

**CALCIUM AND VITAMIN D SUPPLEMENTATION
DURING INFANCY AND EARLY CHILDHOOD**

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In the last two decades there has been growing awareness that in sun drenched India, vitamin D deficiency (as assessed by vitamin D levels below 20ng/ml) is wide spread in all segments of population residing in different regions.

Several studies have documented low vitamin D levels in women in the reproductive age group and in pregnant women .

Poor maternal vitamin D levels has been shown to result in low vitamin D levels in the infants; neonatal tetany have been reported from India also .

There has been efforts to introduce calcium and Vitamin D supplements to pregnant women but in the first decade of the new century very few women from the poorer segments of the population received calcium and Vitamin D supplementation during pregnancy.

**It is well known that the vitamin D content in breast milk is low .
Low vitamin D levels in preschool and school children have been reported across India.**

To ward off the adverse consequences of low vitamin D levels in young children, paediatricians have been prescribing daily calcium and vitamin D supplements to infants and young children.

However the impact of such daily supplementation on vitamin D levels have not been well documented.

Stunting in young children continues to be major public health problem in India.

Low birth length and chronic energy deficiency are two major factors responsible for high stunting rates in Indian children.

As sub-clinical vitamin D deficiency in infancy and early childhood has been reported to be common, it is possible that it may be one of the factors responsible for the observed high stunting rates in preschool children

Objective

To investigate the effect of daily supplementation of calcium and vitamin D (250mg of calcium and 250 IU of Vitamin D) in children from low-income groups from the first month up to 24 months) on height of children at 24 months

Study design

The study was designed as a randomized, double-blind, placebo-controlled trial. The code distinguishing the supplement from the placebo is known only to the manufacturing unit and to the DSMB chairman.

A community based supervised daily supplementation of 250mg of calcium and 250 IU of Vitamin D or placebo to children from the first month upto 24 months of age was under taken to assess the impact of this supplementation on height at 23 months of age.

Anganwadi centres from selected ICDS blocks were chosen, taking into account that they

- are within about 10 km of NFI,**
- have a relatively stable population (not having high proportions of migrant population groups), and**
- have committed staff and a community that is able and willing to participate in this long-term follow-up study .**

Study design

Contact pregnant women in third trimester
Ascertain willingness to participate in the study
Follow up till delivery (579)

Fulfilled Inclusion criteria (324)
Delivered in Delhi
Will stay for the next two years
Willing to participate in the study

Exclusion criteria
Delivered out side Delhi (128)
Parents unlikely to stay for 2 years (79)
Parents not willing to participate (48)

Fulfilled Inclusion criteria (300)
Apparently healthy infants
Between 15-45 days after birth

Excluded (24)
Infant wt <2 Kg /preterm birth
Infant not thriving/ill

At enrolment
Measure length and weight
Randomly allocate infants to Supplement A and B
Start daily supplement A or B under supervision

Follow-up schedule : for administration of supplement 0-23 months
First three months daily supervised administration by a local field worker
After three months : supervised administration when possible ;
Daily verification from mother by field staff whether supplement was given
Once a fortnight check for the doses in the bottle, new bottles of supplement



Follow up schedule for monitoring compliance with supplementation
Daily verification with mother whether of supplement has been given
Verify regularity daily supplements in the previous fortnight by checking
➤ **chart maintained by mother and field worker**
➤ **Remaining doses in the bottle**



Follow up schedule (0-11months)
Record morbidity once in fortnight
Record for information on infant feeding practices, immunization and other nutrition and health interventions once a month ,
Measure weights and lengths of the infants once a month



Follow up schedule (12-23 months)
Record morbidity once in fortnight. Measure weight once a month
Measure length/height once in three months

Sample size

The sample size for the study calculated to be 100 per group based on the following

- 2 cm difference in height at 23+ months of age is expected as a result of supplementation**
- there may be 25 -30 % dropout over the two year period.**

The study was approved by IEC of the Nutrition Foundation of India .

**Permission to conduct the study was obtained from the Department of WCD ,
NCR , Delhi.**

**The study was registered with the Clinical trial registry of ICMR
Reg No : CTRI/2018/02/012187**

**The study was monitored by the Scientific Advisory Committee and the Data
Safety Management Board of Nutrition Foundation of India**

Socio demographic profile(300)		
Age of mother	No	%
<20	9	3
20-29	256	85.3
30-39	35	11.7
Type of family		
Joint	135	45
Nuclear	165	55
Family size		
≥3	50	16.7
4-8	220	73.3
>8	30	10.0
Education(women)		
Primary schooling	202	67.3
Secondary	66	22
College	32	10.7

Socio demographic profile		
Education of husband		
Primary schooling	166	55.3
Secondary	96	32
College	38	12.7
Work : women		
Home maker	285	95
Working	15	5
Work status: husband		
Unskilled	56	18.7
Semiskilled	93	31
Clerical	121	40.3
Business	30	10
Income group		
Low	114	38
Low-Middle income	85	28.3
Middle income	101	33.7

Majority of were from low middle income group and parents were literate.

There were no differences in SD profile between

- **those who received supplement A and those who received supplement B;**
- **those who completed the supplements and those who discontinued.**

Enrolment, continuation and dropouts			
	Enrolled	Drop out	Completed
Suppl A	150	55	95
Suppl B	150	57	93
Total	300	112	188

There were no differences in the continuation rates and drop out rates between supplement A and B

Compliance with daily supplementation assessed by No bottles used				
SUPPLEMENT	37 <u>±</u> 4 bottles	≤10%	≥10%	Total
A	80	15	0	95
B	73	20	0	93
Total	153	35	0	188

The supplement bottle had 20 doses; a plastic cup of 10ml was to be filled the supplement up to the 10 ml mark and given infant every day.

