CHAPTER 3

METHODOLOGY

3.1. RESEARCH QUESTIONS:

1. Primary Research Question:

Is there any difference in weight gain between infants with exclusive and non exclusive breast feeding at the end of first 4 months of life in the urban community of Morang district, Nepal?

2. Secondary Research Questions:

Are there any differences in incidence of diarrhea and ARI between infants with exclusive and non exclusive breast feeding at the end of the first 4 months of life in the urban community of Morang District, Nepal ?

3.2. RESEARCH OBJECTIVES:

1.To identify the difference in weight gain between infants with exclusive and non exclusive breast feeding at the end of the first 4 months of life in the urban community of Morang District, Nepal.

2. To identify the difference in incidence of diarrhoea between infants with exclusive and non exclusive breast feeding.

3. To identify the difference in incidence of acute respiratory tract infection between infants with exclusive and non exclusive breast feeding.

3.3. HYPOTHESIS:

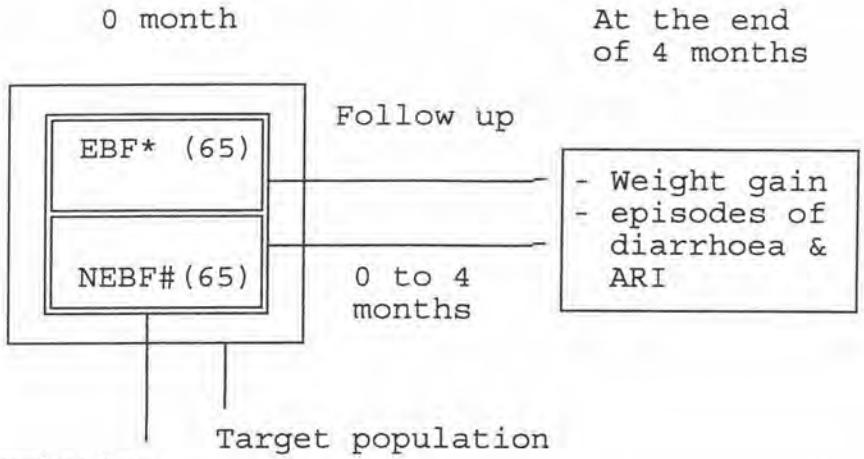
1. There is a difference in weight gain between infants with exclusive and non exclusive breast feeding at the end of the first 4 months of life in the urban community of Morang District, Nepal.

2. There is a difference in incidence of diarrhoea between infants with exclusive and non exclusive breast feeding at the end of the first 4 months of life.

3. There is difference in incidence of acute respiratory tract infection between infants with exclusive and non exclusive breast feeding at the end of the first 4 months of life.

3.4. RESEARCH DESIGN:

Figure 1. Community based Comparative prospective cohort design(28):



* Exclusive breast feeding

\# Non exclusive breast feeding

Community based comparative prospective study: It is designed to perform a comparative prospective study to determine whether exclusive breast feeding protects against growth faltering, and increasing in episodes of diarrhoea and ARI. There were four basic steps in performing this study:

1. Recruitment of the cohort:

Investigator recruited 65 subjects with exclusive breast feeding and 65 with non exclusive breast feeding groups among the target population of post natal mothers since April 15th to June 30, 1996.

2. Measure predictor variables:

Mothers were administered a questionnaire to find out demographic, socio-economic variables, exclusive and non exclusive breast feeding mothers along with the sex, age and birth weight of infants were measured by observers.

3. Follow up the cohort:

After assembling the required subjects, they were follow up for weighing the infants and asking the episodes of diarrhoea and ARI with mothers using followed up sheet every one month interval for 4 months.

4. Measure outcomes:

Impact of exclusive and non exclusive breast feeding on weight gain, episodes of diarrhoea and ARI from 0 to 4 months of life.

