

## Research Article

# Impact of family level counselling on breast feeding practices and weight gain: a community based cluster randomized controlled trial

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## ABSTRACT

**Background:** Objective of the study was to assess the effectiveness of the family level counseling to mothers on breastfeeding practices and weight gain in children.

**Methods:** A community based cluster randomized controlled trial was conducted in Udupi District in Karnataka State, South India. All the children born to pregnant mothers registered in the third trimester were followed until 2 years of age in selected Anganwadi (AW) centres.

**Results:** Baseline characteristics of the subjects were found to be similar in both intervention and control groups. The baseline knowledge assessed on a 15-point scale showed similar mean score in both groups. Mean measured weight increased significantly in the intervention group (0.794 kg,  $p < 0.002$ ) at 24 months of age. At 24 months more babies in intervention group were receiving breastfeeding than control group (68.6 % vs. 14.7 %, 95 % CI 2.01 – 10.80, and  $p < 0.001$ ). Frequency of breast feeding at 4 months was 77.1 % in intervention and 57.8 % in control group ( $p < 0.0001$ ) while at 6 months it was 77.1 % in intervention and 33.3 % in control group ( $p < 0.0001$ ). The breastfeeding position assessed on a ten-point scale showed mothers in intervention group followed more than 7 correct positions than control group at birth, 4 months and 6 months of age ( $p < 0.001$ ).

**Conclusions:** The study shows promotion of child nutrition and breastfeeding practices in developing countries through family level counselling (IYCF strategy) will improve the nutritional status of children less than 2 years of age.

**Keywords:** Child growth, Exclusive breastfeeding, Breastfeeding initiation, Pre-lacteal feeds, Continuation of breastfeeding, Frequency of breastfeeding

## INTRODUCTION

Breastfeeding is a natural and traditional infant feeding practice throughout the world. Pre-modern societies were known to have a high incidence and long duration of breastfeeding. In modernizing societies such as India,

newly emerging social forces are leading to the breakdown of age-old custom that adversely affects certain practices like breastfeeding<sup>1</sup>.

It is well documented that breastfeeding improves child survival by providing protection against infectious

diseases and malnutrition for the baby and some contraceptive effect for the mother.<sup>2,3</sup>

Breast milk is the perfect food for infants in the first six months of life. It has all the nutrients an infant requires to maintain optimal health and growth<sup>4</sup>. Exclusive breastfeeding is a critical child survival strategy, important in preventing and reducing childhood morbidity and mortality.<sup>5</sup> WHO recommends infants should be exclusively breastfed for the first six months of life to achieve optimal growth, development and health. Thereafter to meet their evolving nutritional requirements, infants should receive nutritionally adequate and safe complementary foods while breastfeeding continues for up to two years of age or beyond.<sup>6,7</sup>

Improving breastfeeding practices requiring behaviour changes is recognized in the Global Strategy for Infant and Young Child Feeding (IYCF), which includes community – based interventions as one of the new operational targets. Several randomized studies have demonstrated that the promotion of exclusive breastfeeding can be increased by counseling.<sup>8</sup> A systematic review of the literature on the optimal duration of exclusive breastfeeding concluded that there is no advantage to introducing complementary feeding before the age of six months. This review showed that children who were exclusively breastfed for six months in developed as well as developing countries – showed no deficit in weight or length gain between three and seven or more months of age compared to those who were not exclusively breastfed.<sup>9</sup>

Two strategies have been successful in the promotion of exclusive breastfeeding: the Baby Friendly Hospital Initiative, which increased the likelihood of exclusive breastfeeding in Belarus, where most births take place in health facilities, and the use of peer counsellors in settings where most babies are delivered at home. Promotion of exclusive breastfeeding through existing primary health care services in the state of Haryana in India showed reduction in the risk of diarrhoea and no growth faltering.<sup>10</sup>

Counselling has an inevitable role in successful and sustained exclusive breastfeeding along with early initiation of breastfeeding. Therefore, this study was planned to assess the effect of counselling to mothers on breastfeeding practices, especially early initiation and sustained exclusive breast feeding, prelacteal feeds, feeding colostrum and duration of breastfeeding and weight gain. In view of these findings this cluster randomized controlled trial was designed to look at how specific strategies like breastfeeding practices could make a difference in the nutritional status of children aged 0 to 24 months.

