CHAPTER-III

MATERIAL AND METHODS

Research methodology is an organized and general pattern of procedures to solve the chosen research problem. It combines various strategies to be used to gather and analyses the data to achieve research objectives. Present study was conducted in phases and used both qualitative and quantitative approaches. There was total two phase in the study and this chapter is organized under various subheadings as begin with research approach, research design, variables, research setting, study population, sample and sample size, sampling technique, sampling criteria, description of tool, validity of tool and content, reliability of tool, ethical consideration, pilot study, data collection procedure, data analysis, and interpretation.

RESEARCH APPROACH

It is the basic technique for collecting data in a particular research situation and guides the investigator as what data to gather and how to analyze it. Research approach is an overall plan chosen to conduct the research work. In present study mixed-method approach was considered appropriate to evaluate the effectiveness of Nurse-Led Cognitive Stimulation Program (NLCSP) on cognitive functioning and quality of life among elderly. As in this approach both qualitative and quantitative data are acquired and analyzed with in same study to get in-depth understanding of the research question. Mixed method approach enables the investigator to combine the strength of both qualitative and quantitative methods.

Research Approach: Mixed method approach

Qualitative Research Approach (QUAL) → Quantitative Research Approach (QUAN)

In first phase of the study, qualitatitve approach was used to explore the decline cognition-related problems of elderly and their caregivers. Following this phase there was the development of intervention and then in second quantitative phase, effectiveness of the developed intervention was evaluated.

Phase I: Qualitative approach

Phase II: Quantitative approach

RESEARCH DESIGN

It is the leading idea for identifying and describing the techniques and methods for gathering and analyzing the required information in a research study.

In this study keeping hypothesis and objectives in mind, the researcher used a sequential exploratory design of the mixed-method approach. The study design justifies the objectives of the study and is explained as following:

Research Design: Sequential Exploratory Design

In this study design, qualitative data collection and analysis was followed by quantitative data collection and analysis.

Qualitative phase: Exploratory design

Quantitative phase: Quasi-experimental design (with time series)

Phase I- Qualitative approach

Research design: Exploratory design

Research Settings: This is the actual location in which data has been collected in the research studies depending upon nature of research questions.

This study was conducted in Panipat which is one the largest District of Haryana. It occupies an area of 1,268 square kilometer with total 5 subdivisions/blocks. According to NHSRC report, majority 53.6% of population of Panipat lives in rural area. Moreover,

there is escalation in both numbers of elderlies as well as the prevalence rate of declined cognitive functioning which was found 4.5% in this district.[16] Hence setting for this phase was randomly selected villages Sewah and Risalu which belong to the rural community of district Panipat, Haryana. The description of the Panipat district with its subdivision/blocks is shown in Fig.2 below.

POPULATION

Target population: This is the population under study to which the investigator wants to generalize the research results.

Elderly (Age 60 years and above) who were having a decline in cognitive functioning as measured by Mini Mental State Examination (MMSE) and their caregivers were the target population.

Accessible population: This is that part of the population that is available to the investigator.

In the present study in this phase, elderly of selected villages (Sewah and Risalu) of the district Panipat, Haryana along with their caregivers were the accessible population.

SAMPLE

It is that fragment of the population that has been recruited to represent the population of the researcher's interest.

In present phase of study, sample was elderly and their care-givers belonging to selected villages (Sewah and Risalu) of District, Panipat (Haryana) of age 60 years and above who were having a decline in cognitive functioning as measured by MMSE.

SAMPLE SIZE: It is the minimum number of study participants involved in research.

Following the principle of data saturation, where there no new theme from the

participants emerged total four FGD with eight elderly and eight care-givers in each group were conducted for the first exploratory phase of the study.

SAMPLING TECHNIQUES

"It is the procedure of selecting a fragment of the population that represents the whole population." It is necessary because it is cost-effective and efficient to work with a smaller group.

In this phase purposive sampling technique was used to select the elderly and their caregiver by doing door to door home visits and cognitive screening by MMSE in the selected village Risalu and Sewah.

Data collection method: In this phase focus group discussion technique were used for collecting data.

Data collection tool: Semi-structured interview schedule for focused group discussion were employed. By this method elderly and their care givers express freely about problems they faced due to decline in cognitive functioning.

