International Journal of Advanced Community Medicine

**E-ISSN: 2616-3594**
**P-ISSN: 2616-3586**
IJACM 2019; 2(2): 88-95
Received: 04-03-2019
Accepted: 06-04-2019

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# Counseling to mothers promotes complementary feeding (CF) practices and growth of children under 2 years of age a cluster randomized control trial

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**DOI:** https://doi.org/10.33545/comed.2019.v2.i2b.12

**Abstract**
**Objective:** To promote complementary feeding (CF) practices and to improve the physical growth of children less than 2 years of age through, counseling mothers and the family members.
**Methods:** A community based cluster randomized controlled trial (CRT) was conducted in Udupi taluk. All the pregnant mothers registered during the third trimester and the newborn children followed until 2 years of age in the selected Anganwadi (AW) centers. Home based counseling was provided to the family at different points of time. Counseling was based on continuation of breastfeeding, complementary feeding and different types of foods, optimal feeding, hygiene and care of sick child. All the newborns were followed until 2 year of age.
**Results:** Baseline characteristics of the subjects found to be similar in both the groups. The baseline knowledge assessed on a 15-point scale, the mean score 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. The mean age of introducing CF, intake of total quantity of food in the form of energy and protein ($p<0.001$) was significantly high in intervention group compared to control group during the second year of life.
**Conclusion:** The study findings clearly show that family level counseling does improve the feeding practices and nutritional status of children less than 2 years of age.

**Keywords:** Counseling, complementary feeding, growth, nutrition, weight gain, quantity and quality of food

## 1. Introduction
Growth faltering occurs commonly among children in developing countries between the age of 6 and 24 months, when complementary foods introduced into their diets for the first time[1]. The primary explanations for children's poor growth during this period are insufficient or inappropriate dietary intake and frequent infections [1, 2]. Complementary foods of appropriate energy and nutrient densities are needed in addition to breast milk to ensure adequate growth for infants after the age the of 6 months [1].
The proportions of underweight, stunting and wasting among under-three children has been reported to be 46%, 38.4% and 19% respectively at the national level [3]. Recent studies have recognized the link between malnutrition and child feeding practices [3, 4, 5]. Sometimes, the lack of awareness and not poverty per se may be the likely cause of faulty infant feeding practices (IFP) [6]. The caregivers might not make the beast use of available resources because of cultural beliefs and practices, lack of knowledge of the best foods for young children even when available at home, and lack appropriate advice [7]. There has been few intervention studies that have been conducted in India and elsewhere wherein educational intervention was carried out through existing health care facility [8-13] and through peer counseling methods [7, 14, 15]. Quite a few studies conducted, providing supplementary feeding of different types at different time [16-25]. None of the study showed home based counseling with mothers and their family members considering the age specific recommendations.

## 2. Material and Methods
**2.1. Study area:** This study conducted in Udupi Taluk of Udupi district in coastal Karnataka. A cluster randomized controlled trial was designed to look at how IYCF

(Infant and Young Child Feeding) strategies could make a difference in the nutritional status of children between 6 to 24 months.
The Institutional Review Committee approved the study and all the participants provided written informed consent.

**2.2. Sample size and Randomization:** A two-arm cluster randomized controlled trial was designed. 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 and a standard deviation (SD) of 1.09kg for weight 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 arm of the study [26, 27].
There were 20 circles covering 514 AW centers in Udupi Taluk with an average of 14 to 24 AW centers in each circle. The circle considered as the cluster. For logistic reasons 10 circles more than 10 km. away from Manipal were excluded from the study. Another four circles within the field practice area of Kasturba Medical College were excluded. This study was specifically set outside this area. Of the remaining six circles, two circles selected using a simple random sampling procedure. A simple randomization technique used to assign each circle into the intervention arm and control arm. The circle selected for the intervention arm had 24 AW's and circle selected for control arm had 16 AW's. The distance between two circles was more than 10 kms. This reduced the chances of contamination during the study period. With a prevailing birth rate of 10 to 12 / 1000 population, around five to six deliveries in 6 months time were expected. Thus, it was decided to select seven AW centers in each arm to meet the required number of subjects for the study. In the second stage, all the AW's in both the circles separately listed alphabetically and seven Awe's were allocated to each arm using simple random sampling method.

