CHAPTER 3

RESEARCH METHODOLOGY

This chapter describes method and procedure of research study. The present study was done in two phases. In phase I, barriers related to prevention and home-based management of ARI among mothers having children less than age of five years was explored and need based interventional package for ARI was developed. In phase II, effectiveness of interventional package on knowledge and practice of mothers on prevention and home-based management of ARI and frequency of symptoms and episodes of ARI among under five children was evaluated.

Research approach

Researcher adopted Mixed method approach. It consists of qualitative and quantitative research approach.

Phase I: Qualitative approach

Qualitative approach was used to explore barriers related to prevention and home management of acute respiratory infection among mothers having children less than five years of age followed by development of need based interventional package.

Phase II: Quantitative approach

Quantitative approach was used to evaluate effectiveness of need based interventional package on knowledge and practice of mothers about prevention and home-based management of ARI, frequency of symptoms and number of episodes of ARI among under five children.

Research design

In the present study, sequential exploratory design was adopted.

Phase I: Exploratory design was used to explore barriers on prevention and home management of ARI by conducting focus group discussion among mothers of under five children.

Phase II: Randomized controlled design was used to assess effectiveness of need based interventional package on knowledge and practice of mothers and frequency and number of episodes of ARI in children.

Randomization	**Group**	**Pre-test Assessment at Baseline**	**Intervention 5 Sessions: (45Minutes) For 2 weeks**	**Post-test 1** 1^{st} **Month after intervention**	**Post-test 2** 3^{rd} **Month after intervention)**	**Post-test 3** 6^{th} **Month after intervention)**
	Experimental Group	**EO_1**	**X**	**EO_2**	**EO_3**	**EO_4**
	Control Group	**CO_1**	**-**	**CO_2**	**CO_3**	**CO_4**
Variables		Knowledge of mothers -Practice of mothers -Frequency and number of episodes of ARI in under five children	-Knowledge of mothers -Practice of mothers -Frequency and number of episodes of ARI in under five children	-Knowledge of mothers -Practice of mothers -Frequency and number of episodes of ARI in under five children	-Knowledge of mothers -Practice of mothers -Frequency and number of episodes of ARI in under five children	-Knowledge of mothers -Practice of mothers -Frequency and number of episodes of ARI in under five children

Research variables

Independent variables: Need based interventional package on prevention and home management of ARI in children less than age of five years.

Dependent Variables: Knowledge and practice of mothers on prevention and home management of ARI, frequency of symptoms and number of episodes of ARI in children.

Research setting

Present study was done in the north region of Delhi which is most rural region of Delhi. North Delhi is an administrative district of Delhi and divided in to three zones. These areas include North West Delhi, North East Delhi and North Delhi. The selected North West Delhi district is further divided in to subdivision. It has three subdivisions. These subdivisions are Model town, Alipur and Narela. The selected subdivision for present study was Narela subdivision. This area is about 264 km including 138.20 km urban area and 125.54 km rural area. The total population of Narela subdivision is about 8 lakhs, out of which rural population is 1,68,739 while urban population is 6,41,174. Narela subdivision has 15 villages, out of these, Lampur and Singhola villages were selected for present study. The total geographical area of Lampur village is 511.3 hectares. It has a total population of about 2700 peoples and children's population under six years of age is around 315. Total geographical area of Singhola village is 286.2 hectares. It has a total population of 2,400 peoples and children's population under six years of age is around 290**.**

Population

The population for the present study was mothers with children under the age of five and their children aged one to five years who were residing in rural areas of North Delhi.

Sample

Phase I

The sample for present study were mothers having under five children who met the inclusion criteria for focus group discussion.

Phase II

The sample selected for this phase were children who were one to five years old and mothers of these children who met the inclusion criteria.

Sample size

Phase II

Sample size of mothers having under five children was calculated by considering previously published study by Henny et al. (2017). The sample size was calculated with this formula for present study. Mean ± SD from the mentioned study was used with a good estimate of population effect size.

$$n = 2\,Sp^2\,[Z\ 1\text{-}\alpha/2 + Z\ 1\text{-}\beta]^{\,2} / \mu d^{\,2}$$

$$Sp^2 = S1^{\,2} + S2^{\,2} / 2$$

Where,

$S1^{\,2}$: Standard deviation in the first group

$S2^2$: Standard deviation in the second group

μd^2: Mean difference between the samples

α: Significance level

1-β: Power

So, the estimated sample size calculated was 160 mothers having under five children to accomplish 80% power at 5% level of significance and 254 mothers were recruited for this study with keeping in to mind the power and effect size.

