CHAPTER 3

RESEARCH METHODOLOGY

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Research methodology refers to the methods, processes and techniques adopted to conduct the study. Hence, the present chapter describes the methods adopted to identify the nutritional status of children, risk factors of malnutrition and effectiveness of Family-Based Intervention Program (FBIP) on nutritional status of children. The study was done in two phases. Nutritional status of children was assessed and risk factors for malnutrition was identified in the first phase. Second phase was done to identify the need for the intervention by assessing the knowledge and nutrition related practices of mothers.

This chapter discusses the following: research approach and design, setting, process of randomization, sample and sampling technique, description of data collecting instruments, methodology for intervention development, pilot study, procedure for data collection, and plan for data analysis.

Research Approach

This study aimed to identify the nutritional status of children and risk factors related to malnutrition in children aged 1-3 years and effectiveness of Family-Based Intervention Program (FBIP) among mothers. Hence, multi method research approach was used. For Phase I of the study - Exploratory survey approach was used and for Phase II, Experimental approach was used.

Research Design

For Phase I of the study cross-sectional survey design was adopted to identify the nutritional status of children and explore the risk factors relating to malnutrition in them.

In the Phase II, to find the effectiveness of Family-Based Intervention Program (FBIP) on knowledge and nutrition related practices of mothers, cluster randomized control trial was found to be more appropriate. Randomization of clusters was done in order to reduce the risk of contamination. Hence, the design selected was cluster randomized control trial. The schematic representation of the research design for phase II is presented below.

Groups	Pre-Test	Treatment	Post-Test 1 (1st Month)	Post-Test 2 (3rd Month)	Post-Test 3 (6th Month)	Post-Test 4 (9th Month)
R_E	O_1	X	O_2	O_3	O_4	O_5
R_C	O_1	--	O_2	O_3	O_4	O_5
Variables	• Nutrition Knowledge • Nutrition related Practices	Two weeks	• Nutrition Knowledge • Nutrition related Practices	• Nutrition Knowledge • Nutrition related Practices • Nutritional Status	• Nutritional Status	• Nutritional Status

Research Setting

The present study, was done in Haldwani block, Nainital district, Uttarakhand. The state of Uttarakhand formerly Uttaranchal, is located in northern part of India. Geographically it covers 53483 Sq. Km terrain. Nainital district is located in the Kumaon area of Uttarakhand and is spread over hilly areas as well as the plains. It

has an area of 4,251 Sq. Km square kilometers. The total population of the district is 9,54,605, out of which rural population is 493859 as per 2011 census.[165,] Uttarakhand has two divisions – Garhwal and Kumaon, with a total of 13 districts, 78 tehsils and 95 community development blocks. Garhwal has following districts: Uttarkashi, Chamoli, Pauri, Rudraprayag, Tehri, Dehradun and Haridwar and Kumaon has: Udham Singh Nagar, Nainital, Almora, Pithoragarh, Champawat and Bageshwar as districts.[166] As per NFHS-4 data, the status of malnutrition is more in rural areas of Uttarakhand than urban. As Haldwani was more accessible so it was chosen to explore the nutritional status of children aged 1-3 years residing in rural areas. The description of Uttarakhand state with districts and blocks is shown in Fig. 2 below.

Population: The population for the present study comprised of children aged 1-3 years of age and their mothers in Haldwani block.

Sample

The samples selected for the first phase of the study were 703 children in the aged 1-3 years. In the second phase, the samples included were 149 malnourished children identified in the first phase and their mothers.

Sample Size

Phase I:

The prevalence of malnutrition in Kotabag block was found to be 18% during the pilot study. As malnutrition is a major problem in India, the sample size estimated for main study based on pilot study was not adequate to explore the prevalence in the selected setting. So, for the present study the sample size to

Fig. 2. Map of Study site – Haldwani, Nainital District, Uttarakhand

identify the prevalence was established based on previous studies done in Uttarakhand. The prevalence of malnutrition taken for the present study was 61.78%. Considering this, with absolute precision of 5% at 95% CI and design effect of 1.5, sample size was estimated.