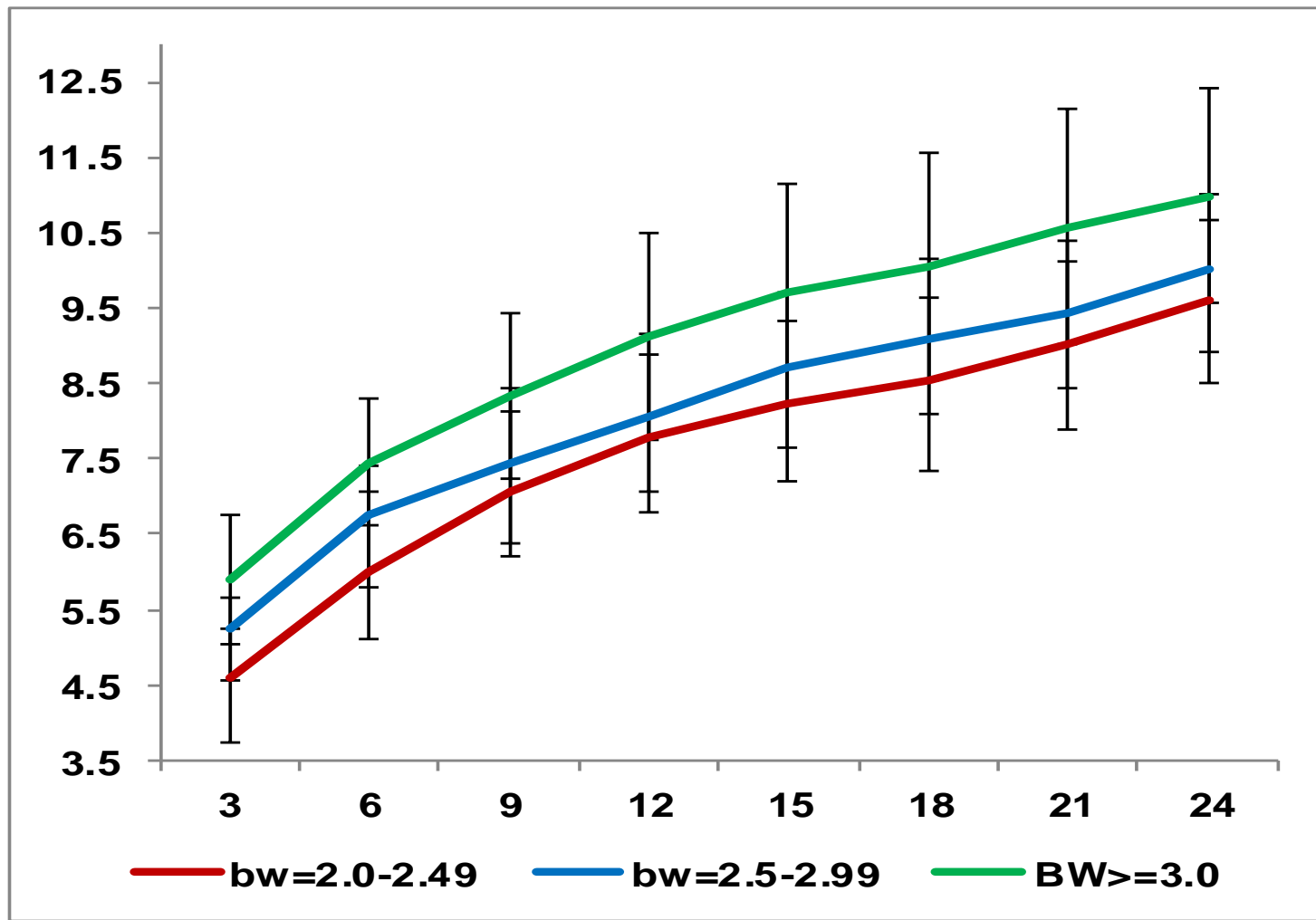
Prior to the study, mothers and anganwadi workers were given 200ml of water and asked to measure 10ml into the cup and put it in a beaker 20 times. The number of doses they measured from 200 m of water, ranged between 18-22 .

So completion of the bottle between 18-22 days was accepted as regular use. In terms of bottles of supplements to be completed between 0-23months, this variation works out to be between 37 \pm 4 bottles .

Compliance with daily dose regimen rates in those who completed the supplementation in Group A was 84.2 % and Group B was 78.5% . Considering that the daily supplementation was for 23 months, the compliance rates were very good. Differences in compliance rates between Group A & B were not statistically significant

Three factors known to affect the growth during first two years of life are

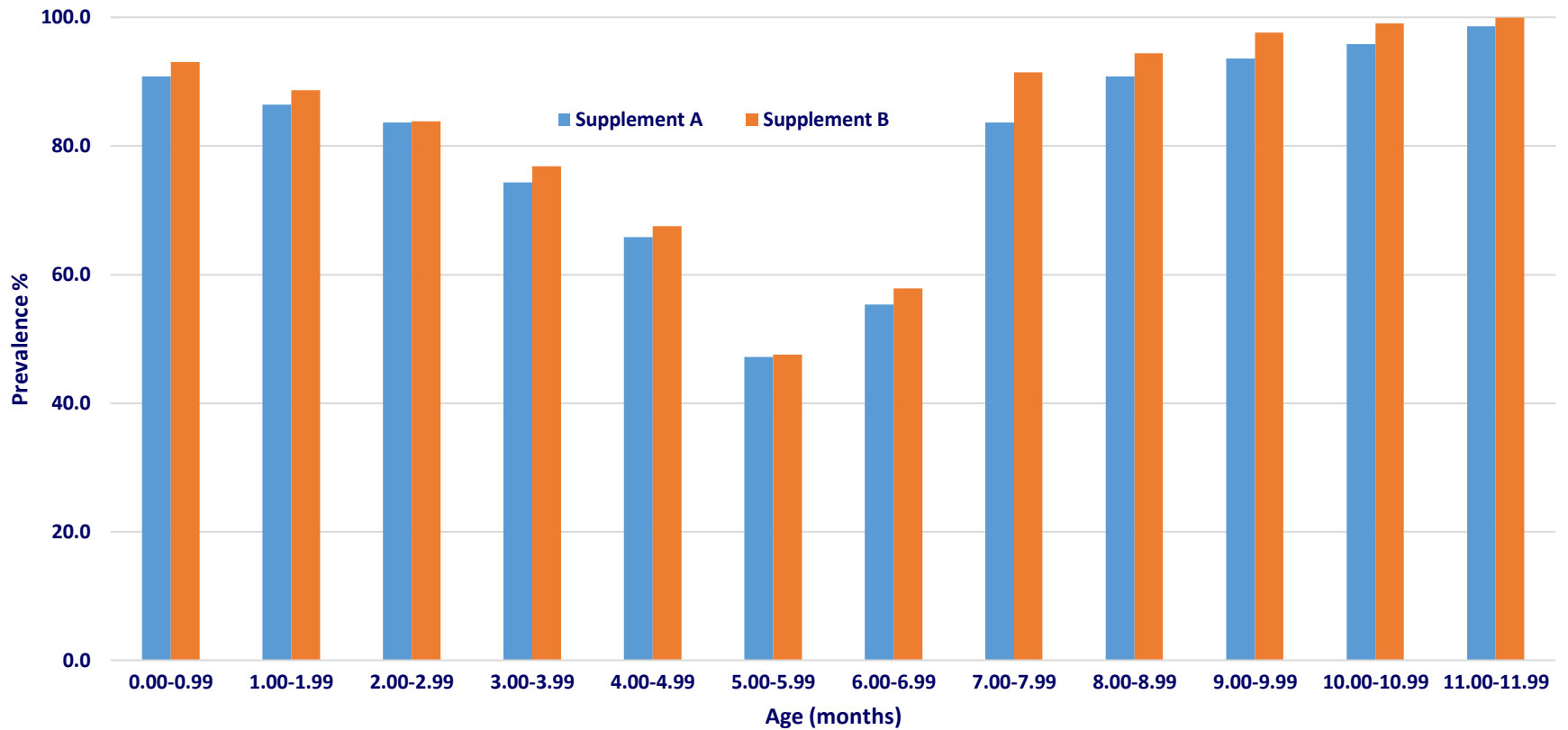
- **Weight at birth/ first month of life**
- **Infant and young child - feeding and**
- **Morbidity due to infections**