## METHODS

### *Study area*

This study was set 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 from the area have reported prevalence of more than 35% underweight for age among children in the age group of 0 to 24 months.<sup>11</sup>

### *Development of the intervention tool*

A formative research, using qualitative techniques was conducted to obtain information on community characteristics, nutritional status, prevailing feeding practices, cultural beliefs, norms and childcare practices.<sup>12</sup> Based on these findings a health education module was prepared incorporating the WHO, UNICEF recommendations.<sup>13</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 and a standard deviation (SD) of 1.09 kg 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.<sup>14,15</sup>

There were 20 circles covering 514 AW centers in the taluk with 14 to 24 AW centers in each circle. Each circle was considered as a cluster. For logistic reasons 10 circles at a distance of more than 10km. from Manipal were excluded from the study. Another 4 circles were excluded as they were within the field practice area of Kasturba Medical College and this study was specifically set outside this area. Of remaining six circles, two circles were selected using a simple random sampling procedure. A simple randomization technique was used to assign each circle into the intervention arm and control arm. The circle selected for the intervention arm had 24 AW's and the circle selected for control arm had 16 AW's. The distance between the two circles was 10 kms. This reduced the chances of contamination during the study period. With a prevailing birth rate of 10 to 12/1000 populations, around five to six deliveries could be expected in six months' time in one AW area. Thus it was decided to select seven AW centers to meet the required number of subjects for this study. In the second stage all the AW's in both the circles were alphabetically listed separately. Seven AWs were allocated to each arm using simple random sampling method.

### **Recruitment of participants**

In the selected AW centers of both groups all the pregnant mothers who were in last trimester of pregnancy who fulfilled the inclusion criteria (mother's permanently residing in the 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 was done using a pre-tested questionnaire. Within the 2nd week of delivery, all the children who fulfilled the exclusion criteria (child with congenital malformation, preterm babies, home delivery and birth weight is not available) were included in the study. 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 Uda Parikh scale. All infants recruited into the study were followed from birth to 24 months of age.

### **Intervention tool**

Based on the results of formative research 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 also distributed.

### **Delivery of intervention**

The researcher attended the training program on IYCF Training from BPNI for 7 days and qualified as IYCF counseling specialist. Researcher himself delivered home based intervention to mother and family members at their residence in the intervention group. Intervention was based on individual counseling to family members with help of flip chart. The intervention counseling commenced during the third trimester of pregnancy and was continued after delivery at 2, 5, 8, 11, 14, 16 and 20 months of age of the child. This was carried out in the local language to be acceptable to the population at large.

### **Intervention arm**

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.

### **Control arm**

The women in the control arm were assessed in the similar manner as in the intervention arm except for the delivery of the intervention.

### **Anthropometric measurements**

Child 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 to the nearest error of 1cm.

### **Outcome measures**

1. The primary outcome measure was weight gain at 2 years of age.
2. The secondary outcomes were improvement in breastfeeding practices like initiation, exclusive breastfeeding, duration and frequency of breastfeeding.

### **Statistical analysis**

Data was entered and analyzed using SPSS version 15.0 (SPSS South Asia). The socio-demographic details are presented using percentages and the anthropometric data at different time points using mean and Standard Deviation (SD). A Linear Mixed Model was used to see the effect of intervention for repeated measures at unequal time points. Feeding practices are presented as percentages and chi-square-test has been performed to see the significance level fixed at  $< 0.05$  for independent variables.

## **RESULTS**

A total of 77 pregnant women (Figure 1) and their families were recruited for the study out of which 40 were assigned to the intervention group and 37 to the control group. Five families in intervention area (2 infant deaths, 3 families migrated) and three families in control group (1 home delivery, 2 families migrated) were excluded from the study, 35 in intervention and 34 in control area were followed up until the child was 2 years of age.

As seen from (Table 1) both the groups appears to be similar in the baseline characteristics related to religion, socio-economic status (SES), mode of delivery, gender, birth weight, hospital stay in days, and mothers knowledge assessed at third trimester using a 15 point scale as per the WHO recommended feeding practices.