**2.3. Development of the Intervention Tool:** A formative research, using qualitative techniques was conducted to obtain information on community characteristics, nutritional status and prevalent feeding practices, cultural beliefs, norms and childcare practices [28]. Based on these findings a health education module was prepared incorporating the WHO and UNICEF recommendations [29]. The module converted into a flip chart for ease of use in the field.

**2.4. Recruitment of Participants:** In the selected AW centers of both groups, all the pregnant mothers who were in last trimester of pregnancy and permanent residents of that area were registered and 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. Baseline knowledge assessment done, using a pre-tested questionnaire and the family was recruited for the study. Within the 2nd week of delivery, all the children who fulfilled the inclusion criteria were included in the study. Information pertaining to birth weight, length/ height feeding practices and socio- demographic data was obtained using a pre-tested perform. Using the Revised Udai Parikh scale [30].
Socio-economic status of the family was assessed. All the children recruited into the study and followed from birth to 24 months of age.

**2.5. Intervention:** Based on the results of formative research a booklet 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. 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 on age specific appropriate feeding practices at regular intervals in the intervention arm. Timely introduction of complementary foods, feeding adequate density and nutritious foods, unhealthy practices like introducing water, additional milk before 6 months and starting the family diet was the focus of the visit. The intervention counseling commenced during the third trimester of pregnancy and continued after delivery at 2, 5, 8, 11, 14, 16 and 20 months of age of the child. Intervention was in the local language acceptable to the population at large. The women in the control arm were assessed in the similar manner as in the intervention arm accept for the delivery of the intervention.

**2.6. 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.

**2.7. Outcome measures:** The primary outcome measured was growth of children (weight, length/height). The secondary outcome was CF practices in terms of initiation of complementary foods, feeding additional liquids before 6 months (other than breast milk) initiation of family diet and frequency of feeding.

**2.8. Statistical analysis:** Data entered and analyzed using SPSS version 15.0. 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 used to see the effect of intervention for repeated measures at unequal time points. Feeding practices presented in the form of percentages and simple t-test performed to see the significance level. The significance level for the independent variables fixed at $p<0.05$.