Data from the study clearly indicated that birth weight is a major determinant of growth during infancy

In this randomised study the different birth weight categories were evenly distributed between the group that received the supplements and the group that received the placebo

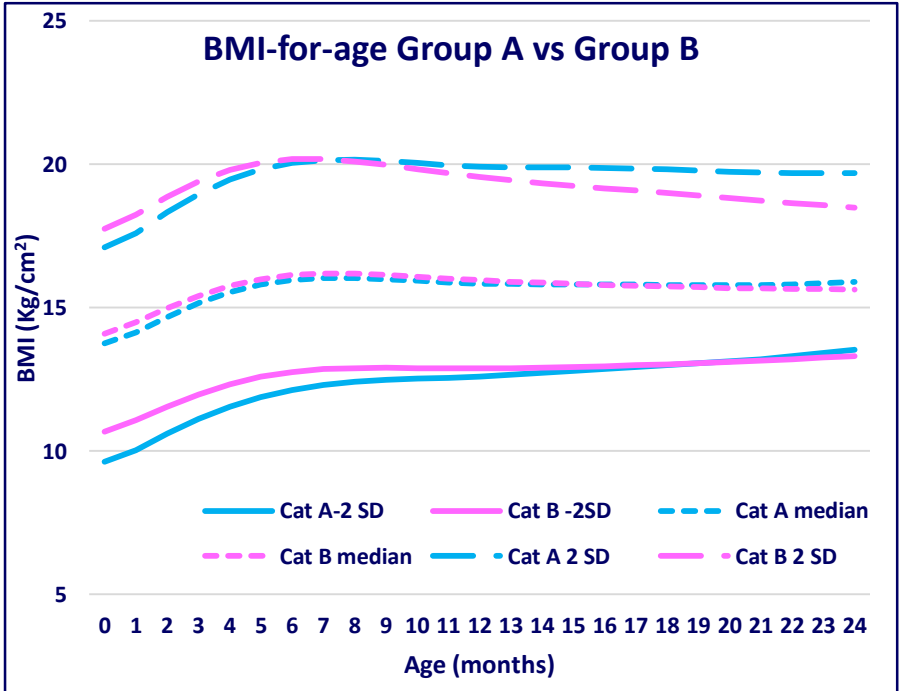
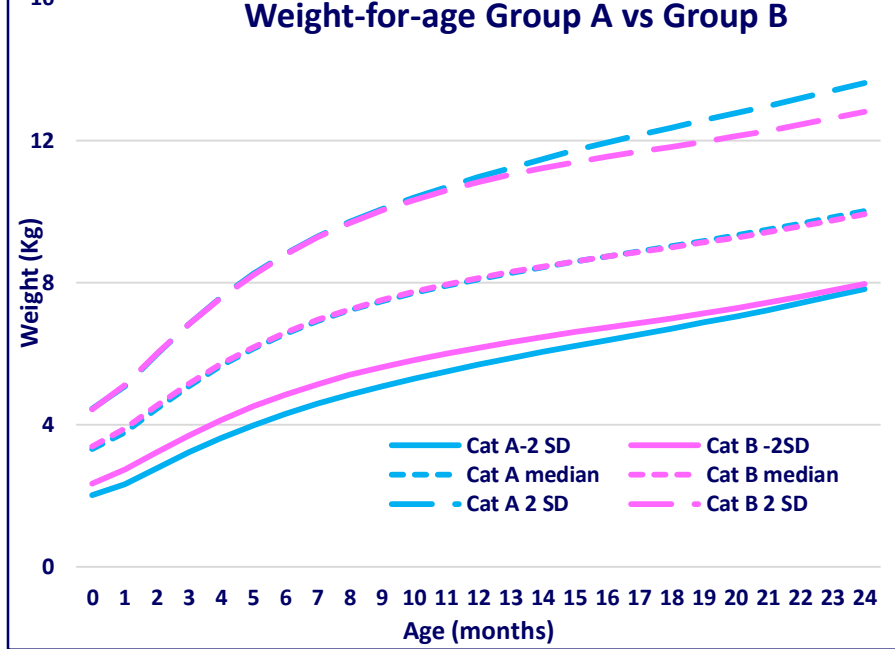
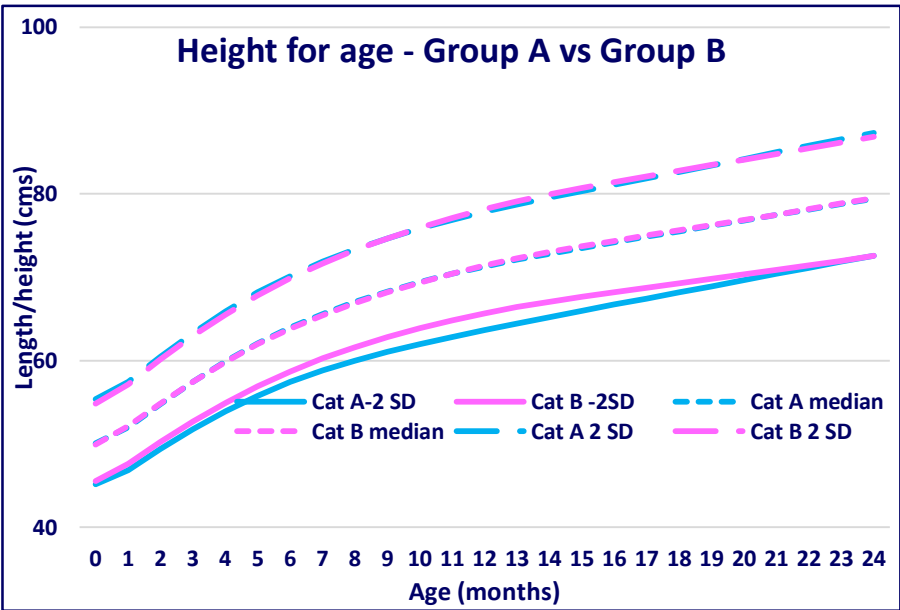
INFANT FEEDING PRACTICES