Following formula was used:

$$n = \frac{Z_{1-\alpha/2} \; P \; (1-P) \; x \; 1.5}{d^2}$$

Z $_{1-\alpha/2 \; is}$ the normal distribution value at 95% CI,

P is the prevalence from the study [77]

d is the allowable error = 5%, design effect = 1.5

The estimated sample size was 622 and 703 samples were recruited for the survey.

Phase II: The sample size for phase II was also estimated based on previous study[164] and not on basis of pilot study. During the pilot study the follow-up was done on 15th, 30th and 45th day and the time duration was not adequate to develop significant changes in children weight and height. Thus, the sample size was calculated considering weight gain as primary outcome variable. Taking 90% power and 5% level of significance and 10% attrition rate, we consider 64% change in malnutrition to normal category in control group and we assume 25% more improvement in intervention group as compared to control group. Thus, we require minimum 67 samples in each group i.e., a total of 134. Thus, the subjects recruited in the study were 149 (75+74), from four subcenters selected of Haldwani block, that is two in control and two intervention group.

The formula used was:

$$n_1 = (Z_{1-\alpha/2} + Z_{1-\beta})^2 \frac{p_1(1-p_1) + p_2(1-p_2)}{(p_1 - p_2)^2}$$

Proportion of outcome from group one (p_1) = 0.89

Proportion of outcome from group one (p_1) = 0.64

Level of significance (α) = 0.05

Power (1- β) = 0.90

Z alpha value = 1.96

Z beta value = 1.28

Design Effect = 1.5

Attrition rate = 10%

Sampling Criteria

Inclusion criteria

Phase I

1. Children in the age group of one to three years

2. Availability of the children at the time of data collection.

3. Mothers willing to participate in the study.

4. Mothers who are able to understand Hindi language.

Phase II

1. Children having mild to moderate malnutrition.

Exclusion criteria

Phase II:

1. Mothers who are mentally challenged.

2. Children having congenital deformities like Mal Absorption Syndrome, Celiac diseases, and Lactose Intolerance, Down Syndrome and Pierre Robin Syndrome, Cleft Lip and Cleft Palate, Tracheoesophageal Fistula, Congenital Dysplasia of Hip and Cerebral Palsy.

3. Children with severe malnutrition or undergoing any kind of treatment for malnutrition.

4. Children who are not staying with biological mother.

Sampling Technique

Phase I: For this phase**,** multi staged sampling technique was adopted.

There are total of eight blocks in Nainital district.[167] Out of eight blocks one block was conveniently selected i.e., Halwani block. In Haldwani block there is one community health center in Kaladungi, so it was purposively selected. Under community health center, there are seven primary health care centers covering 21 sub- centers.[168.] In order to meet the estimated sample size, the researcher randomly selected sub-centers by lottery method for screening children. The procedure of selecting subcenter continued till estimated sample size was achieved. Thus, four sub-centers were selected randomly. Each sub-center was chosen as a cluster for selection of samples. All the children aged 1-3 years in the villages of selected sub-centers were screened for malnutrition. The description regarding the multi

staged random sampling is explained in Fig.3 below. Help from ANM supervisors and Aganwadi workers of selected villages was taken and door to door screening was done.

Phase II: For this phase, random allocation of subcenters as clusters was carried out. Two sub-centers were randomly allocated to control and intervention group. Schematic representation of the research methodology along with randomization procedure was developed according to CONSORT guidelines (consolidated standards of reporting clinical trials) and is presented in Fig. 4

Data Collecting Tools

Tool 1: Socio demographic Proforma

Tool 2: Tools for Assessment of Nutritional Status

      2A: Weighing Machine

      2B: Tape measure

      2C: Shakir Tape

      2D: Proforma to record Nutritional Status

      2E: Post Intervention Nutritional Status monitoring Sheet

Tool 3: Semi Structured questionnaire to assess risk factors related to malnutrition in children