Sample size for under five children was calculated based on previous study conducted in Delhi by Sneha et al. (2017) reported a prevalence rate of 34.3%. Considering this prevalence rate, with an absolute precision of 5% at a 95% confidence interval (CI), the sample size was determined.

The following sample size calculation formula was used for present study

$$n = Z^2 p (1- p) /d^2$$

Z= 1.96, the normal distribution value at 95% CI.

p = 0.343, prevalence (34.3%) from the previous study by Sneha P et al. (2017)

d = 0.05, Precision (margin of error = 5%)

So, estimated sample size calculated was 345 under five children and 430 were recruited for the study.

Sampling Criteria

Samples were selected according to these inclusion and exclusion criteria.

Inclusion criteria

Phase I

1. Mothers having children one to five years old.

Phase II

1. Children who were in one to five years of age group
2. Mothers having children in one to five years of age group
3. Mothers who were able to understand Hindi language
4. Mothers who wanted to take part in study

Exclusion criteria

Phase I

1. Mothers having any mental illness

Phase II

1. Mothers who were not available during data collection
2. Mothers who were mentally challenged
3. Children who were having severe respiratory infection and taking any medical treatment for this.

Sampling technique

In the context of this research study, simple random sampling technique was adopted to select the setting. Multi-stage cluster random sampling technique was adopted to

select villages. The schematic representation of sampling technique is represented in figure no .3

Stage I: One district of North Delhi was selected randomly

Stage2: One subdivision of selected district of North Delhi was selected randomly

Stage 3: Two villages of selected subdivision were selected randomly through computer generation method.

Stage 4: Home to home visit was done to recruit sample as per the inclusion criteria.

North Delhi is an administrative district of Delhi in India. North Delhi is divided in to three zones/districts. These are North West, North East and North Zone. Firstly, North West district was randomly selected out of three district of North Delhi region. North West district has three subdivision. One subdivision was randomly selected out of these subdivisions. This selected subdivision (Narela) has 15 villages. Random allocation of selected villages as cluster was carried out. At last two villages were selected randomly out of these villages by lottery method. Home to home visit was done and with the help of anganwadi workers mothers having under five children were identified. One village was allocated in to the experimental group and another village was put in to the control group randomly.

Data Collection Tools

Following tools were used to collect data in the present study

Tool 1: Sociodemographic variables

Tool 2: Open ended questionnaire on exploring barriers related to prevention and home management of acute respiratory infection

Tool 3: Semi structured questionnaire to explore risk factors of acute respiratory infection.

Tool 4: Structured ARI screening Tool

Tool 5: Structured knowledge questionnaire on prevention and management of acute respiratory infection

Tool 6: Structured self-reported practice scale on prevention and management of acute respiratory infection