The children in the intervention group at 24 months (Table 2) gained 794 grams more compared to children in control group (weight at 24moths minus birth weight) which demonstrated the positive effect of educational intervention ( $p < 0.002$ , Linear Mixed Model analysis). The intervention group witnessed a 10.1% excess weight gain over control group as anticipated in the power calculation.

Among the mothers who had normal vaginal delivery (Table 3) 65.7% of mothers in intervention group and 67.6% mothers in control group initiated breast-milk

within first hour of birth. Mothers who underwent caesarean section initiated within 4 hours of delivery were more or less similar in both groups. No significant difference was observed in initiation of breastfeeding between the groups (20% vs. 17.7%) among those

underwent caesarian. Only 14.5% of mothers in intervention group (3 mothers had given lactogen milk and 2 mothers glucose water) as against 26.5% of mothers in the control group (lactogen milk) gave pre-lacteal feeds.

**Table 1: Baseline characteristics of children and mothers.**

Characteristics	Intervention group (n=35) No (%)	Control Group (n=34) No (%)	P -Value
<b>Religion</b>			
Hindu	34 (97.1)	29 (85.3)	0.081
Christian	01 (2.9)	05 (14.7)	
<b>Socio Economic Status (SES)</b>			
Low	11 (31.4)	09 (26.5)	0.902
Middle	23 (65.7)	24 (70.6)	
High	01 (2.9)	01 (2.9)	
<b>Mode of Delivery</b>			
Vaginal delivery	21 (60.0)	25 (73.5)	0.233
Caesarian section	14 (40.0)	09 (26.5)	
<b>Parity</b>			
Primi gravid	24 (68.6)	23 (67.6)	0.934
Multi gravid	11 (31.4)	11 (32.4)	
<b>Gender</b>			
Male	18 (51.4)	20 (58.8)	0.537
Female	17 (48.6)	14 (41.2)	
<b>Anthropometry</b>			
Birth weight, grams, (mean, $\pm$ SD)	2858 $\pm$ 305	2916 $\pm$ 444	0.531
Birth length, cm's, (mean, $\pm$ SD)	48.7 $\pm$ 1.64	48.8 $\pm$ 1.75	0.791
<b>Duration of hospital stay</b>			
Duration of hospital stay after delivery in days (mean $\pm$ SD)	6.1 $\pm$ 2.2	5.0 $\pm$ 1.8	0.028
<b>Baseline knowledge</b>			
score of mothers (mean, $\pm$ SD)	7.51 $\pm$ 3.5	7.38 $\pm$ 2.9	

**Table 2: Weight of children (in grams) in intervention group compared to control group at different time points.**

Age of the child	Birth Weight	4 <sup>th</sup> month	6 <sup>th</sup> month	9 <sup>th</sup> month	12 <sup>th</sup> month	15 <sup>th</sup> month	18 <sup>th</sup> month	21 <sup>st</sup> month	24 <sup>th</sup> month
<b>Intervention</b>									
No = 35	2858	6313	7223	8193	8871	9606	10304	10844	11513
Mean $\pm$ SD	$\pm$ 305	$\pm$ 689	$\pm$ 923	$\pm$ 1020	$\pm$ 1033	$\pm$ 1214	$\pm$ 1604	$\pm$ 1595	$\pm$ 1691
<b>Control</b>									
No = 34	2916	6470	7462	8178	8827	9265	9686	10215	10777
Mean $\pm$ SD	$\pm$ 444	$\pm$ 1203	$\pm$ 1377	$\pm$ 1209	$\pm$ 1331	$\pm$ 1456	$\pm$ 1564	$\pm$ 1502	$\pm$ 1565

During the fourth month, 71.4% and 48.5% of children in intervention and control group respectively were exclusively breastfed. At six months, a statistically significant difference ( $p < 0.001$ ) in the number of children exclusively breastfed was noticed in the intervention group (68.6%) and in control (30.3%) group.

Mothers continuing to breastfeed the infant at 1 year of age were similar (94.3% vs. 97.1%) in intervention and control group children respectively. Continuation of breast feeding till 2 years of age was practiced by 68.6% of mothers in intervention group while only 14.7% ( $p < 0.001$ ) of mothers in control group, which was statistically significant.