3.5. RESEARCH METHODOLOGY:

1. STUDY LOCATION:

There are 3 main regions in Nepal consisting of mountainous, hilly and tarai region. A tarai region is a plain and fertile region. Morang district is located in eastern tarai region and is one of the 75 districts of Nepal. Eight villages are situated in the hilly region while 58 villages are covered by the tarai region. Biratnagar is municipality of Morang District Which is a industrialized region with population about 130,129. It has 22 wards. Ward

means the subdivision of Biratnagar into small community parts. Tharu and Dhimal are the aborigine of Biratnagar municipality. About 55% of population are Dhimal, Tharu, Rai, and 45% of population are Newar, Brahmin. They have own local spoken language. This urban area is adjoining district of Bihar of India. Some of them have own a piece of land to grow crops and most of the families used to keep one or two milking cows but not good enough to maintain socio-economical status. So, Most of people are civil service holder, daily paid workers and business men. This study was conducted in Urban community of Biratnagar from April 1995 to May 1996. Only 3 wards of Biratnagar was chosen to be the study area, because

- the rate of exclusive breast feeding mothers have been declining in urban region.

- the population size is big enough to get adequate sample for this study.

- situated in the hospital catchment area, so the problem of transportation, communication and health manpower could be somewhat minimized.

- there is no similar type of study carried out in the Biratnagar.

2. POPULATION

2.1. Target Population:

All mothers with new borne infants in the urban community of Morang District, Nepal.

2.2. Sampled Population:

Mothers with new borne infants in the Biratnagar of Morang District, Nepal. Eligible infants whose mothers intended to exclusively breast feed were recruited into the exclusive breast fed group. Eligible infants whose mothers did not intend to exclusively breast feed were recruited in the non exclusive breast fed group. 130 subjects were recruited within two and half months and followed up prospectively 65 infants with exclusive and 65 infants with non exclusive breast feeding in each of two arms for a period of 4 months. The paternal characteristics in terms of socio-economic status and education were compared between exclusive and non exclusive breast feeding groups. But sex and age of infant were matched between exclusive and non exclusive breast feeding groups.

2.3. Eligibility criteria:

1. Inclusion Criteria:

Subjects were recruited to meet the following selection criteria:

Mother: I. Mother who has been settled permanently and is not intending to migrate in the study time period.

II. Nepali Nationality

Baby: III. New born infant

IV. Birth weight 2500 to 3200 grams

V. Either boy or girl

VI. Gestational age between 38 to 42 weeks

2. Exclusion Criteria:

Subjects were excluded, if she or he had the following conditions:

Mother: I. Known mastitis and severe inverted nipple

II. Known Chronic illness: Tuberculosis, Cardiac diseases, anaemia, malnutrition, AIDS and diabetes.

III. Known neurological disorders: epilepsy, postpartum psychosis and mental illness

IV. Post partum complication: toxemia, hemorrhage

Baby: V. Malformation: cleft palate, unable to swallow or suck, facial paralysis and congenital heart disease.

VI. Neuromuscular disorders:cerebral palsy, neonatal meningitis, tetanus, Down's syndrome.

VII. Premature

VIII. Twins

3. METHOD OF SELECTION:

Non probability consecutive sampling technique:

Data obtained from maternal child health workers showed

that on an average they attend 6 post-natal mothers per day per ward. So the total would be 2190 post natal mothers per year per ward. The total population of post-natal mothers of Biratnagar is about 48180. But investigator selected only 3 wards of urban community as study area. So the target population of three wards is about 6570 post-natal mothers with new born infant.

The sample of consecutive, subjects were selected every patient who met the selection criteria by the trained health workers. They were informed about the birth of baby by local traditional birth attendance. The name of head of the family and house number were recorded by health workers. After that they interviewed the mothers and measured the birth weight of infants , who met the inclusion criteria in this study areas from 15th April to 30th June. The sample size of this study was 100. It was anticipated that the drop out rate could be very high . So a drop out rate of 30% was considered and calculated to add with the required sample. Infants were followed up at monthly intervals for the first 4 months for identifying in terms of birth weight, episodes of diarrhoea and ARI and recorded on follow up sheet.