There were no significant differences in the IYCF between the group that received supplement and the group that received placebo

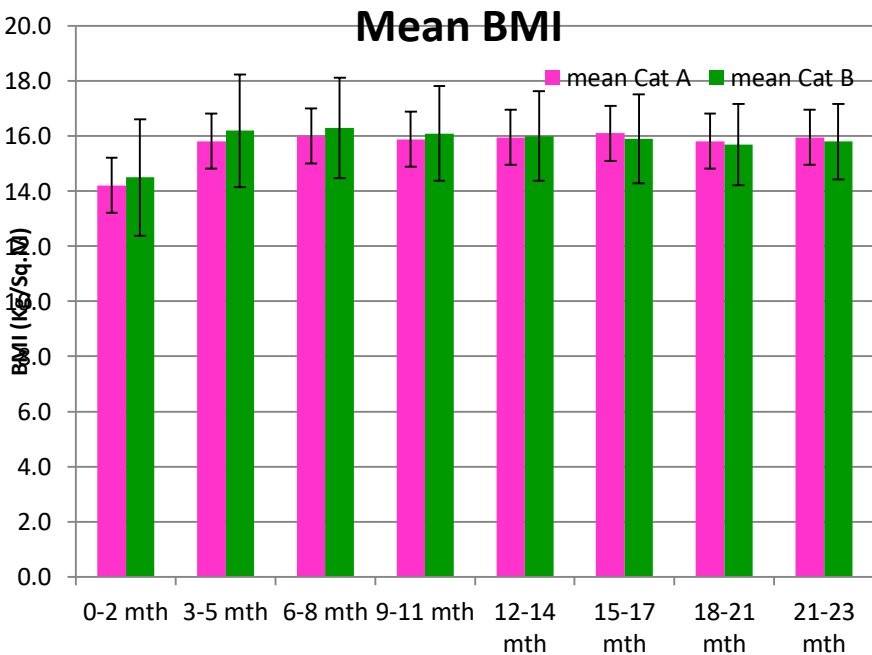
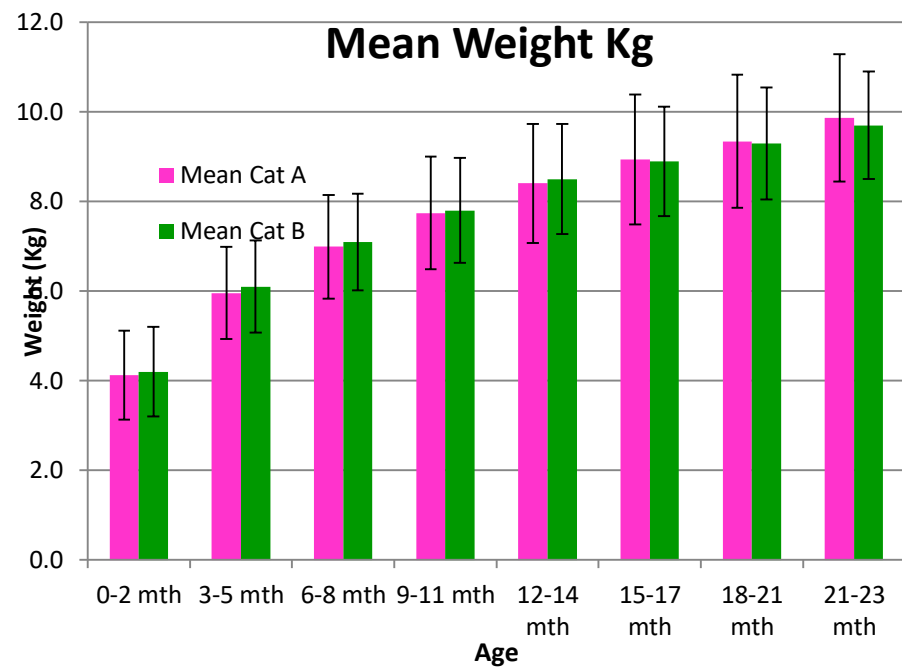
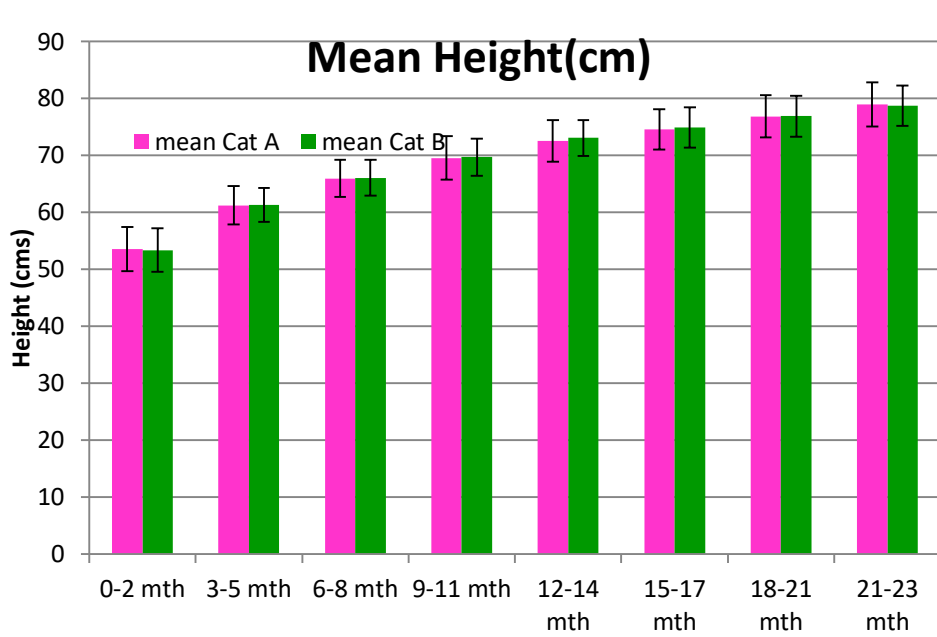
Group	Morbidity Present	Morbidity not present	Total	Prevalence of Morbidity %
A	661	3898	4559	14.5
B	687	3746	4433	15.5.
	1348	7644	8992	14.9
Group A vs Group B Chi square test p =0.184 (NS)				