Tool 4: Structured Knowledge questionnaire on Nutrition of children

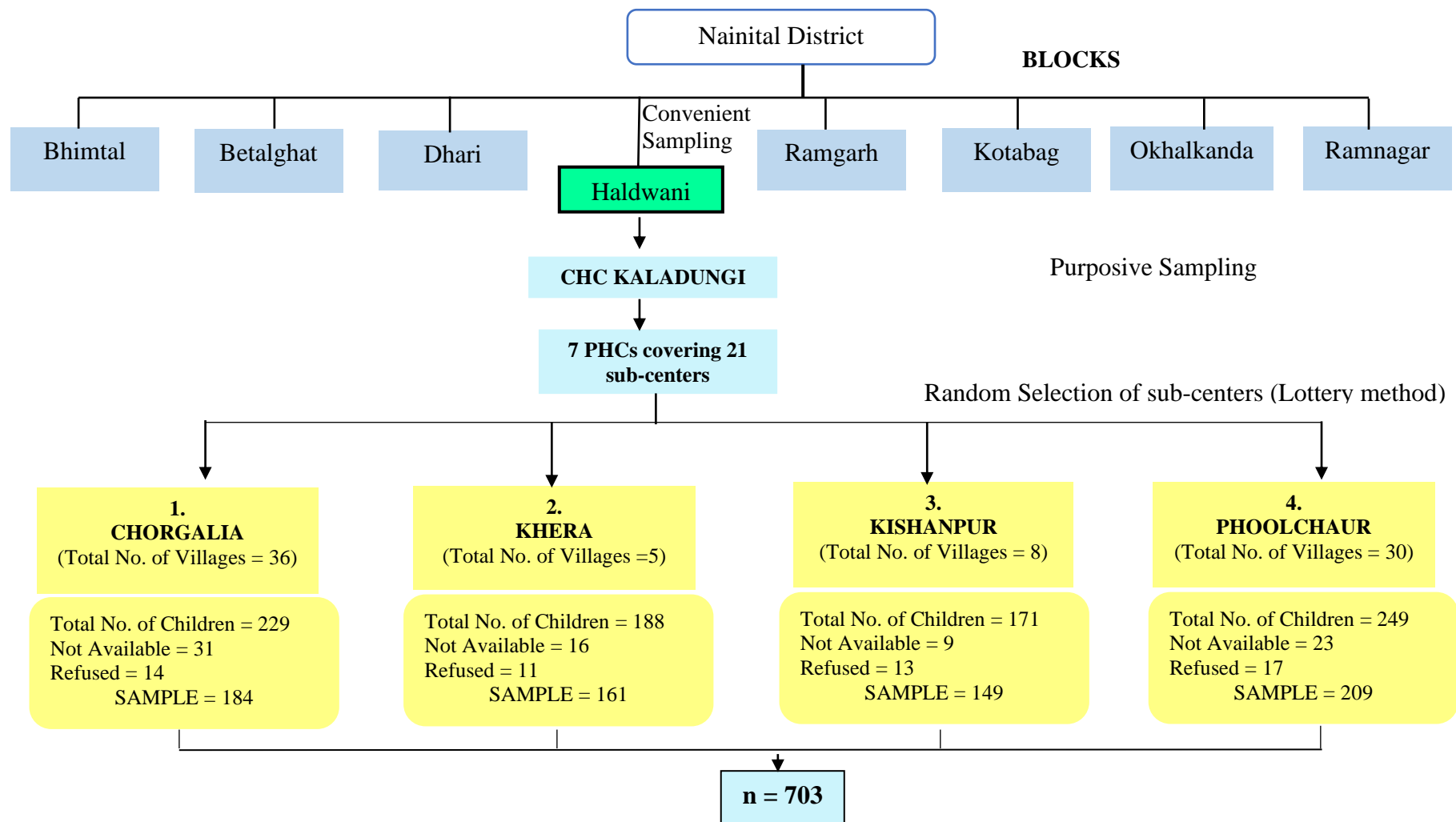Tool 5: Structured questionnaire on nutrition related practices adopted by mothers