## 3. Results

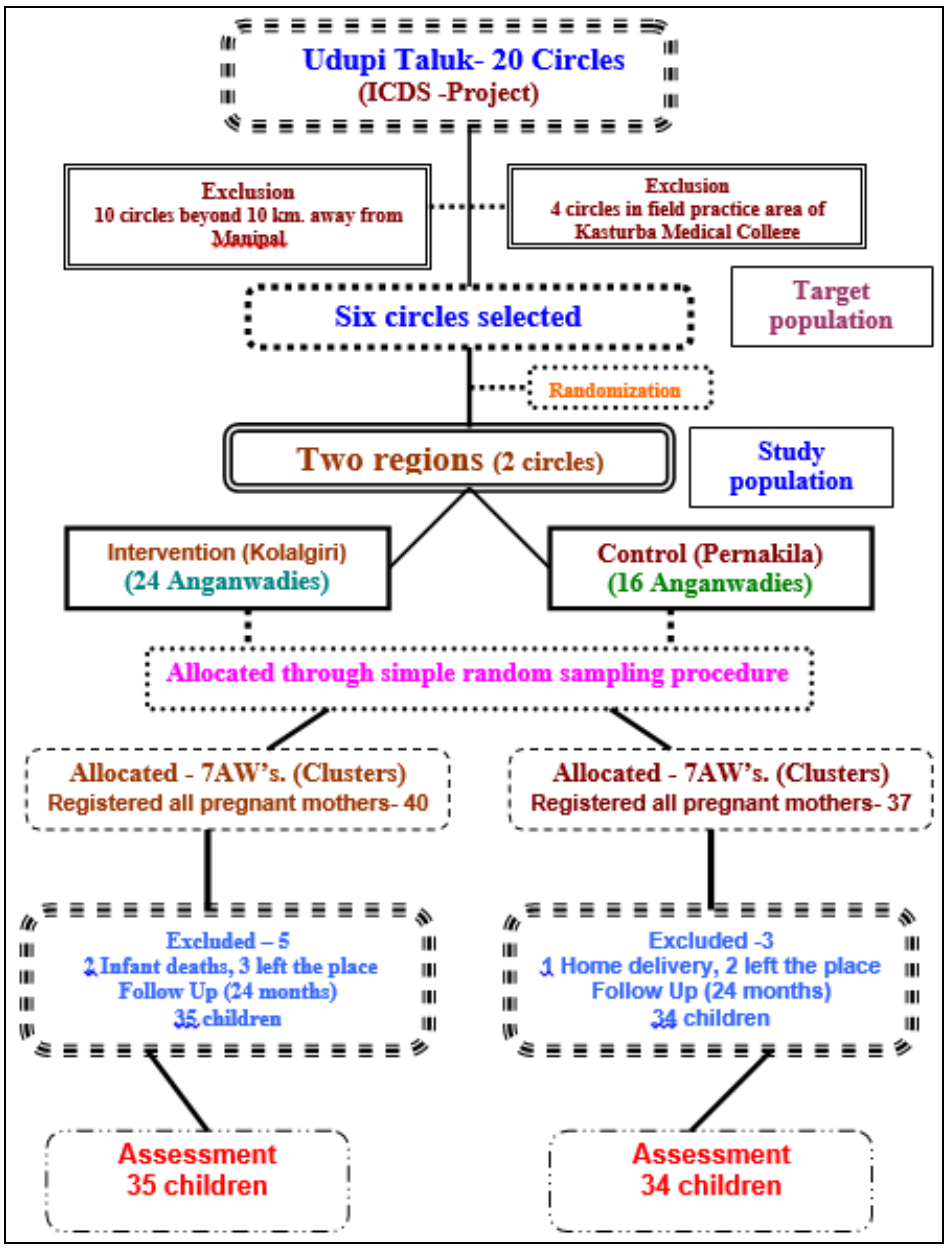


**Fig 1:** Flow diagram of study design

Fig. No. I (Flow diagram) show the profile of the cluster-randomized trial. 40 pregnant mothers in the intervention area and 37 pregnant mothers in control area were recruited for the study. Five families in intervention area (two infant deaths, 3 families migrated), and three families in control area (one home delivery and two families migrated) were excluded from the study. 35 families in intervention and 34 families in control area were followed up until the child was 2 years of age.

**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) |
| Prime gravida | 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 ±2.2 | 5.0 ±1.8 |
| Base line knowledge of mothers (15 point scale) | 7.51 ±3.5 | 7.38 ±2.9 |

The base line characteristics with respect to religion, socio-economic status, mode of delivery, gravida, gender, mean birth weight, hospital stay in days as seen in Table: No. I. 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 ±3.5 in intervention were as 7.38 ±2.9 in control group very much similar.