There were no significant differences in prevalence of morbidity due to infection between group that received supplement and the group that received placebo



There were no differences in linear growth as assessed by height for age between the group that received supplement and the group that received placebo .

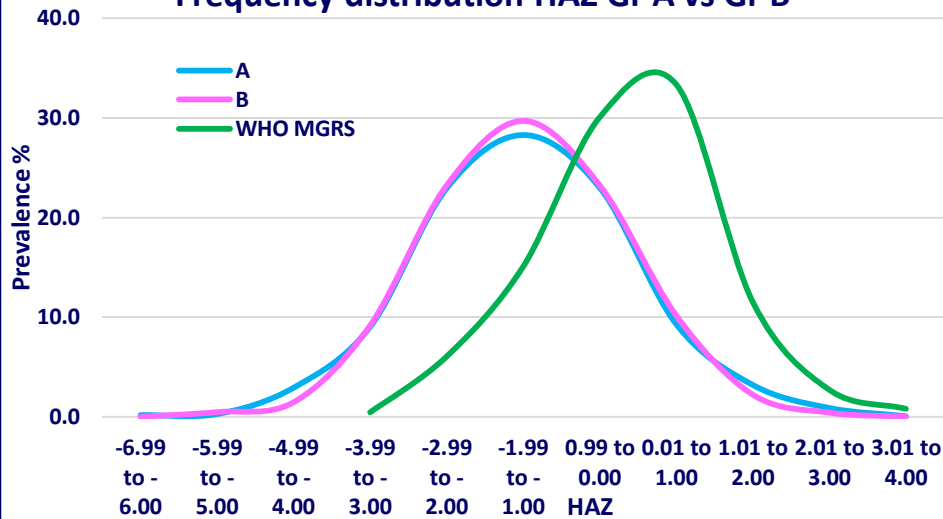
There were no differences in weight for age or BMI for age between the the group that received supplement and the group that received placebo



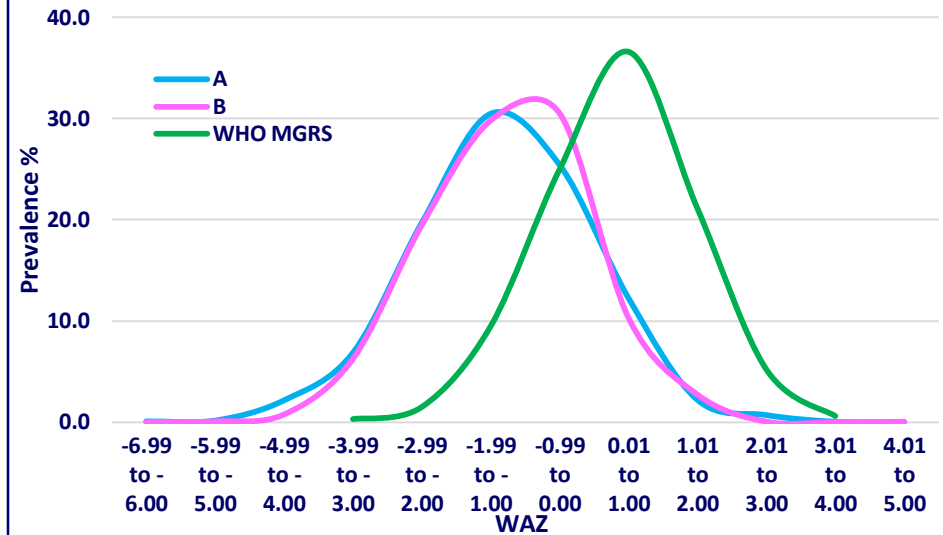
There were no significant differences in height initially, during follow up and at 21-23 months of age between the group that received supplement and the group that received placebo

There were no differences in terms of weight and BMI between the group that received supplement and the group that received placebo

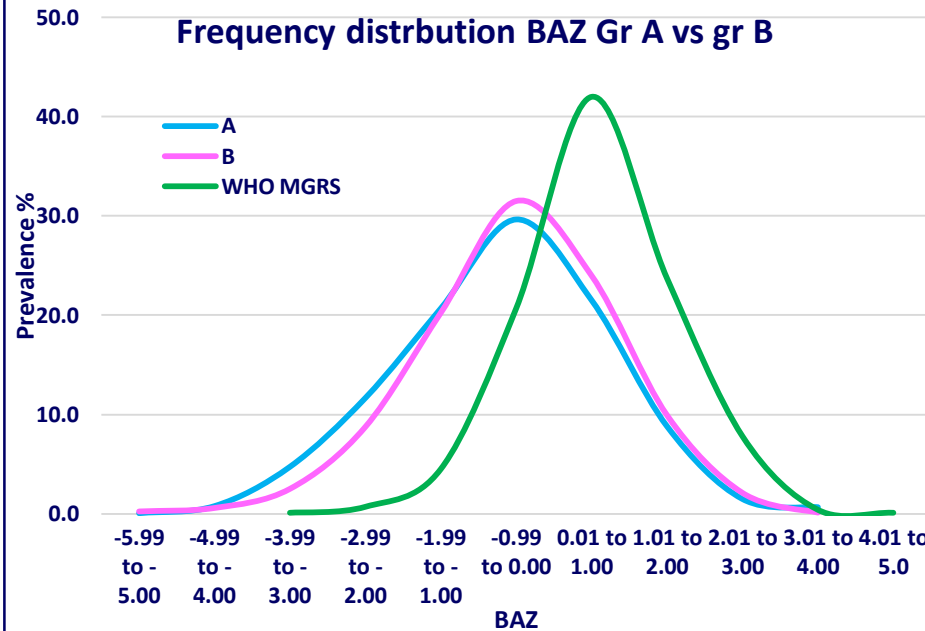
Frequency distribution HAZ Gr A vs Gr B



Frequency distribution WAZ Gr A vs Gr B



Frequency distribution BAZ Gr A vs gr B



There were no significant differences in the frequency distribution of HAZ, WAZ and BAZ at 21-23 months between the group that received supplement and the group that received placebo. Data suggest that daily supplementation of the Calcium and vitamin D from 0-23 months did not have any impact on linear growth.