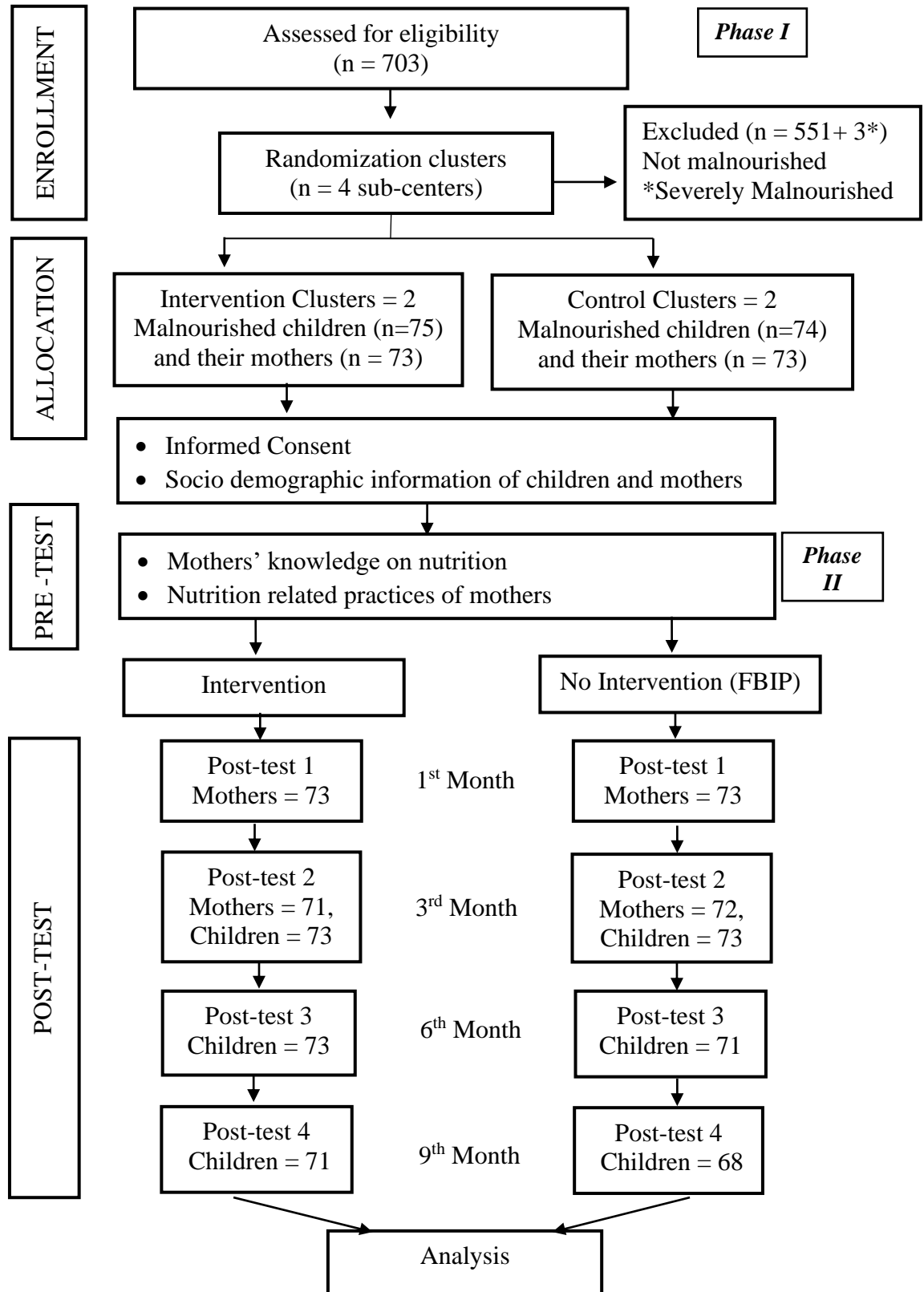**Fig. 3.** Schematic representation of Sampling technique of Phase I

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ENROLLMENT

Assessed for eligibility
(n = 703)

Phase I

Randomization clusters
(n = 4 sub-centers)

Excluded (n = 551+ 3*)
Not malnourished
*Severely Malnourished

ALLOCATION

Intervention Clusters = 2
Malnourished children (n=75)
and their mothers (n = 73)

Control Clusters = 2
Malnourished children (n=74)
and their mothers (n = 73)

- Informed Consent
- Socio demographic information of children and mothers

PRE -TEST

- Mothers' knowledge on nutrition
- Nutrition related practices of mothers

Phase II

Intervention

No Intervention (FBIP)

