the children at different time points.

The difference in dietary intake of calories between intervention and control group is significantly higher at 12 months, 18 months, and 24 months of age (p < 0.001). There is an increasing trend in calorie intake between intervention and control group. At 6 months the difference was only 48.8 kcal which gradually increased over time at different time points leading to a difference of 300 kcal at 18 months of age.

At  $6^{th}$  month of age, the protein intake in intervention group was slightly less (5.1 grams vs. 6.9 grams) than in control group. From  $9^{th}$  month onwards, the trend of difference in protein intake was increasing in intervention group as compared to control group. The difference was significantly higher at 12 months, 18 months and 24 months of age (p < 0.001).

#### DISCUSSION:

This study demonstrates nutritional intervention at family level interacting with mothers and family members to improve quality and quantity of complementary feeding has a positive impact on the nutritional status of children. The educational intervention greatly improved the weight, timely introduction of complementary foods, quality and quantity of complementary foods.

At the end of 24 months the children in intervention group gained 8655 grams of weight compared to children in control group who gained 7861 grams which was statistically significant. The children in the intervention group at 24 months gained 794 grams more compared to children in control group which shows the positive effect of educational intervention (p < 0.002, Linear Mixed Model analysis). Linear Mixed Model was used to see overall pattern observed in all variables is statistically significant across intervention and control group.

The intervention which lead to change in practices regarding timely initiation of complementary feeding (68.6% vs 9.1%), quality (16.1 grams vs 13.8 grams of protiens) and quantity of complementary foods (640 kcal vs. 549 kcal per day) could be responsible for differential weight gain in the age group of 7 to 9 months. In the age group of 13 to 15 months and 16 to 18 months the different weight gain is best explained by better improvement in feeding practices like continuation of breastfeeding (68.6% vs. 14.7%) and right time of initiation of family diet (68.6% vs. 23.5%) in the intervention and control groups respectively.

Chess K Lutter et al.<sup>19</sup> study reported weight gain between intervention group and control group found to be at different points of time was 162 grams, 319grams, 59grams, 110grams, 36grams and 98 grams during 3 to 6 months, at 6 months, during 6 to 9 months, 9 to 12 months, 12 to 18 months and 18 to 24 months respectively. The difference in weight gain between two groups at 6 months, during 9 to 12 months and 18 to 24 months found to be statistically significant. Our study findings are similar to findings of study conducted by Chess K Lutter et al.<sup>19</sup> in which there is a similar trend of increase in weight gain at different time points. A hospital based study by MJ Mehta et al.<sup>20</sup> documented a mean weight gain of 5.49 kg at the end of one year. Similar findings were observed in our study, where in weight gain during infancy in intervention and control group was 6 kg and 5.9 kg respectively. The study conducted in Baroda by Chinnamma et al.<sup>21</sup> revealed that children who consumed mean addition of food in terms of 150

kcal/child/day to the home diet of children in the experimental group (age 6-24 months) resulted in weight increments which was significantly better than control group (p<0.001).

The mean age of introducing complementary foods in our study was  $5.2 \pm 1.1$  months in intervention group as compared to  $3.9 \pm 1.2$  months in control group and the difference between the groups was statistically significant (p < 0.001). R. Singh et al. 22 in a study conducted in district of Lucknow pointed out the solid foods were introduced at a mean age of 8.2 months and included rice, kheer, porridge, bread, biscuits, boiled eggs, egg yolk, bananas, pudding curd and wheat. A similar type of food items were also introduced by the mothers in our study.

A nutritional surveillance survey conducted in Hubei province by Jing Chen and Douglas et al.23 in China, showed rice was introduced always first in diet. The common foods consumed by infants included rice (60%), eggs (50%), vegetables (35%), soybean (27%) and fruits (20%).

Nita Bhandari et al.24 in a study at Haryana (intervention trial), showed that energy intakes from complementary foods were significantly higher in the intervention group children. At 9 months (mean energy intake  $\pm$  SD: 1556 kJ  $\pm$  1109 in intervention group vs.1025  $\pm$ 866 kJ in control group; p < 0.001) and at 18 months (mean energy intake  $\pm$  SD:  $3807 \text{ kJ vs.} \pm 1527 \text{ vs.} 2577 \text{ kJ} \pm 1058$ ; (p < 0.001). Our study findings show that at 9 months of age mean energy intake of 2679.4 kJ in intervention group compared to control group (2298.1 kJ) was not significant. At 18 months of age, mean energy intake of 4633.2 kJ in intervention group was significantly higher than control group 3378.2kJ; (p < 0.001). The study conducted in Delhi by Nita Bhandari et al.25 showed that the median energy intake from non-breast milk sources higher in the food supplementation group than in the visitation group by 1212 kJ at 26 weeks of age (p < 0.001), 1739 kJ at 38 weeks of age (p <0.001) and 2257 kJ at 52 weeks of age (p <0.001). The nutritional counseling group had higher energy intake ranging from 280 kJ to 752 kJ at different ages (p < 0.05 at all ages). Chinnamma John et al.21 study showed that energy intake per kg body weight was 73 kcal and 62 kcal respectively (6 to 24 months) in the experimental and control groups at the end of the study. Similar results are shown in our study where energy intake/kg body wt. /day was 104 kcal and 86 keal respectively in intervention and control groups at the end of the study. The recommended energy intake from complementary foods at 7 to 9 months, 10 to 12 months and 13 to 24 months is 300 kcal, 480 kcal and 900 kcal respectively. In our study the calorie intake of the children in both the groups was more than the recommended quantity.

The study conducted by Hotz G et al.26 in Malawi, Central Africa, revealed that the amount of complementary foods (g/day) and intake of protein and other macronutrients were significantly higher in children in intervention group compared with control group children. D Kapur et al. 12 in a randomized controlled trial of children aged 9 to 36 months showed that protein consumption at 16 months of age was significantly higher in intervention group than control group (66 grams in intervention group vs. 36 grams in control group p < 0.001).

This study shows dietary intake of fats, calcium, vitamin A, Vitamin C, were also significantly higher in intervention group compared to control group at 12 months, 18 months and 24 months of age (p < 0.001).

#### **CONCLUSION:**

The study findings demonstrate family level counseling will improve the growth of children through improving better feeding practices, quality and quantity of food intake in children less than 2 years of age.

#### **RECOMMENDATIONS:**

The study findings strongly suggest that effective implementation of child nutritional programs through family level counseling concentrating more on 0 to 2 years children by regular home visit and health education will improve their nutritional status.

#### **FUNDING:**

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#### CONFLICT OF INTEREST:

We declare that there is no conflict of interest what so ever.

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