**IMPACT OF INTENSIVE NUTRITION EDUCATION ON IYCF AND
NUTRITIONAL STATUS DURING THE FIRST TWO YEARS**

The importance of nutrition education in improving appropriate infant and young child feeding practices is well recognised

The Mother Child Protection Card provides pictorial and written messages on optimal infant and young child feeding practices

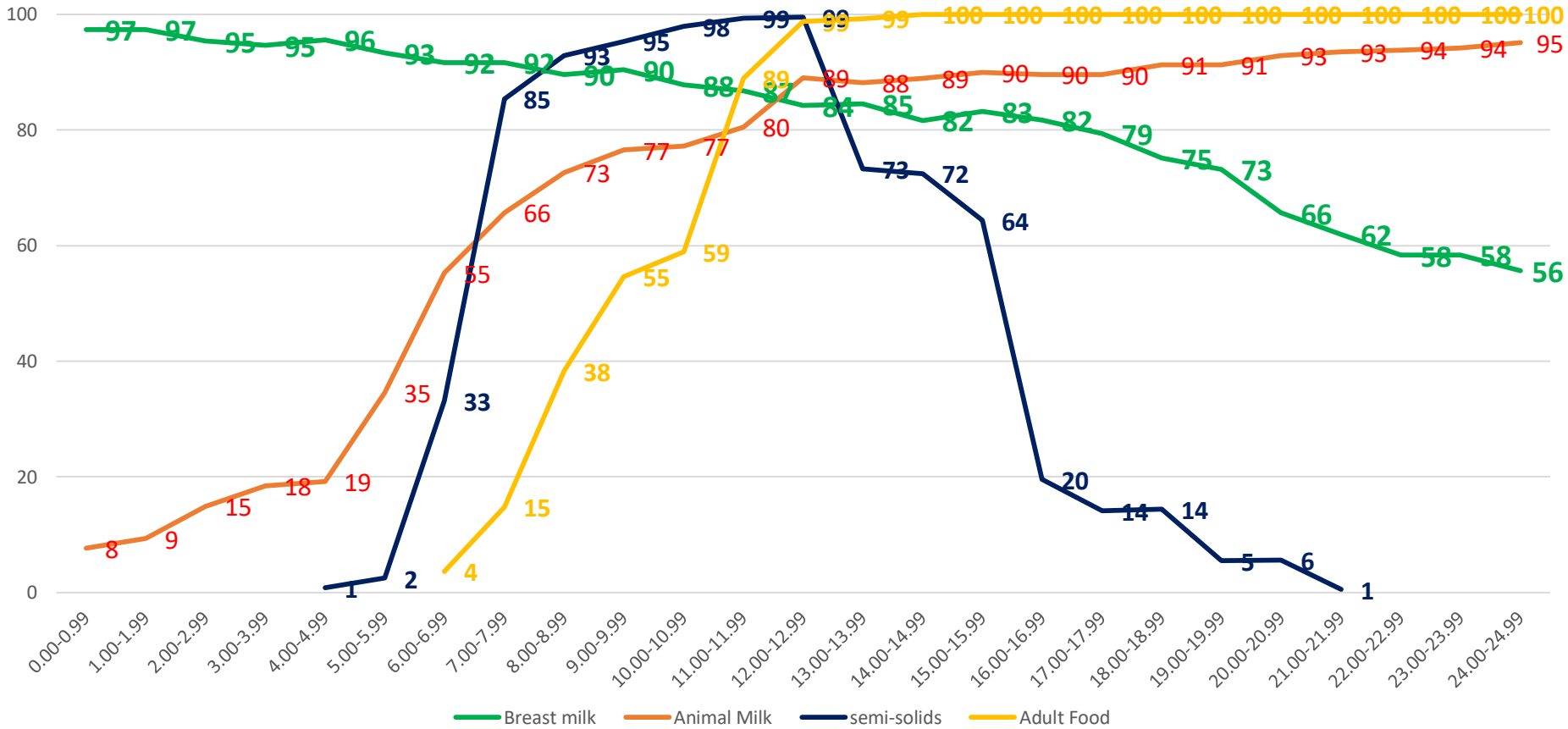
MCPC was used by the research team to emphasise and authenticate the nutrition education regarding IYCF to the mothers and their families

Though the actual IYCF data collection was done once a month the team checked the practices regarding breast feeding animal milk and semi solid introduction once a week

If they found the mother has started introducing animal milk early or has not started semisolids by sixth month , intensive counselling was done by the field workers and research team .

As there was no difference in the IYCF between Group A and Group B data from both the Groups were compared and the prospectively collected data on infant and young child feeding between 0 and 23 months were combined and the impact if any of the intensive nutrition education on IYCF was assessed