3.6. SAMPLE SIZE CALCULATION:

$$N/group = \frac{2(Z_\alpha + Z_\beta)^2 \sigma^2}{\Delta^2}$$

$Z_\alpha = 1.96$, $\alpha = .05$ (95% level of significance)
$Z_\beta = 0.84$, $ß = .20$ (80% power)
$\sigma^2 = 1$ Kg(16)
$\Delta^2 = 0.57$ kg (set width which equals to 19% of normal weight gain 3 Kg. at the end of 4 months i.e. 0.57 Kg.)
N = 48/ group, Approximately 50/group

Total number of study population 100

To account for an estimated drop out rate of 30 %. A minimum number of 130 new born were needed for this study. So 65 new born were either exclusive or non exclusive breast feeding group.

3.7. OUTCOMES OF MEASUREMENT:

Variables to be measured:

Part 1. Demographic data:

Section I. Parental characteristics

- Age of mother
- Number of children
- Educational level of mother and father
- Occupation of mother and father
- Income of mother and father

Section II. Infants' characteristics

- Age of infants
- Sex of infants
- Birth weight

Part 2. Independent variables:

Breast feeding pattern

- Exclusive breast feeding
- No exclusive breast feeding

Part 3. Dependent Variables(Outcome variables):

- Weight gain of infants
- Episodes of ARI
- Episodes of diarrhoea

Primary outcome:

Difference in the weight gain between infants with exclusive and non exclusive breast feeding at the end of the first 4 months of life.

Secondary outcome:

Differences in number of episodes of diarrhoea and ARI between infants with exclusive and non exclusive breast feeding at the end of first 4 months of life.

3.8. OPERATIONAL DEFINITION:

1. Exclusive breast feeding:

Providing solely breast milk in the first 4 months of life of the new born.

2. Non exclusive breast feeding:

Providing breast milk including supplementary food, fluids or breast milk substitutes in the first 4 months of life.

3. Weight gain:

It is defined as the increment of weight normally gained from birth weight of the infant.

4. Incidence of diarrhoea and ARI:

No of episodes of diarrhoea and ARI within the first 4 months of life in the study period.

5. ARI:

Any acute infection of the respiratory tract which includes all upper, middle, and lower respiratory tract infection(17).

6. Diarrhoea:

It is defined as passage of loose stool more than 3 times within a 24 hours period, or any passage of mucous and/or bloody stool(18).

3.9. INSTRUMENTS:

Questionnaire:

At the first time mothers were interviewed by the well trained health workers using valid questionnaire for the following data:

Part 1. Demographic data

Section I. Parental characteristics:

I.1 Age of mother

I.2 Educational level of mother

1.3 Occupation of mother

I.4 Income of mother

I.5 Educational level of father

I.6 Occupation of father

I.7 Income of father

Section II. Infant's characteristics

II.1 Infant's age

II.2 Infant's sex

11.3 Birth weight of infant

Part 2. Breast feeding patterns

III. 1 Exclusive breast feeding

III. 2 Non exclusive feeding

Part 3.Episodes of diarrhoea and ARI during the given time period.

Weighing Scale:

A beam balance scale had been used to weigh the baby in this study because this scale has great accuracy and is already standardized.

Follow up sheet:

Follow up sheet was used by well trained health workers in order to record the weight gain, the incidence of ARI and diarrhoea as well as the breast feeding patterns during each monthly visit.

3.10. **MEASUREMENTS:** Reliability on Measurements:

The weight of infant :

In order to increase the accuracy and to minimize the inter observers variability the following **weighing procedure** recommended by (WHO and UNICEF) was followed:

- A beam balance scale was used.
- Health workers showed the scale mark on the balance.
- Checked that the scale read zero before weighing.
- Particularly health workers showed the way to prepare the beam balance scale how to hold the baby during weighing.
- Checked whether the baby was touching anything beyond the scale pan.
- Placed anything in the beam balance scale to demonstrate different weight ranges.
- Let them practice weighing a baby using beam balance

- Test for accuracy was done daily using an object of known weight in the range of the weights of the children.
- Weighed child without clothing.
- Read the scale at eye level.
- The measurements was carefully taken and recorded by one trained supervisor. Showed them how to fill up infants' weight in a standardized questionnaire and follow up sheet.