POST-TEST

Post-test 1
Mothers = 73

1st Month

Post-test 1
Mothers = 73

Post-test 2
Mothers = 71,
Children = 73

3rd Month

Post-test 2
Mothers = 72,
Children = 73

Post-test 3
Children = 73

6th Month

Post-test 3
Children = 71

Post-test 4
Children = 71

9th Month

Post-test 4
Children = 68

Analysis

Fig. 4. Schematic representation of Research Methodology

Description of Tools

Tool 1: Socio demographic Proforma

The present tool was developed by the researcher to collect baseline information which included: Gender, Age in years, Gender, Religion, Type of family, Number of siblings, Place of stay, Socio-economic status, patent's Education and Occupation, Birth order, Diet type and ANC services. A total of 17 items were there in the tool. The items did not have any scoring. *(Appendix I)*

Tool 2: Tools for Assessment of Nutritional Status

The instruments used to assess the nutritional status were - Digital weighing machine to measure weight of the child, Inch tape was used to measure the height and Shakir tape was used to measure the mid upper arm circumference. It consisted three colour codes i.e., Red, Yellow and Green. In which red indicate severe acute malnutrition (below 11.5 cm), yellow as moderate acute malnutrition (12 cm) and green as no malnutrition (more than 13.5 cm). Proforma was used to record weight, height and mid upper arm circumference of children. *(Appendix II, III)*

Tool 3: Semi Structured questionnaire to assess risk factors related to malnutrition in children

The tool comprised of questions in the following areas i.e., birth related factors, breast feeding Practices, childhood illness, environmental characteristics, dietary characteristics, health seeking behavior and utilization of health services. The tool was dichotomous with yes and no response. The total items in the tool were 29. The items did not have any scoring as the proforma was intended to collect only factual information by researcher through interview method. *(Appendix IV)* The blue print of the tool is presented in Table 1.

Tool 4: Structured Knowledge questionnaire on Nutrition of children

To assess the knowledge of mothers regarding nutrition of children structured knowledge questionnaire was used. The tool developed was a multiple-choice questionnaire having following domains: malnutrition, minor deficiency diseases and nutrient rich diet, feeding and importance, complementary feeds, management, prevention, and complications and utilization of services. The total items in the tool were 28. A score of one was be given for correct answer and zero for wrong answer or no response. The total score of the tool was 26. It was further categorized into Good (above 20), Average (10–20) and Poor below 10 based on responses given. *(Appendix V)* The blue print of the tool is presented in Table 2.

Table 1: Blue print of tool on risk factors related to malnutrition in children

Sl. No.	Factors	Questions	No. of Ques.	Percentage
1.	Birth related factors	12	1 – 12	35.3%
2.	Breast feeding practices	8	13 – 20	23.5%
3.	Childhood illness	2	21 – 22	5.8%
4.	Environmental characteristics	10	23 – 32	29.4%
5.	Health seeking behaviour	3	33 – 35	3%
6.	Utilization of health services	1	36	3%
TOTAL		**36**	-----	**100%**

Table 2: Blue print of tool on structured questionnaire on Nutritional knowledge

Sl. No.	Areas	Questions			Total	%
		Recall	Comprehension	Application		
1.	Malnutrition and causes	3	1, 2,4	–	4	14
2.	Balanced diet and nutrients	5	6	–	2	7
3.	Symptoms and deficiencies	–	7,8,9,10	11	5	18
4.	Weaning and feeding	14	12 – 15	16	5	18
5.	Food sources	24	18 – 23	17	8	29
6.	Health services	–	–	25 – 28	4	14
	TOTAL				**28**	**100**

Tool 5: Structured questionnaire on nutrition related practices used by mothers

To identify the nutrition related practices as reported by mothers a structured five-point Likert scale was developed having following responses: Daily (5), Four to five times (4), Two to three times (3), Once (2) and Never (1). The tool consisted of following areas: feeding practices, eating practices, cooking practices and hygienic practices. The tool had 26 items with 20 items having positive questions and 6 items having negative questions thereby having reverse scoring. The total score of the tool was 130. It was categorized into adequate (above 104), moderately adequate (66 – 30) and inadequate practices (below 65). *(Appendix VI)* The blue print of the tool is presented in Table 3.