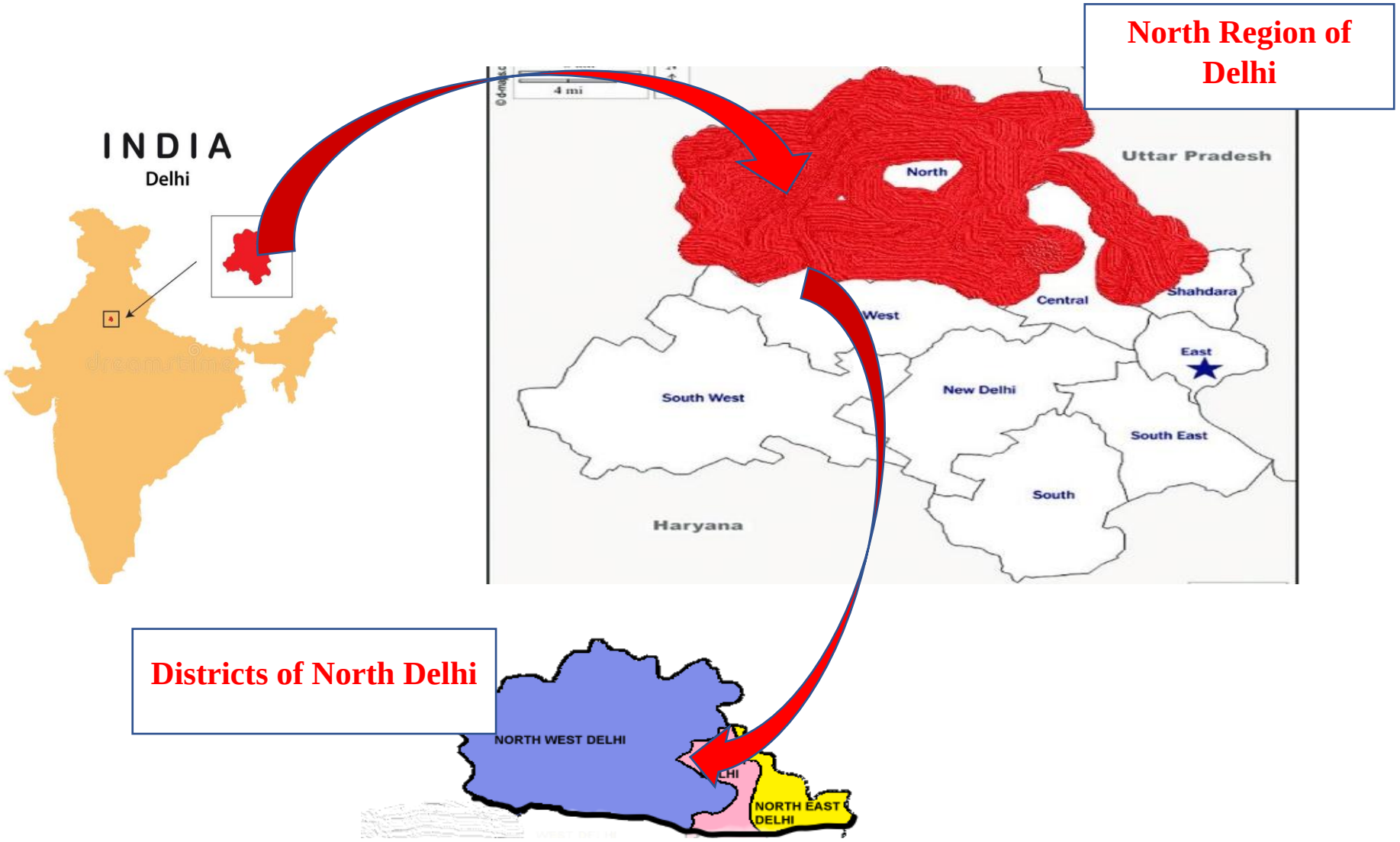

Figure no 2: **Research setting – North West Delhi Subdivision, North District, Delhi**