Infant and young child feeding practices



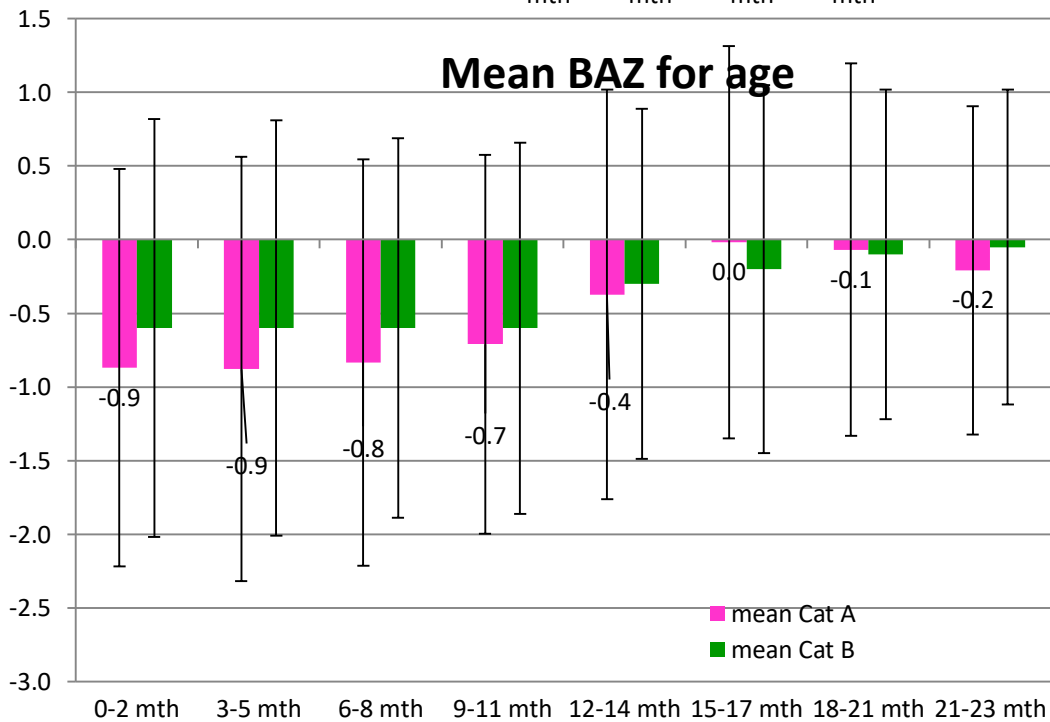
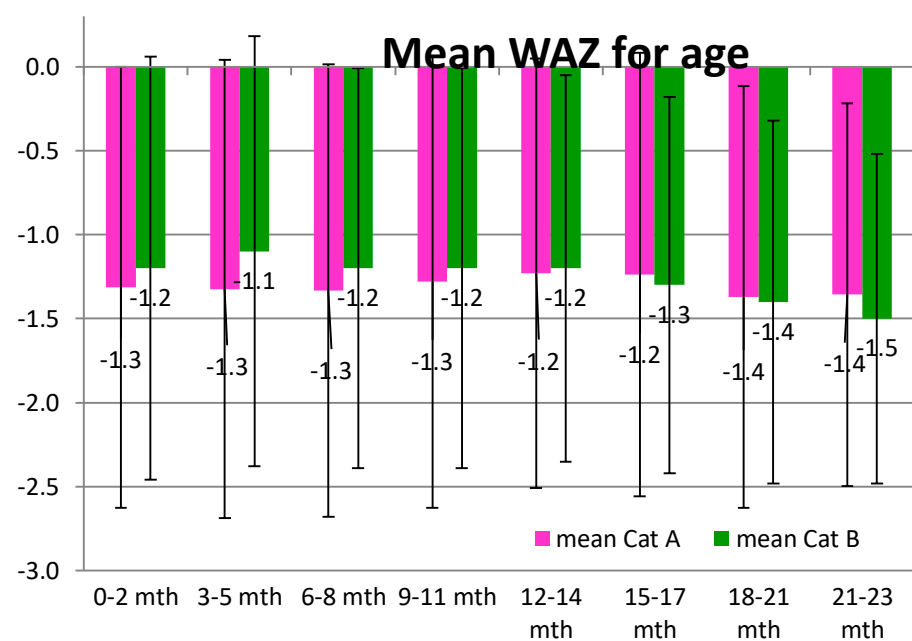
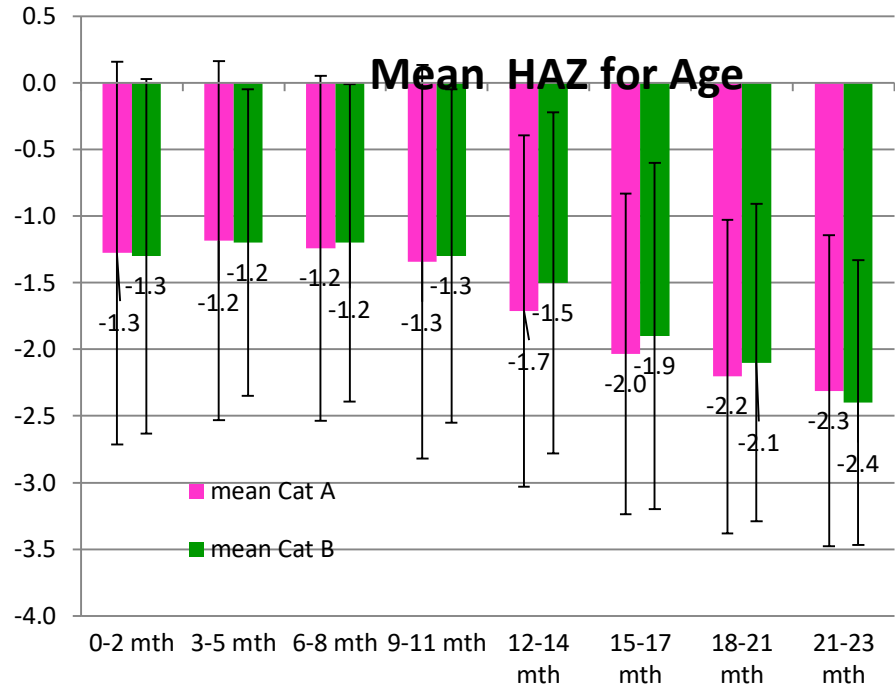
Upto 5 months 80% solely breast fed their infants .

Animal milk was given by 4th month in less than 20%

Semisolids were given in 85% by 7th mth, nearly all provided semisolids by 12months ; semisolids were stopped in over 80% by 16 mth

By 12th month all children started eating adult food

Majority followed optimal IYCF practices. However dietary diversity was low .