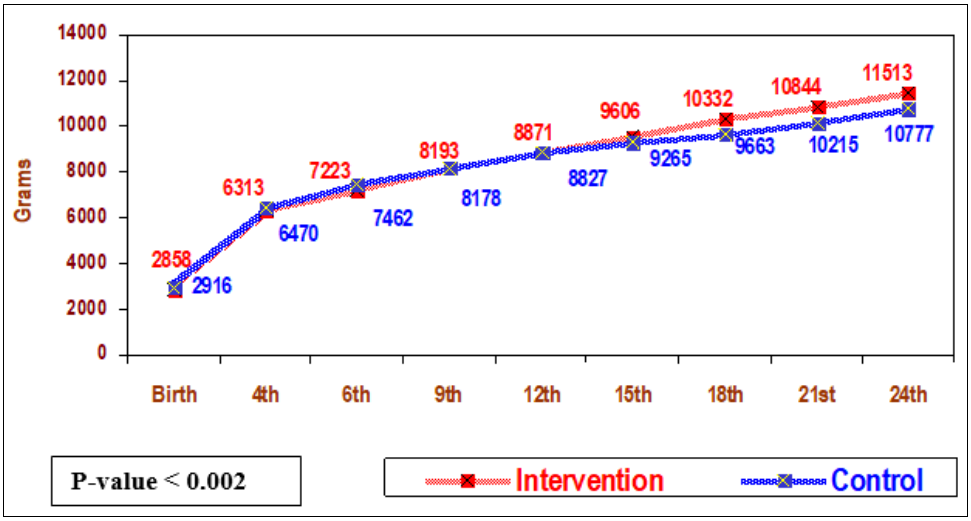


**Fig 2:** Mean Weight (g) of the children at birth to 24 months of age (intervention and control groups)

Fig. No. II demonstrates the impact of intervention in a period of 2 years shows the 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 through out 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 from birth to 2 years among children in intervention group was 794 grams more than control group (p-value < 0.002) which is statistically significant. As seen in the graphs until 15 month of age the growth of the children in both the groups was same. The impact of the intervention started taking effect after the 15th month.

The mean length of the children at birth was 48.7 cm in intervention group and 48.8 cm in control group. At 24 months, the mean length measured to be 84.2 and 84.3cm respectively and was statistically not significant difference.

**Table 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) | 04 (9.1) | < 0.0001 |
| **Water** | | | |
| < 4 months of age | 11 (31.4) | 21 (63.6) | 0.008 |
| 4 to < 6 months of age | 02 (5.7) | 10 (30.3) | 0.006 |
| At 6 months of age | 22 (62.9) | 02 (6.1) | < 0.0001 |
| **Milk** | | | |
| < 4 months of age | 05 (14.3) | 14 (41.2) | 0.019 |
| 4 to < 6 months of age | 04 (11.4) | 10 (30.3) | 0.012 |
| At 6 months of age | 26 (74.3) | 10 (30.3) | 0.001 |
| 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. II. shows in the intervention group 31.4% of the mothers introduced complementary foods before 6 months as compared to 90.9% in the control group. Similarly 68.6% of mothers in intervention group and 9.1% of mothers in control group introduced complementary foods after completing 6 months of age. Both these were found to be statistically significant at a p – value < 0.001.

The mean age of introducing complementary foods was 5.2 ± 1.1 months in intervention group as compared to 3.9 ± 1.2 months in control group and this difference was statistically significant ($p$<0.001).

Ideally, exclusively breastfed infants do not require any artificial feeds until 6 months of age. The study results showed before 4 months of age 31.4% of mothers in intervention group and 63.6% of mothers in control group started giving water ($p$<0.008), and 14.3% and 41.2% ($p$<0.019) of mothers in intervention group and control group respectively introduced additional milk (cow's milk) to their infants.

At 4 to 6 months of age, 5.7% of mothers in intervention group 30.3% ($p$<0.006) of mothers in control group introduced water and 11.4% in intervention group and 30.3% ($p$<0.012) of mothers in control group introduced cow's milk to their infants.

After completion of 6 months of age 62.9% of intervention group and 6.1% ($p$<0.001) of control group mothers introduced water and 74.3% and 30.3% ($p$<0.001) of mothers in intervention group and control group introduced additional milk respectively.

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

Frequency of feeding at I year and later in the second year of life is gradually increasing in both intervention and control groups which found there is no significant difference between the groups.