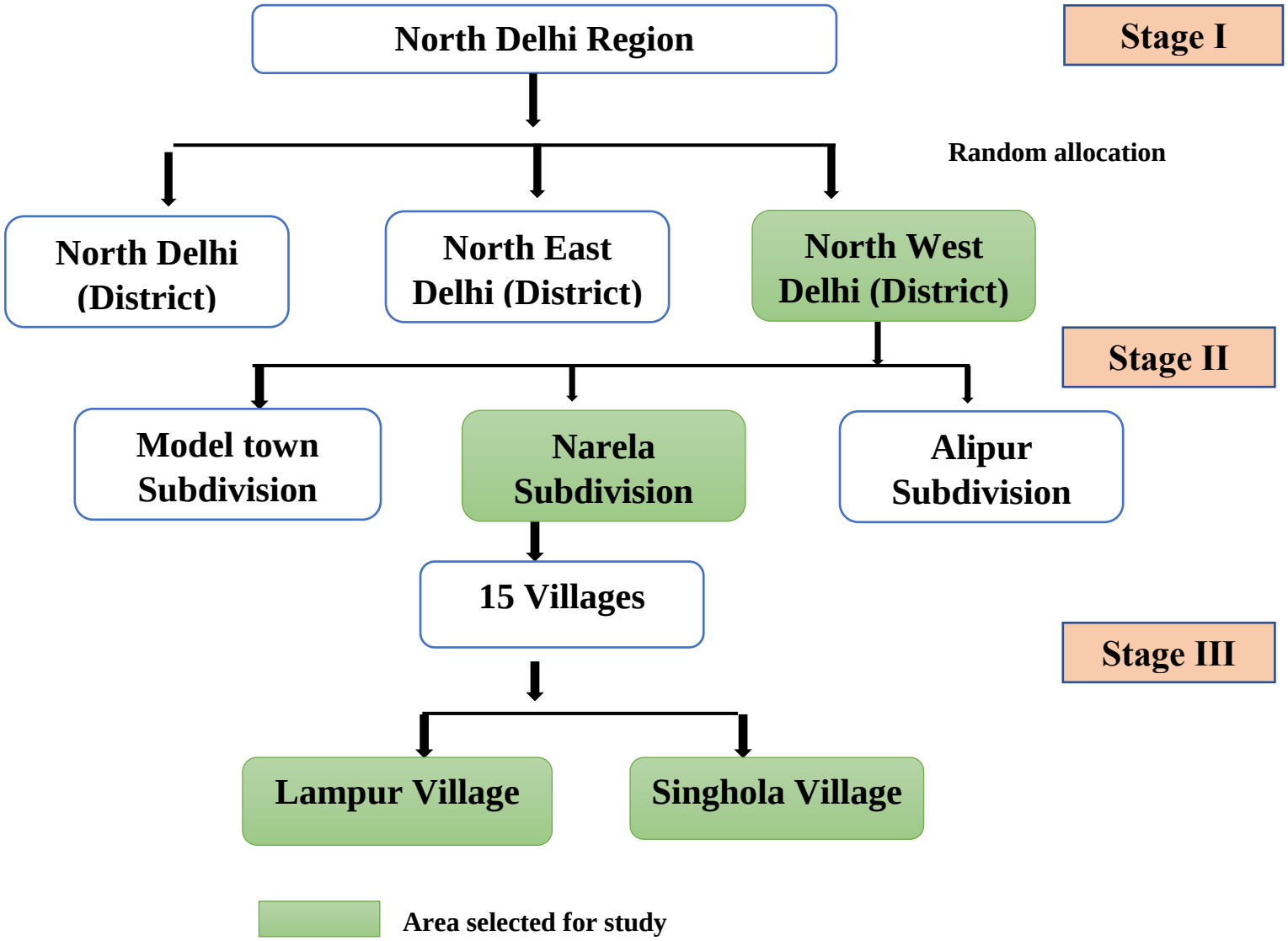

Figure no 3: Schematic representation of sampling technique

Description of tool

Tool 1: Sociodemographic variables

This tool was developed by the researcher to collect information of child viz. age, gender and information of mother viz. occupation and education status, family type, socioeconomic status, religion, history of any respiratory infection in family, dietary pattern and number of children.

Tool 2: Open ended questionnaire

Open ended questionnaires consisted of questions on prevention and management of ARI in under five children.

Tool 3: Semi structured questionnaire on risk factors of ARI

This tool comprised of questions related to child characteristics, environmental characteristics, history of illness in last six months and nutritional variables. The total items in this tool were 23. The items were intended to gather only factual information and did not have any score associated with them.

Blue print on risk factors related to ARI in under five children

S.no	Factors	Questions	No of questions	Percentage
1	**Child's characteristics**	1-4	04	16%
2	**Environmental characteristics**	5-16	12	50%
3	**History of illness in last six months**	17-18	02	9%
4	**Nutritional history during infancy period**	19-24	06	25%
Total			**24**	**100%**

Description of level of Environmental characteristics for Risk factors of ARI

There were 12 items in risk factors of ARI for assessment of environmental condition. The total score was 12. Scores were categorized in to (0-4) poor, (5-8) fair and (9-12) good environmental condition.

Tool 4: Structured ARI screening tool

This tool consisted of items for assessment of children for presence of acute respiratory infection and used to identify cases of acute respiratory infection, frequency of symptoms and number of episodes of ARI in under five children.

Tool 5: Structured knowledge questionnaire on prevention and home management of ARI

This tool consisted of multiple choice questions in the following domains viz. meaning of acute respiratory infection, mode of transmission, sign and symptoms, preventive measures, home management and complications. There were 25 items in the tool. A one mark was awarded to the right response and no mark was awarded for wrong response and no response. Maximum score was 25.