Frequency of breast-feeding (Table 4) in 24 hours at different point of time during the follow-up was higher in intervention group. At 4<sup>th</sup> month 77.1% in intervention group and 57.8% in control group, and at 6<sup>th</sup> month

77.1% and 33.3% mothers respectively were breastfeeding more than 10 times per day ( $p < 0.001$ ) which was highly significant.

**Table 3: Breastfeeding practices in intervention group compared with control group (4th, 6th and 24th month).**

Breastfeeding practices	Intervention (n=35) No (%)	Control (n=34) No (%)	P – value
Initiation of breastfeeding (n 35, 34)			
Within 1 hour of delivery	23 (65.7)	23 (67.6)	0.996
1 to 4 hours of delivery	07 (20.0)	06 (17.7)	
Pre-lacteal feeds given (n 35, 34)	05 (14.5)	09 (26.5)	0.169
Exclusive breastfeeding			
At 4 months of age (n 35, 33)	25 (71.4)	16 (48.5)	0.046
At 6 months of age (n 35, 33)	24 (68.6)	10 (30.3)	0.001
Continuation of breastfeeding (n 35, 34)			
At 1 year of age	33 (94.3)	33 (97.1)	0.001
2 years and beyond	24 (68.6)	05 (14.7)	

Chi – Square test used :  $<0.05$  was considered as significant

**Table 4: Breast feeding frequency and positioning in intervention group compared to control group.**

Breast feeding practices	Intervention (n=35)		Control (n=34)		P-value
	Mean	SD	Mean	SD	
Breast feeding frequency/day					
10 or more (at birth) (I= 35, C= 34)	31 (88.6)		22 (64.7)		0.019
10 or more (at 4 <sup>th</sup> month) (I= 35, C= 33)	27 (77.1)		19 (57.8)		0.034
10 or more (at 6 <sup>th</sup> month) (I= 35, C= 33)	27 (77.1)		1 (33.3)		0.001
Correct breast feeding position (10 point scale)					
Score 7 or more (at birth) (I=35, C= 34)	12 (34.3)		03 (8.8)		0.001
Score 7 or more (at 4 <sup>th</sup> month) (I=35, C=33)	14 (40)		03 (9.1)		0.001
Score 7 or more (at 6 <sup>th</sup> month) (I= 35, C= 33)	14 (40)		03 (9.1)		0.001

Chi – Square test used –  $<0.05$  was considered as significant

For an optimal breastfeeding, correct breastfeeding position is very much important. During the counseling session, mothers were explained clearly 10 correct position and attachment to be followed to feed the child optimally, through a flip chart. The information gathered and few observations made during the home visits showed that mothers practicing more than seven correct positions were higher in intervention group. At birth (34.3% vs. 8.8%,  $p < 0.001$ ), during 4<sup>th</sup> month (40% vs. 9.1%,  $p < 0.001$ ) and at 6<sup>th</sup> month (40% vs. 9.1%,  $p < 0.001$ ) in intervention group compared to control group was found statistically significant.

## DISCUSSION

This study demonstrates that a culturally adoptable educational intervention at family level interacting with mothers and family members on breastfeeding practices has a positive impact on the nutritional status of children. The educational intervention greatly improved the

breastfeeding practices such as exclusive breastfeeding until 6 months of age. Our study results showed that intervention group children gained 794 grams more at the end of 2 years than control group ( $p < 0.002$ ). Onyango AW et al a prospective cohort study showed children in the longest-duration breastfeeding group gained 3.4 cm ( $p=0.0001$ ) and 370 g ( $p=0.005$ ) more than those in the shortest duration group, and 0.6 cm ( $p=0.0015$ ) and 230 g ( $p=0.038$ ) more than children in the intermediate group.<sup>16</sup> The follow-up study by M J Mehta et al in civil hospital Surat, documented infants gained 5.49 kg at the end of two years.<sup>17</sup> In contrast, a randomized controlled trial conducted by Nita Bhandari et al in Haryana the trained health workers counsel the mothers for exclusive breastfeeding at multiple opportunities showed no significant differences in mean weight and length between groups.<sup>10</sup>

This study showed 85.7% of mothers in intervention group and 85.3% of mothers in control group initiated