The study region was separated in three parts according to the local traditional birth attendance's house catchment area. 6 health workers were recruited as observers and 6 local traditional birth attendance were recruited as helpers for this study. The instruments were calibrated and health workers were trained for the measurement. Each group of two observers was allocated in each three parts and assigned to interview with 10 mothers and assess the weight of 10 infants who met the inclusion criteria for pre test. The weight of infants was measured by well trained observers within 24 hours of birth of baby after being informed by local traditional birth attendance. Observers independently weighed using beam balance scale. There are chances of variability due to difference between observer to observer. Therefore reliability coefficient was assessed to determine variability between two observers. The result of infant's weight was shown in table 3.1.

Table 3.1. Infants' weight in Kilogram of three areas:

INFANTS	Area 1			Area 2			Area 3		
	Obs 1	Obs 2	Tot.	Obs 1	Obs 2	Tot.	Obs 1	Obs 2	Tot.
1	3.5	3.3	6.8	2.6	2.5	5.1	3.0	3.5	6.5
2	3.0	3.4	6.4	2.5	2.7	5.2	3.4	3.7	7.1
3	3.0	3.0	6.0	3.5	3.3	6.8	3.4	3.0	6.4
4	2.5	2.7	5.2	2.5	2.9	5.4	2.5	2.6	5.1
5	2.5	3.0	5.5	2.5	2.5	5.0	2.7	2.5	5.2
6	3.0	3.1	6.1	2.7	3.0	5.7	3.3	3.6	6.9
7	3.3	3.6	6.9	2.6	2.5	5.1	2.5	2.5	5.0
8	3.6	3.5	7.1	3.0	3.1	6.1	3.0	3.2	6.2
9	2.7	2.5	5.2	3.7	3.5	7.2	3.3	3.2	6.5
10	2.7	3.0	5.7	3.2	3.0	6.2	3.0	3.1	6.1
Tot	29.8	31.1	60.9	28.8	29.0	57.8	30.1	30.8	61.0

For quantitative data, agreement index was measured in terms of intra-class correlation coefficient(ICC, r_1) Intra-class correlation of the two observers was analyzed using technique of Analysis of Variance(ANOVA). Mean square of variables were computed by the SPSS/PC+ and found that:

Area 1

Table 3.2. ANALYSIS OF VARIANCE

Source	Sum of squares	DF	Mean square	F	P
Infants	2.1845	9	.2427		
Observers	.0845	1	.0845	2.711	.134
Error	.2805	9	.0312		
Total	2.5495	19	.1342		
Grand mean	3.0450				

$\delta^2_{err.} = MS_{err.} = .0312$

$\delta^2_{inf.} = (MS_{inf.} - MS_{err.})/2 = (.2427 - .0312)/2 = 0.1057$

$\delta^2_{obs.} = (MS_{obs.} - MS_{err.})/10 = (.0845 - .0312)/10 = 0.0053$

Reliability coefficient:

$$R = \frac{\delta^2_{inf.}}{\delta^2_{inf.} + \delta^2_{obs.} + \delta^2_{err.}}$$

$$= \frac{0.1057}{0.1057 + 0.0053 + 0.0312} = \frac{0.1057}{0.1422} = 0.74$$

Area 2

Table 3.3. ANALYSIS OF VARIANCE

Source	Sum of squares	DF	Mean square	F	P
Infants	2.6780	9	.2976		
Observers	.0020	1	.0020	.083	.780
Error	.2180	9	.0242		
Total	2.8980	19	.1525		
Grand mean	2.8900				