Interpretation of score

S.no	Level of Knowledge	Score range	Percentage
1	Poor	0-12	Below 50%
2	Average	13-18	>50% - 75%
3	Good	19-25	>75% - 100%

Blue print on structured knowledge questionnaire

S.no	Areas	Questions	No of questions	Percentage
1	**Information on ARI**	1-7	07	28%
2	**Prevention of ARI**	8-19	12	48%
3	**Home management of ARI**	20-25	06	24%
Total			**25**	**100%**

Tool 6: Structured self-reported practice scale on prevention and management of ARI

A three-point Likert scale was developed to identify mother's practices such as hygiene, feeding, eating, cooking and home remedies for management of ARI in children. It had 19 items with scores viz. always (2), sometimes (1), never (0). Maximum score was 38.

Interpretation of score

S.no	Level of Practice	Score range	Percentage
1	Inadequate	0-18	Below 50%
2	Moderately adequate	19-29	>50% - 75%
3	Adequate	30-38	>75% - 100%

Blue print on self-reported practice scale

S.no	Areas	Questions	No of questions	Percentage
1	**Hygiene practice**	1-5	05	26.3%
2	**Cooking/ Feeding practice**	6-11	06	31.57%
3	**Home management of ARI**	12-19	08	42.10%
Total			**19**	**100%**

Validity of tools

The tools were provided to nine experts from Child Health Nursing, Community Health Nursing, Midwifery and obstetrical Nursing and Community medicine department for validation of tools. Tools were modified as per suggestions given by experts.

The content validity index was evaluated for the following tools:

S.no	Tool	Content validity index
1	ARI screening tool	0.96
2	Semi structured interview questionnaire	0.89
3	Structured knowledge questionnaire	0.98
4	Self-reported Practice scale	0.96

Reliability of tools

Tools were given to 20 participants to check reliability of tools. The tools were found to be reliable.

Reliability coefficient of tools

S.no	Tools	Methods	Statistical test	r value
1.	ARI screening tool	Test -retest	Karl Pearson's correlation	0.85
2	Knowledge questionnaire	Split -half	Spearman Brown's Prophecy	0.88
3	Self-reported practice scale	Test -retest	Karl Pearson's correlation	0.82

Translation of tools

Validated tools were translated in to Hindi language and given for validation to Hindi language experts.

Pre-testing of tools

The tools were given to 10 mothers of under five children to check clarity of items, language difficulty in understanding and time required to fill the tool. The participants took about 30 minutes to fill the tools. They had no difficulty in understanding while filling up the tools.

Description of intervention package

Need based interventional package was developed after conducting focus group discussion on exploring barriers related to prevention and home-based management of

ARI. It was designed to provide information to mothers of under five children. It consisted of 5 sessions and each session was for 40-45 minutes. The duration of intervention was 2 weeks

The need based interventional package was given to two paediatrician, five experts from community health nursing and child health nursing experts for content validity. Suggestions were incorporated in the intervention package. The content validity index of intervention package was 0.96.

Ethical Consideration

1. Ethical permission was obtained from Ethics Committee of SRHU.
2. Permission was obtained from the block development officer of Narela subdivision of North West Delhi.
3. Participants information sheet was given to mothers having under five children and written informed consent was obtained from mothers who wanted to participate in the study.
4. Confidentiality and anonymity of participants were maintained.

Pilot study

Pilot study was done in Shajanpur and Bhalaswa villages of district North West Delhi from January to March 2021. Formal permission was received from concerned administrative authority and written informed consent from participants. For Phase I, one Focus group discussion was done among mothers having children less than age of five years to explore barriers related to prevention and home management of ARI. For Phase II, door to door home visiting was done to identify mothers of under five children. Screening of children was done for presence of symptoms of ARI. Pre-intervention knowledge and practice of mothers was assessed with structured

knowledge questionnaire and self-reported practice scale. After this, intervention was given to experimental group. Posttest was done on 15^{th}, 30^{th} and 45^{th} days after intervention in both groups. The study was found to be feasible to conduct study.