Data analysis method: Content analysis was done with the gathered information. The data were further coded and various categories were developed to generate themes. Also, complementary triangulation method was used for validating the concepts and themes related to exploration of the problems of decline cognitive functioning.
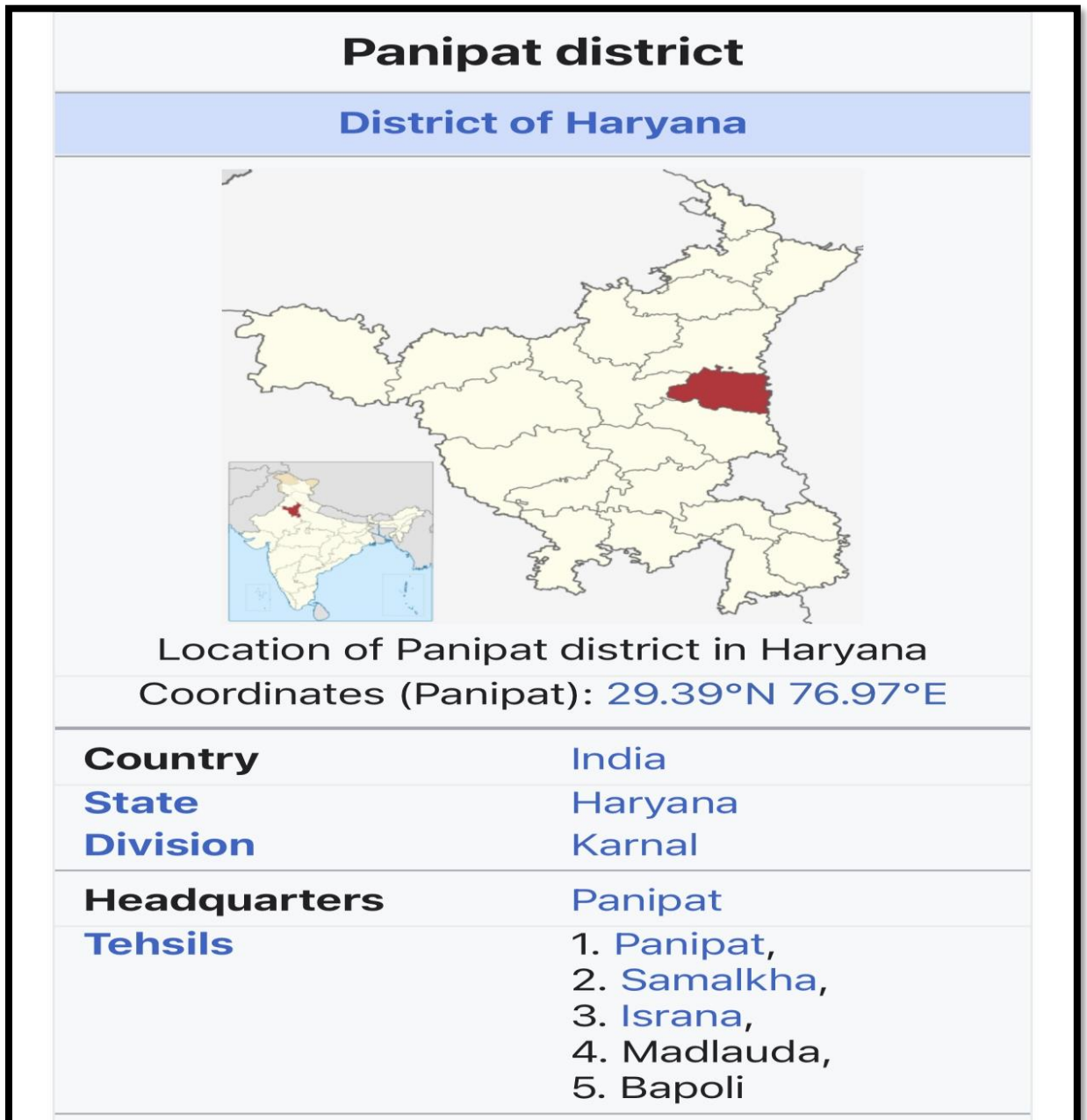
Panipat district	
District of Haryana	
Location of Panipat district in Haryana Coordinates (Panipat): 29.39°N 76.97°E	
Country	India
State **Division**	Haryana Karnal
Headquarters	Panipat
Tehsils	1. Panipat, 2. Samalkha, 3. Israna, 4. Madlauda, 5. Bapoli

Figure 2: Study site -District Panipat, Haryana

Phase II- Quantitative approach

Research design: Quasi-experimental design (with time series)

Research design on notation

Group	Pre-test	Intervention	Post-test 1 (immediate)	Post-test 2 (After 3 months)	Post-test 3 (After 1 year)
Experimental Group	O_1	X (7 weeks)	O_2	O_3	O_4
Control Group	O_1	-	O_2	O_3	O_4

O_1: Pre-test before intervention

X: Nurse-Led Cognitive Stimulation Program, 75 minutes session each, 14 sessions biweekly for a total of 07 weeks

O_2: Post-test 1 at the end of the intervention

O_3: Post-test 2 at 3 months after the intervention

O_4: Post-test 3 at 1 year after the intervention.