Table 3: Blue print of tool on structured questionnaire on Nutrition related practices

Sl. No.	Practices	Questions	No. of Questions	Percentage
1.	Feeding practices	1	1	4
2.	Eating practices	2 – 18	17	65
3.	Cooking practices	19 – 23	5	19
4.	Hygienic practices	24 – 26	3	12
	TOTAL		**26**	**100**

Validity of the Tool

The tool was given to nine experts from the department of Pediatric Medicine, Community Medicine, Child Health Nursing and Community Health Nursing to establish content validity. Necessary modifications were made as suggested by the experts and guides. For tool I, there was 100% agreement for all sixteen items and 87% agreement for one item in the tool. The items retained in the tools were 16 after modification. There was 100% agreement for all items in the tool II. For tool III, there was 100% agreement for 23 items, 87% agreement for 10 items and 80% agreement for three items out of 36 items in the tool. Four items were removed. Hence, the total number of items after modification was 30. There was 100% agreement for 15 items, 87% agreement for 15 items and 75% agreement for 8 items out of 36 items in the tool IV. Thus, 8 items were removed from the tool. The total number of items after modification were 28. For tool V, there was 100% agreement for 22 items and 88% agreement for 6 items in the tool. The total number of items after modification is 26 after removing two items. *(Appendix VII)*

Pretesting

The pretesting of the tool was done on 1st February, 2020 to determine the clarity of the items, identify the difficulty in understanding the terms and the time required to complete the tool. The tool was administered to five mothers of children. The mothers did not face any difficulty in answering and understanding the questions in the tool. To complete the entire tool the average time taken was thirty minutes.

Reliability

Reliability for tools was established by administering it to 30 children aged 1-3 years and their mothers and is described below:

Tool II: Tools for Assessment of Nutritional Status

Inch tape and weighing machine was calibrated with 0.1% error. Reliability for equivalence was established by inter rater reliability and the tool was found reliable (r = 1). *(Appendix VIII, IX)*

Tool 4: Structured Knowledge questionnaire on Nutrition of children

The reliability for internal consistency was calculated by Cronbach's alpha and Split half. For stability it was calculated by test – retest and also Spearman Brown rank coefficient and described in Table 4 below.

Tool 5: Structured questionnaire on nutrition related practices used by mothers

The reliability for internal consistency was calculated by Cronbach's alpha and Split Half. For stability was calculated by test – retest and Spearman Brown rank coefficient. It is described in Table 4

Table 4: Reliability coefficient for knowledge and practice questionnaire

Sl. No.	Method	Reliability Coefficient	
		Knowledge Questionnaire	Practice Questionnaire
1.	Test – retest	0.72	0.74
2.	Split Half	0.80	0.71
3.	Spearman – Brown Rank	0.82	0.72
4.	Cronbach's Alpha	0.79	0.72

Language Validity of Tools

Validated tool was translated to Hindi and was given for validation to three experts in Hindi. Necessary modifications were made as suggested by the experts. Re-translation to English was done to check language validity by another expert. *(Appendix X)*

Description of Intervention

Family Based Intervention Program (FBIP) referred to multi–component training program which was prepared by researcher. It was designed to provide information to mothers and family members in a group of 10 – 20 on malnutrition and its prevention in children aged 1-3 years. It was prepared by keeping in mind the study population are rural mothers and their family members, their income, educational status, cultural eating practices of the selected area. To achieve the objectives, the content was made simple, clear and comprehensive. *(Appendix XI)*

The objectives of the training program for mothers were to:

1. To enhance knowledge of mothers regarding malnutrition and its prevention.

2. To develop competency among mothers on the assessment of dietary pattern, selection of food items and improving nutritional intake.

3. To create understanding among mothers in methods of assessing nutritional status of children.

4. Demonstrate skill in preparation of healthy diets

The key features of FBIP were:

- Enhancing the knowledge and competency of mothers regarding identifying, selecting and using locally available food items for their children.