Procedure for data collection

Phase I

Before data collection, formal permission was received from administrative authority of Narela subdivision in north Delhi region. To conduct focus group discussion among mothers researcher conducted door to door home visiting to identify mothers having children who are less than age of five years and invited them to anganwadi centre and explained them about purpose of FGD. Researcher obtained written informed consent from mothers participating in focus group discussion and asked open ended questions with the help of moderator. The mother's responses were audio recorded. Researcher conducted three FGDs comprising of 8-10 in each group in anaganwadi centre on separate days.

The discussions were listened multiple times then transcription was done from audio recorded version to written verbatim in Hindi. The transcribed Hindi version was then translated in to English. Based on verbatim, subthemes and themes were generated. Based on above qualitative analysis, the need-based interventional package was developed and validated.

Phase II

Two selected villages viz. Lampur and Singhola were randomly allocated to experiment and control group by lottery method respectively. In Lampur village (Experimental group), there were three Anganwadi centers and in Singhola village

there were two Anganwadi centers. In both the villages list of mothers of under five children was taken from Anganwadi workers. Firstly, researcher went to Lampur village, with help of anganwadi worker researcher visited homes to identify mothers of children between one to five years. Mothers have given written informed consent after explanation about purpose of study. Researcher collected information regarding risk factors of ARI with the help of questionnaire. Information regarding child was obtained from mother and about immunization it was verified by seeing immunization card. Information regarding environment was observed such as ventilation of house, type of house, house location, types of water drainage system and information regarding number of persons living in room, indoor smoking by family members, types of fuel used for cooking, sources of drinking water, methods of waste disposal, health facility available in the area, pets in house etc. were asked to mothers.

ARI screening tool was used to screen 209 children between one to five years of age for presence of symptoms of ARI and frequency and duration of these symptoms were asked to mothers. Mothers were also asked about number of episodes of ARI in her child in past six months. After that structured interview was conducted with the mothers and information regarding their socio-demographic variables was collected. Pre-test knowledge of mothers on prevention and home-based management of ARI was assessed by structured knowledge questionnaire and practice of mothers was assessed by self-reported practice scale. It took 20 days to collect above mentioned data in Lampur village.

After that researcher went to Singhola village (Control group) and with the help of anganwadi worker visited homes to identify mothers of children between one to five years of age. Mothers have given written informed consent after explanation about purpose of study. Researcher collected information regarding environmental

condition, screened 221 children for presence of symptoms of ARI, assessed pre-test knowledge of mothers on prevention and home-based management of ARI, assessed practice of mothers by using self-reported practice scale. It took 25 days to collect above mentioned data in Singhola village. As few of mothers having more than one or two children between one to five years of age then they have been included for study as per eligible inclusion criteria of study.

On completion of above pre-test, researcher went to Lampur village (Experimental group). Researcher divided mothers into 8 groups with 15-20 mothers in each group. After that, researcher invited each group to nearby anganwadi center and administered need based interventional package by conducting one teaching session per day for five days

Details about administration of need based interventional package

S.no	Session	Content	Duration	AV Aids
First week				
1	Session 1	Teaching on **i**ntroduction of ARI, risk factors, mode of transmission of ARI, and diagnostic and assessment criteria of ARI	40 -45 mins	charts, posters, pamphlets
2	Session 2	Teaching on preventive measure of ARI (Immunization, nutrition, breast feeding, weaning diet, child safety and child hygiene)	40 -45 mins	charts, posters, pamphlets
3	Session 3	Teaching on home management and home remedies for ARI	40 -45 mins	Charts, poster, Video, pamphlets
Second week				
4	Session 4	**Demonstration on** • Handwashing ▪ Steam inhalation ▪ Chest physiotherapy	50-60 mins	Demonstration, videos

5	Session 5	**Demonstration of breathing exercise** • Candle and flower activity ▪ Blowing bubbles ▪ Pursued lip breathing Re-briefing of sessions Distribution of information booklet	50-60 mins	Demonstration, videos

Researcher completed administration of need based interventional package to 121 mothers in 8 weeks. Reinforcement related to practice and home-based management of ARI was done to mothers at 1st and 3rd month. Researcher also provided information booklet after completion of intervention.

Post-test was conducted after 1st, 3rd and 6th month after intervention. Screening of children for presence of ARI symptoms and number of episodes of ARI in previous months and assessment of mother's knowledge and practice was done from experiment and control group.