$\delta^2_{err.} = MS_{err.} = .0242$

$\delta^2_{inf.} = (MR_{inf.} - MS_{err.})/2 = (.2976 - .0242)/2 = 0.1367$

$\delta^2_{obs.} = (MS_{obs.} - MS_{err.})/10 = (.0020 - .0242)/10 = -0.0022$

Reliability coefficient:

$$R = \frac{\delta^2_{inf.}}{\delta^2_{inf.} + \delta^2_{obs.} + \delta^2_{err.}}$$

$$= \frac{0.1367}{0.1367 - 0.0022 + 0.0242} = \frac{0.1367}{0.1587} = 0.86$$

Area 3

Table 3.4. ANALYSIS OF VARIANCE

Source	Sum of squares	DF	Mean squares	F	P
Infants	2.5045	9	.2783		
Observers	.0245	1	.0245	.786	.398
Error	.2805	9	.0314		
Total	2.8095	19	.1479		
Grand mean	3.0450				

$\delta^2_{err.} = MS_{err.} = .0314$

$\delta^2_{inf.} = (MS_{inf.} - MS_{err.})/2 = (.2783 - .0314)/2 = 0.12345$

$\delta^2_{obs.} = (MS_{obs.} - MS_{err.})/10 = (.0245 - .0314)/10 = - 0.00069$

Reliability coefficient:

$$R = \frac{\delta^2_{inf.}}{\delta^2_{inf.} + \delta^2_{obs.} + \delta^2_{err.}}$$

$$= \frac{0.12345}{0.12345 - 0.00069 + 0.0314} = \frac{0.12345}{0.15416} = 0.80$$

The intra-class correlation (ICC) used to assess the reliability and agreement between the observers in area 1, 2 and 3 are 0.74, 0.86 and 0.80 respectively. Which are closed to 1. So, ICC between two observers within each area in performing weight is indicated good agreement between observers.

3.11. ETHICAL CONSIDERATION:

There is no harm to the study population, because this is the observational study. In addition, informed consent was obtained from the study mothers. Any sick infants were referred to the hospital for investigation and treatment.

3.12. DATA COLLECTION:

The study area, were divided into 3 parts. In each part, one team consisting of 2 observers and 2 local traditional birth attendance. A cohort of eligible mothers who have given birth to babies in the study area from April to October 1995 had been recruited into the study after obtaining verbal consent. Well trained health workers were assigned for data collection from all mothers, about parental socio-economic status, and education and sex, age, breast feeding practices episodes of diarrhoea and ARI and assessed the weight of infants. After that infants were followed up to measure weight one month interval up to 4 months. Furthermore, the following steps were performed for data collection:

Community Surveillance:

All eligible households were listed when occurrence of birth was identified through surveillance technique by local traditional birth attendance.

-The study area was divided into three parts and two well trained health workers were assigned to carry out their job

description in each area for a 7 month period.

-The well trained health worker weekly visited to every traditional birth attendance's home in assigned area to identify any new born baby.

-If the mother and baby met the eligibility criteria, they were enrolled into the study.

-The health workers followed up the household of the study mother once monthly for 4 months to assess the weight gain of study infants.

- The mothers were provided with an appointment card for each scheduled visit by the trained health workers as to conduct the study.

At the same time all mothers had been asked about the episodes of ARI and diarrhoea related symptoms in the past weeks since the last visit. Some infants found being ill by the interviewers were referred to the hospital. The sick infants were examined more closely and treated by the pediatrician who was the consultant of this study. One pediatrician was consultant for this study. He was responsible to diagnose the infants with diseases which were excluded from the study and to treat the baby when necessary.

3.13. DATA PROCESSING:

The information obtained from the questionnaire and the assessment of weight were checked, coded and tabulated by the investigator to the coding sheet. All the data collected and recorded in the recording sheet were entered data and checked before analysis. The collected data were analyzed by using SPSSPC+. Three parts of data were analyzed to answer the primary and secondary research questions by the investigator under close supervision of a biostatistician.

The demographic information which were continuous variables were analyzed and were summarized by mean and SD, while those discrete data were analyzed and were summarized by percentage and analyzed using Chi square.

The increment of weight gained were analyzed and were summarized by ANOVA to identify weight gain among breast feeing groups and sex. T Test was used to identify the difference in mean weight gain between exclusive and non exclusive breast feeding groups.

T Test was performed to assess the difference in the mean of episodes of diarrhoea and ARI between exclusive and non exclusive breast fed infants.