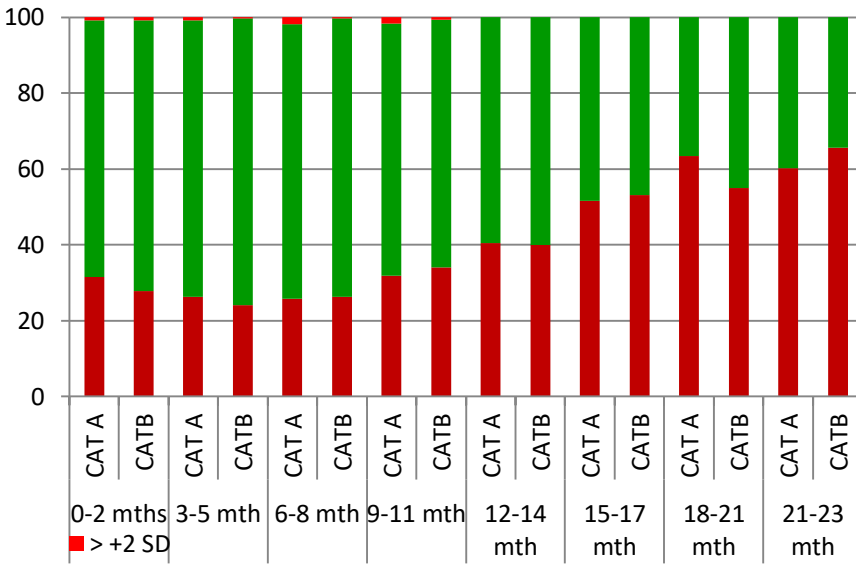
There was no change in the mean HAZ, WAZ and BAZ in the first 12 months

Mean HAZ increased from 1.9 in 12 months to 2.4 by 23 months

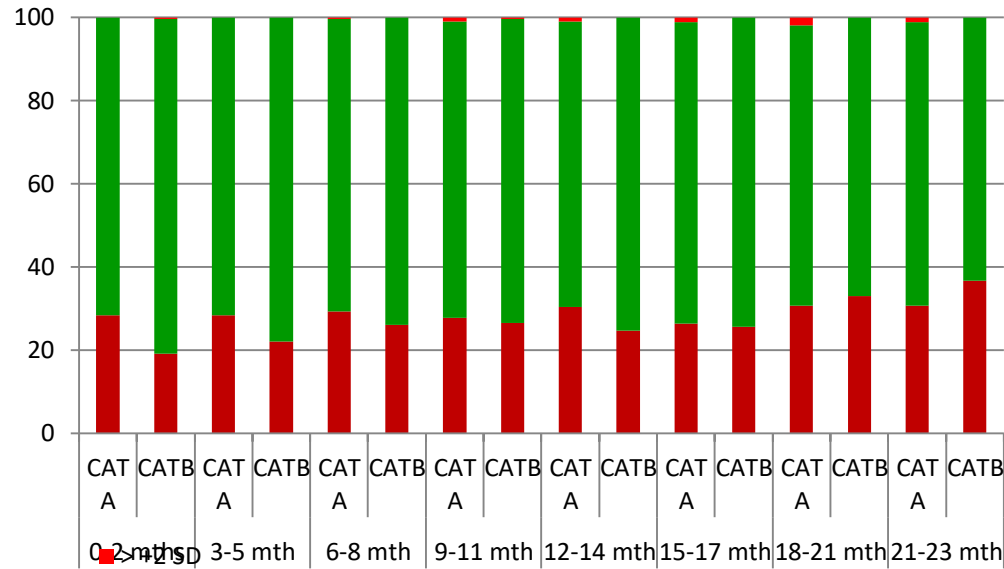
There was no change in WAZ over first 12 months and increase of 0.2 between 12 -23 months.

As a result of increase in stunting rates wasting rates showed significant decline after 12 months .

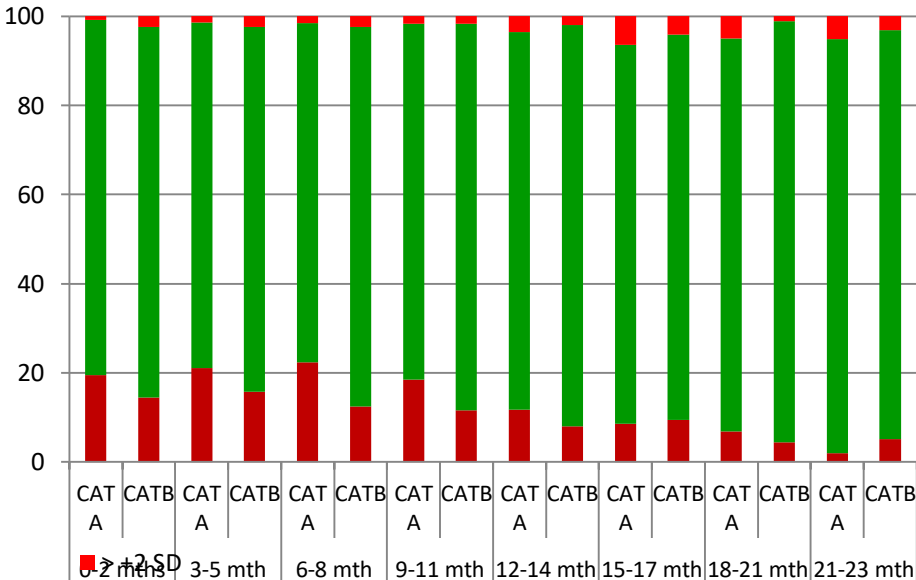
Nutritional status (Ht for age)



Nutritional status (Wt for age)



Nutritional status (BMI for age)



As a result of appropriate infant feeding there was no increase in under-nutrition in the first 12 months as assessed by height, weight and BMI for age

Between 12-23 months there was an increase in stunting rates from 40-60% but the increase underweight rates was only 10% .

As a result there was reduction in wasting rates between 12-23 months

SUMMARY AND CONCLUSION

Daily supervised administration of calcium and vitamin D (250mg of calcium and 250 IU of Vitamin D) in children from low-income groups from the first month up to 24 months) **did not have any impact either on linear growth or on morbidity in children.**

Because of the close contact with the family, **it was possible to improve IYCF practices through nutrition education by front line workers using MCPC card to authenticate the messages .**

Optimal infant feeding prevented deterioration in the nutritional status in the first 12 months of life

After 12 months there was progressive increase in z scores for height for age and stunting rates. The reason for this has to be explored.

As the deterioration in the stunting rates were higher than deterioration in the underweight rates , wasting rates decreased after 12 months

This should not be interpreted as improvement in nutritional status in the 12 -23 month child.

THANK YOU

The image features the words "THANK YOU" in a bold, blue, sans-serif font. The text is centered horizontally and has a slight 3D effect with a soft shadow. Below the text is a clear, semi-transparent reflection of the words, creating a mirror-like effect on a white background.