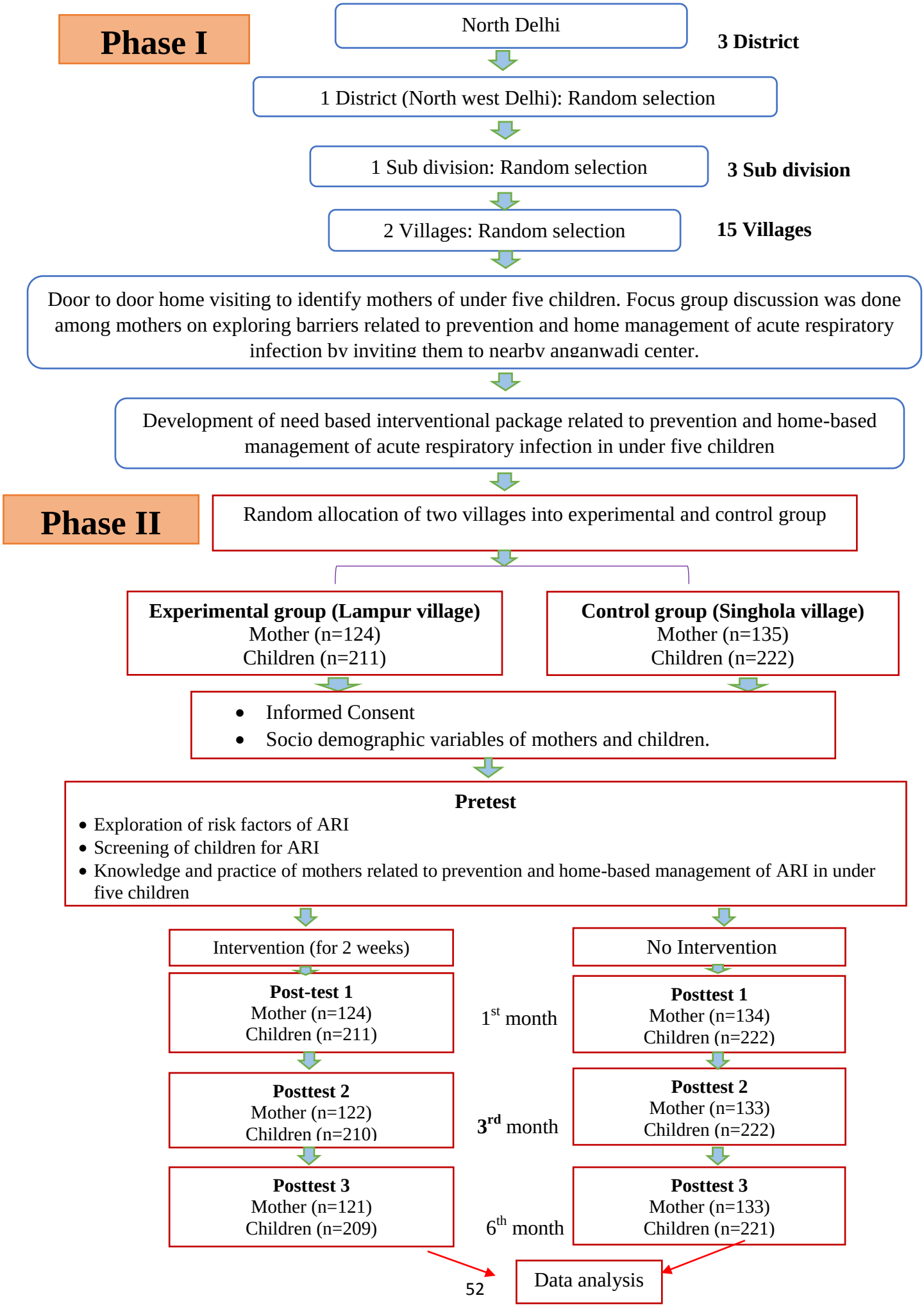

Figure no 4: Schematic representation of data collection procedure

Plan for data analysis

Thematic analysis was done for qualitative data in phase I. In phase II, descriptive statistics viz. mean, standard deviation, frequency, mean difference, percentage. Inferential statistics viz. independent 't' test, r Anova, Chi square, Odds ratio by regression analysis was used for data analysis. Further, correlation between the variables was calculated by using the two-tailed Spearman correlation formula.

Summary

This chapter discussed methodological strategies adopted in study.