**Table 3:** Twenty four hours frequency of intake of complementary foods and non- breast milk energy (g) and proteins (g) by children at 12, 18 and 24 months of age (intervention and control groups)

| Types of complementary foods at different ages | Intervention (N0 = 35) | Control (N0 = 34) |
|---|---|---|
| **At 12 months** | | |
| Meal frequency | 4.54 | 4.06 |
| Total energy | 841.26* | 644.54 |
| Proteins | 22.93* | 16.82 |
| **At 18 months** | | |
| Meal frequency | 5.5 | 5.18 |
| Total energy | 1107.35* | 874.1 |
| Proteins | 32.21* | 24.30 |
| **At 24 months** | | |
| Meal frequency | 6.14 | 5.74 |
| Total energy | 1196.89* | 932.29 |
| Proteins | 40.12* | 30.95 |

* p value = < 0.001 (Analysis using Mixed ANOVA)

From nine month onwards, the total energy consumption and protein intake (Table: No. III) by the children in intervention group was higher than children in control group at all-time points. However, the difference in dietary intake of total calories and proteins between intervention and control group was significantly higher at 12 months, 18 months and 24 months of age ($p$<0.001).

## 4. Discussion

This study demonstrates a culturally adoptable educational intervention at family level interacting with mothers and family members on complementary feeding practices 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, frequency of feeding and optimal feeding practices.

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 educational 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 timely initiation of family diet (68.6% vs. 23.5%) in the intervention and control groups respectively.

Chess K Lutter *et al*. [31] study reported weight gain between intervention group and control group found to be at different points of time was 162 grams (3 to 6 months), 319grams (6 months), 59grams (6 to 9 months), 110grams (9 to 12 months), 36 grams (12 to 18 months) and 98 grams during 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*. [31] 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*. [32] 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 mean age of introducing complementary foods in our study was 5.2 ± 1.1 months in intervention group as compared to 3.9 ± 1.2 months in control group and the difference between the groups was statistically significant ($p$<0.001). R.Singh *et al*. [33] in a study conducted in the 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. Kumar S. *et al*. [34] in a study conducted in New Delhi pointed out that one quarter of the children less than 3 months of age received animal milk and 44.6% of children between 3 to 6 months of age. The mean age of introducing complementary foods was 10.3 months, where as among one third of children introduction of complementary foods delayed beyond one year of age. Marianne S. Jakobsen *et al*.

[35] conducted an intervention study in Africa which revealed that water was introduced significantly, later in the intervention group compared to control group ($p$<0.003). The study conducted by Kulsoom U. *et al*. [36] in Lahore pointed out 55.4% of mothers fed water to their newborn children, which they found very essential from the very first day of birth. The study designed to determine the need for water supplementation by HPS Sachdev *et al*. [37] revealed that 97% of 34 nurses and 63% of 70 doctors advocated the need for supplementation of water to infants aged 1 to 4 months of age.

The study conducted in Baroda by Chinnamma *et al*. [38] revealed that children who consumed mean additional food in terms of 150 kcal/child/day to the home diet of children in the experimental group (6-24 months) resulted in weight increments which was significantly better than control group ($p$<0.001). Nita Bhandari *et al*. [39] 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 ± SD: 1556 kJ ± 1109 in intervention group vs.1025 ±866 kJ in control group $p$<0.001) and at 18 months (mean energy intake ± SD: 3807 kJ vs. ± 1527 vs. 2577 kJ ±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. However 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*. [40] 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*. [38] 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 kcal respectively in intervention and control groups at the end of the study. In intervention trial conducted by Nita Bhandari *et al*. [41] in Haryana, the results demonstrated that the proportion of children consuming the recommended calories for 18 months of age increased significantly with increasing number of contacts at which counseling was received ($\chi^2$ value for trend, p = 0.004). Our study also showed that the intake of calories increased as the counseling visits increased. The study conducted by Hotz G *et al*. [42] 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*. [6] 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). Our study showed similar results in protein intake after 12 months of age in intervention group found highly significant.

## 5. Conclusion

The study findings demonstrated that counseling to mothers would improve the growth of children through improving better feeding practices, quality and quantity of food intake in children less than 2 years of age.

## 6. Recommendations

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

## 7. Acknowledgement

We deeply appreciate the co-operation of parents and the little children who participated in the study. We are also thankful to the CDPO, the anganwadi staff members, and the supervisors for their support.

## 8. Funding Agency

ICICI Bank (Social Initiative Group) has provided the required funding to carry out the study. We are very much grateful for the ICICI bank authorities and all those supported to avail the funding.

## 9. Conflict of interest

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

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