RESEARCH VARIABLES

It is a factor or values that varies. In the present study variables were:

Independent variables: These are the factors or attributes which believed to impact the outcome variables.

For this study, Nurse Led Cognitive Stimulation Program was the manipulated variable. It was one of the multicomponent theme-based programs that were planned systematically for seven weeks covering a total of 14 sessions for the study after referring to related

literature, research studies, and taking certified training on it. This program includes various activities, tasks, and games that aim in building cognitive functioning and quality of life. For clear picture refer to Appendix-VIII which describes the whole intervention.

Dependent variables: These factors are hypothesized to depend on some other variable In this present study Cognitive functions and Quality of life among elderly were the outcome variables that were measured by MMSE and QOL-AD.

Associated variables: Preceding attributes of the study samples, which the investigator simply observes and measures.

In this study, associated variables are age, gender, literacy status, marital status, occupational status, type of family, financial dependency, illness status, availability of caregiver and any previous exposure to Nurse Led Cognitive Stimulation Program.

Extraneous variables: Those variables which are not part of the study but can affect its outcome such as elderly's previous knowledge on CST, media, and interaction with health professionals

RESEARCH SETTING

Setting for this phase was randomly selected villages Sewah and Risalu which belong to the rural community of district Panipat, Haryana.

POPULATION

Target Population: For this phase target population was the elderly (Age 60 years and above) who were having a decline in cognitive functioning as measured by MMSE.

Accessible population: In this phase, only elderly of selected villages (Sewah and Risalu) of district Panipat Haryana were the accessible population.

SAMPLE

In present study, sample was elderly belonging to selected villages (Sewah and Risalu) of District, Panipat (Haryana) of age above 60 years and above who were having a decline

in cognitive functioning as measured by MMSE.

SAMPLE SIZE:

For this phase of study, sample size was 100 elderlies (50 in experimental and 50 in control group) belonging to selected village (Sewah and Risalu) of District Panipat, Haryana. Power analysis was conducted to compute the sample size for the present investigation considering this analysis sample was selected. The investigator calculated and finalized the sample size by doing this analysis in a finite population.

Sample size calculation: For this phase sample size was calculated on the previously published research studies (Gurung & Upendra 2018), considering the cognitive functions and quality of life as the main outcomes. Mean±SD from the mentioned study was used, with a good estimate of population effect size, it requires 43 samples in each group to accomplish 90% power at 5% level of significance. Assuming 10% lost to follow-up, so minimum 47 subjects in each group was estimated. But it was rounded up to 50 in each group, so total 100 participants were taken also keeping in to mind power and effect size.

$$n = 2\ Sp^2[Z_{1-\alpha/2} + Z_{1-\beta}]^2 / \mu_d^2$$
$$Sp^2 = S_1^2 + S_2^2/2$$

where, S_1^2: Standard deviation in first group

S_2^2: Standard deviation in second group

μ_d^2: Mean difference between the samples

α: Significance level

$1-\beta$:Power

Sp: Pooled standard deviation

Multi-stage random sampling to select villages, from Panipat district, Haryana

Sample Size

Home to home visit was done to screen elderly 60 years and above

SAMPLING TECHNIQUES

Multi-stage random sampling was used in present study.

Panipat District

Subdivisions/Blocks (Lottery method)