- Monitoring the nutritional status by the mothers

- Dietary Recall and Diet Analysis (Diet-Cal Software) *(Appendix XII, XIII, XIV)*

- Nutritional Poster for children and Nutritional Calendar for mothers *(Appendix XV)*

- Information booklet *(Appendix XVI)*
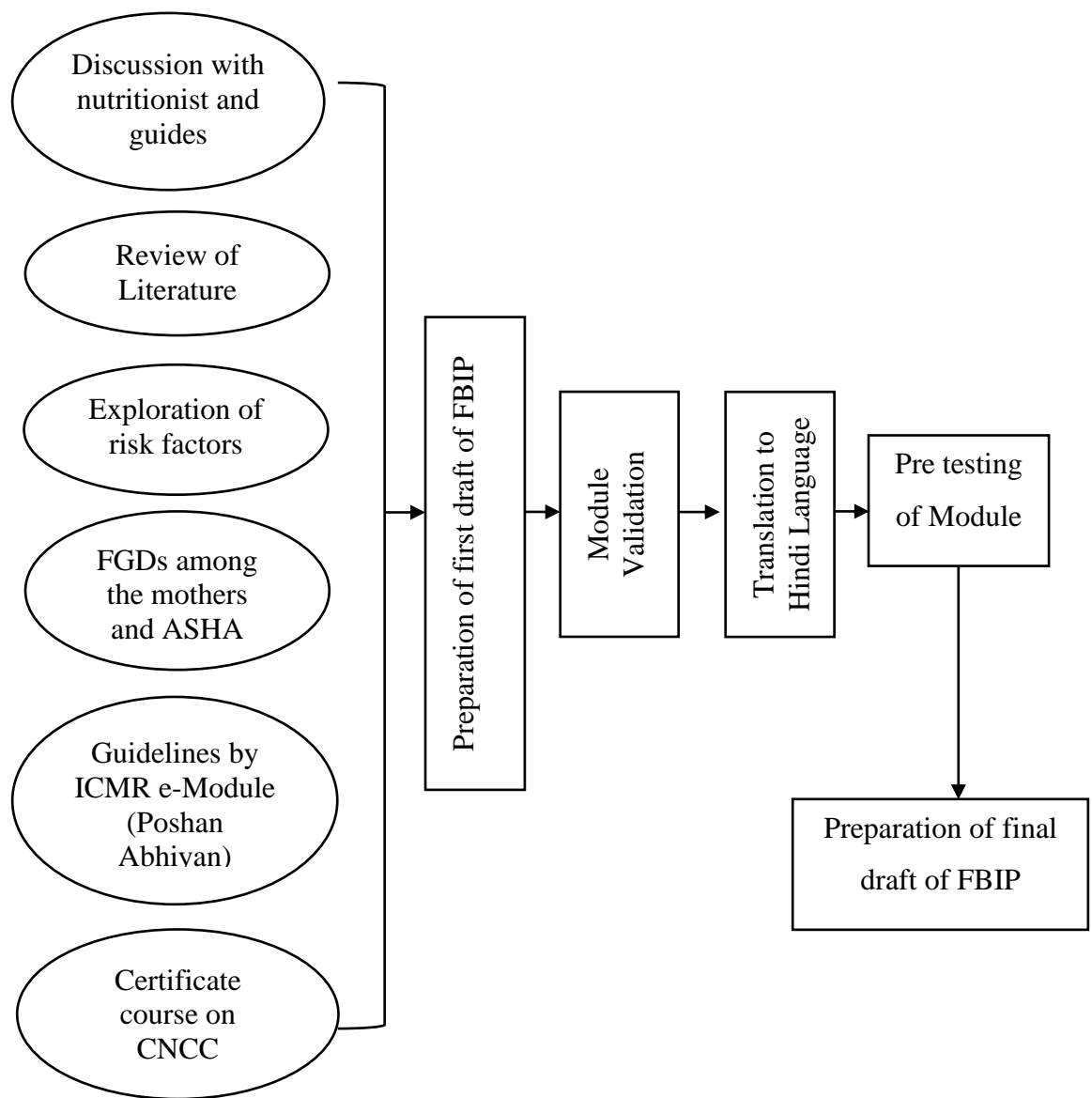
- Recipe booklet *(Appendix XVII)*

The entire FBIP was of 2 weeks (14 days) duration and the medium of instruction was Hindi. PowerPoint, Chart, Flip Chart, weight and height monitoring chart, diet record sheet, Nutritional poster and information brochure were used as audio visual aids. Following sessions were untaken as part of intervention program: Nutrition at a glance – Overview of nutrition and its need, Nutrition and malnutrition related awareness, Nutrition monitoring, Diet recall and Diet analysis, Re-briefing: Nutrition chart, Information poster and Booklet.