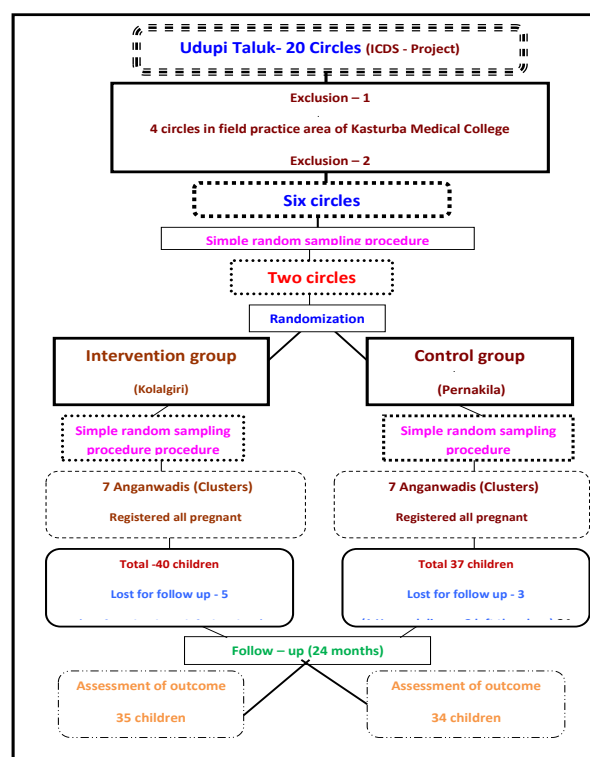


breast milk within recommended time of birth (if normal delivery within 1<sup>st</sup> hour of delivery and if caesarian within 4 hours) to their infants. A previous KAP study conducted by Shalini et al. in this area showed only 32% mothers felt breast milk to be the first feed.<sup>18</sup> Ruksana Haider et al. study in Dhaka showed a significantly higher (64% and 15%) proportion of mothers initiating breast milk within an hour of birth using a peer counseling.<sup>19</sup> Multi centric community-level behavior change study to improve breastfeeding practices implemented in Bolivia, Ghana, and Madagascar documented timely initiation of breastfeeding (within 1 hour of birth) increased from 56% to 74% ( $p < 0.001$ ) in Bolivia, 32% to 49% ( $p < 0.05$ ) in Ghana and 34% to 78% ( $p < 0.001$ ) in Madagascar.<sup>20</sup> Cynthia PG et al review the summary of available specific interventions intended to improve four key breastfeeding behavior showed, in follow up group 60% initiated breastfeeding within 1 hour of delivery compared to 3% in control group (average time was 6.7 hours in the control group and 2.8 hours in the intervention group  $p < 0.001$ ).<sup>21</sup> Lassi ZS conducted a meta-analysis of studies reporting initiation of breastfeeding within an hour of birth (early breastfeeding), which showed that interventions consisting of antepartum newborn care and breastfeeding education to mothers doubled the rates of initiation of breastfeeding.<sup>22</sup> Our study shows initiation of breastfeeding within one hour of life is culturally accepted in this area and there is no significant difference between the two groups. A cross sectional study conducted by Chandrasekhar TS et.al in Nepal showed 72.7%, Dinesh Kumar et al study 17.4% and Abhusuleh Shariff at Bangalore documented 32% of mothers initiated breast milk within 1 hour of birth to their infants.<sup>1,23,24</sup>

Mothers exclusively breastfeeding their children at 6 months of age in intervention group compared to control group was significantly higher in the present study. The KAP study conducted in the area showed mothers consider 3 to 5 months to be the optimal duration of exclusive breastfeeding.<sup>18</sup>

Nita Bhandari study documented 79% in intervention group and 48% in control group mothers exclusively breastfeeding at 3 months ( $p < 0.001$ ).<sup>10</sup> A systematic review by Haroon et al out of 66 studies 27 were conducted in developing countries shows educational interventions significantly increased EBF rates at day 1 by 43% (RR: 1.43, 95% CI: 1.09-1.87), at <1 month by 30% (RR: 1.30, 95% CI: 1.19-1.42) and at 1-5 months by 90% (RR: 1.90, 95% CI: 1.54-2.34).<sup>25</sup> Michael SK et al. study shows infants from the intervention sites were more likely to be exclusively breastfed at 3 months (43.3% vs. 6.4%;  $P < 0.001$ ) and at 6 months (7.9% vs. 0.6%;  $P = 0.01$ ).<sup>26</sup> Valdes V. et al. at 6 months, 32% of the infants in the control group and 67% of those in the intervention group were being exclusively breastfed ( $p < 0.0001$ ).<sup>27</sup> Similar results were reported from our intervention study. Cross sectional study by Sinha A. et al shows 83% at 6