Madlauda	**Israna**	**Panipat Subdivision**	**Samalkha**	**Bapoli**

Random allocation of villages

Village Sewah   Village Risalu

Using old age pension list as sampling frame

No. of Houses 769 No. of Elderly 363	No. of Houses 678 No. of Elderly 213

House to house cognitive screening by MMSE and following inclusion criteria

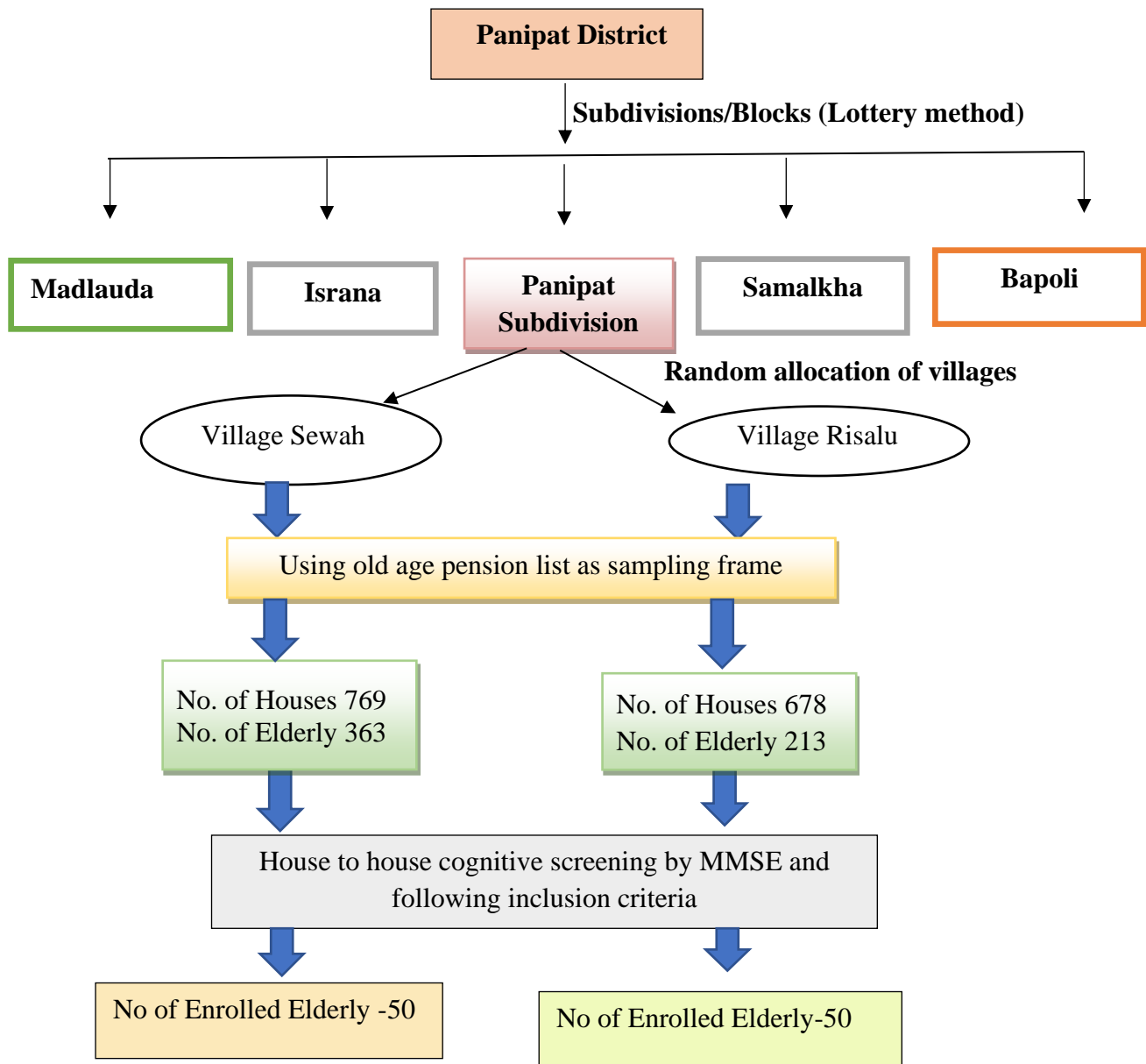| No of Enrolled Elderly -50	No of Enrolled Elderly-50

Fig. 3: Schematic presentation of sampling technique

The process of sampling is depicted as follows: -

At stage I: One subdivision/block (Panipat) was selected

At stage II: Two village were selected randomly and allocated intervention and control group

At stage III: Home to home visit and elderly were recruited as sample

First from 5 subdivisions/blocks of district Panipat one subdivision/block (Panipat) has been randomly selected. Then from the selected subdivision/block again two villages have been selected randomly and allocated as intervention and control groups. And as Haryana Government provides pension (Rupees 2500 per month) to each elderly of 60 years and above as per Haryana old age pension scheme. In the study using that village pension list as a sampling frame home to home visit has been done to identify the elderly in both the villages. Eligible participants were recruited as per the criteria in the study.

SAMPLING CRITERIA

It describes about attributes of the study population by detailing it as inclusion and exclusion criteria in the study. Inclusion and exclusion criteria for both phases were described as following:

<u>Inclusion criteria:</u>

1. Those who were of age 60 years and more of both sexes

2. Elderly of the selected community area and interested to take part in study.

3. Elderly who had cognitive impairment according to MMSE scored 11-23.

4.Elderly who could engage in a group activity of 75 minutes and had some abilities to communicate and understand.

<u>Exclusion criteria:</u>

1. Elderly who were not present during the period of data collection and also who did

   not complete the entire program.