Development of FBIP

In order to develop intervention intense reading of literature of published journal articles in various sources, personal experiences, discussion with research guides, based on identified risk factors of malnutrition, focused group discussions with mothers and ASHA workers, expert opinion was done for module preparation. Following steps were undertaken to develop family-based intervention program (FBIP) as described in Fig.5

Ethical consideration

1. Research Protocol was prepared considering the ethical principles and ICMR guidelines. Ethics committee clearance was obtained from University Ethics Committee with following registration number: SRHU (SRHU/HIMS/ E-1/2019/92), *(Appendix XXII)*

2. Permission was also obtained from Child Development Project Officer (rural), Haldwani. *(Appendix XXIII)*

3. Explanation about the study in detail was given to mothers by the researcher. Participant information sheet was given to the mothers of malnourished children. *(Appendix XXIV)*

4. Written Informed Consent was obtained from the parents (mothers) after explanation of the study purpose. *(Appendix XXV)*

Discussion with nutritionist and guides

Review of Literature

Exploration of risk factors

FGDs among the mothers and ASHA

Guidelines by ICMR e-Module (Poshan Abhivan)

Certificate course on CNCC

Preparation of first draft of FBIP

Module Validation

Translation to Hindi Language

Pre testing of Module

Preparation of final draft of FBIP

(Appendix XVIII-XXI)

Fig. 5. Development of Family Based Intervention Program

Trial Registration

The phase II of the present study was registered in Clinical Trial Registry of India (CTRI) and the trial registration number is: CTRI/2021/01/0308205. *(Appendix XVI)*

Pilot Study

To determine the possibility of the study, pilot study for phase I was done among 100 children aged 1–3 years in February 2020. The prevalence of malnutrition identified was 12%. Focused group discussions were also conducted as part of the study to further explore the factors and need for intervention among mothers of children and ASHA workers.

Phase II pilot was done in the month of March 2020 i.e., children identified as malnourished and their mothers were randomly allocated to intervention and control arm (entire village was randomized). Follow up visits were done on 15th day, 30th day and 45th day. The study was found feasible.

Procedure for Data Collection

The data collection procedure has been discussed phase wise.

Phase I: After obtaining the administrative permission, list of sub-centers and villages was obtained from the Block office. Random selection of sub-centers was done using lottery method and all the villages in the selected sub-centers were included till the estimated sample size was achieved. Door to door home visiting was conducted to identify the eligible children. Mothers and family members were

explained about the purpose of data collection followed by which informed consent was obtained from mothers. Screening of the children for malnutrition was done by measuring weight, height and MUAC. Exploration of factors relating to malnutrition was done through semi- structured interview method among the mothers. Focused group discussions were also conducted to identify mothers' perception of risk factors of malnutrition.

Phase II: The children identified malnourished in the phase I were allotted to control and intervention group through concealed random allocation of sub-centers. Knowledge and nutrition related practices was assessed in the mothers of children identified as malnourished in both the groups. Experimental group received need-based intervention (FBIP) and control group no intervention. Post-test was done for mothers in both intervention and control group at 1st month, and 3rd month and in their children, it was done at 3rd month, 6th month and 9th month respectively.

Plan for Data Analysis

The analysis for the data was done as per objectives of the study.

Phase I

First phase of the study, frequency, percentage, mean and standard deviation was used to describe the sample characteristics and nutritional status. Odds ratio by regression analysis was used to determine the risk factors.

Phase II

Descriptive statistics i.e., frequency and percentage were used to describe knowledge and nutrition related practices of mothers. Inferential statistics was used to identify the effectiveness of intervention i.e., independent 't' test, r Anova,

Chi square, coefficient of correlation was used to meet the objectives of the second phase.

Chapter Summary

Methodologically the entire study was divided into two phases. The design for the first phase was exploratory design and for the second phase was randomized controlled trial design. Further this chapter discussed setting, population, sample and sampling technique, development and description of tool, its validity and reliability. It also discussed about the development of intervention, pilot study, procedure of data collection and plan of data analysis.