months of age, CR Banapurmath et al. study documented 94.1 % at one month and only 26.8% at 6 months of age, Onayede AA et al. study reveals that 76.5% at 6 months of age.<sup>28-30</sup>



**Figure 1: Consort diagram of study design.**

Information obtained from mothers shows 14.5% of children in intervention and 26.5% of children in control group were deprived of breast milk as their first feed and received lactogen milk and glucose water in this study. Ruksana Haider et al. study showed 31% of mothers in intervention group and 89% of mothers in control group fed prelacteal feeds to their newborn infants.<sup>19</sup> Cynthia PG. et al. review showed 96% of the control group used prelacteal feeds whereas only 43% of the early follow-up group did so ( $p < 0.001$ ). In the late follow-up group, 97% of the mothers who did not receive health education used prelacteal feeds, compared with 42% of those who received health education.<sup>21</sup> Few cross sectional studies showed majority of mothers feeding prelacteal feeds to their children in contrast our study shows a majority of mothers were not feeding any prelacteal feeds.<sup>1,31-34</sup>

The initial milk, which is thick and slightly yellowish, called colostrum, is very essential for, the newborn baby. All the mothers in both the groups had given colostrums for their newborn babies. Cynthia PG et al review reported in the intervention groups, 33% of those in Group A (lectures) and 43% of those in Group B (pamphlets) fed colostrum exclusively.

An additional 23% of those in Group A and 10% in Group B fed some colostrum as well as honey/water.

None of the mothers in the control group fed colostrum, even with supplements.<sup>21</sup> The cross sectional studies conducted by Kulsoom et al. showed 65.4%, Katiyar GP et al in Varanasi showed 90% of children not received colostrum; Dinesh Kumar et al. showed only 34.8% children received colostrum to their newborn.<sup>24,35,36</sup>

WHO recommends breastfeeding should be continued till two years of age or beyond.<sup>6</sup> In our study 68.6% of mothers continued breastfeeding at 2 years of age. WHO, UNICEF, Innocenti Declaration recommends children should continue to be breastfed, while receiving appropriate and adequate complementary foods, for up to two years of age or beyond.<sup>37</sup> Anne M. et al. study suggests breastfeeding should continue as long as mutually desired by mother and child.<sup>38</sup> Nita Bhandari et al. study pointed out two third of mothers stopped breastfeeding before one year of age.<sup>10</sup> A systematic review of six studies concluded that evidence on the medium-term effects of breastfeeding up to two years of age or beyond is scarce and contradictory; hence, further research is needed regarding this practice.<sup>39</sup> Shalini C. et al. study documented 78.5% of women view that breastfeeding should be continued beyond one year of age.<sup>18</sup> Few cross sectional studies conducted showed only 54.3% of mothers until one year of age by Kulsoom et al and Shariff A et al 53% of urban mothers and 85% of rural women continued breastfeeding after one year of age.<sup>1,35</sup> Lack of studies evaluating the effects of breastfeeding up to two years of age or beyond on child growth and development limits any firm conclusions regarding these effects.<sup>39</sup>

## CONCLUSION

A family based health education intervention applying IYCF counselling strategy was adopted in this study. The timely appropriate message to the mothers and other family members regarding breast feeding practices was implemented. The intervention was regularly conducted from third trimester of pregnancy till the period when child attained two years of age. The intervention clearly shows the weight gain in intervention group children especially from 9th month onwards till two years of age. The intervention effect also demonstrated exclusive breastfeeding till 6 months of age, not feeding any prelacteal feeds and continuing breastfeeding till two years of age or beyond was significantly higher in the intervention group of children.

The study shows promotion of child nutrition and breastfeeding practices in developing countries through family level counselling will improve the nutritional status of 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.

## Limitations

The sample size was not large enough to draw a community based conclusion.

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