2.Elderly having major physical or psychiatric illness (schizophrenia and mental retardation) which could affect their participation

3.Elderly who scored less than 10 in MMSE

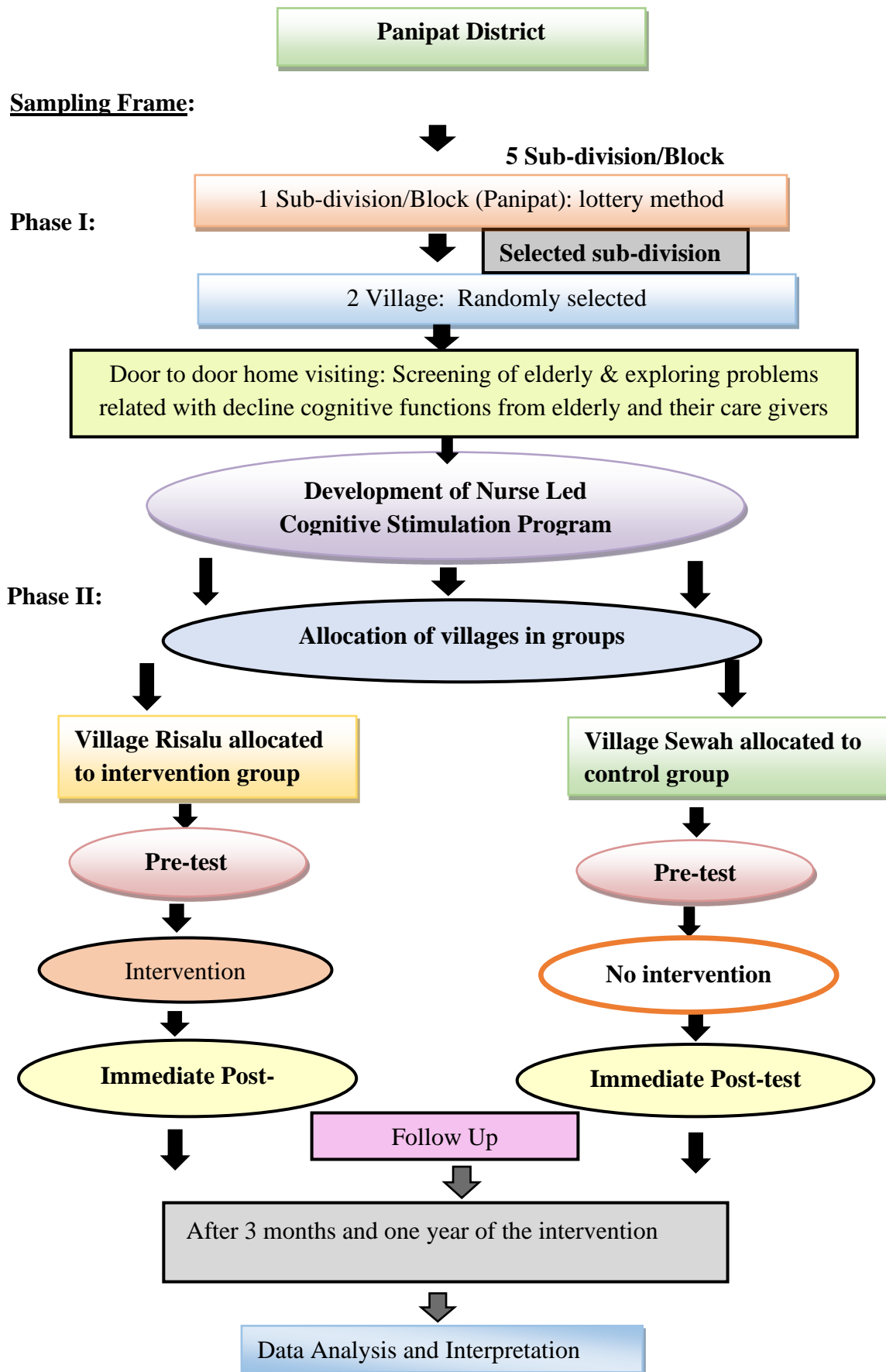4.Elderly who were previously exposed to such interventions

Panipat District

Sampling Frame:

5 Sub-division/Block

Phase I:

1 Sub-division/Block (Panipat): lottery method

Selected sub-division

2 Village: Randomly selected

Door to door home visiting: Screening of elderly & exploring problems related with decline cognitive functions from elderly and their care givers

Development of Nurse Led Cognitive Stimulation Program

Phase II:

Allocation of villages in groups

Village Risalu allocated to intervention group

Village Sewah allocated to control group

Pre-test

Pre-test

Intervention

No intervention

Immediate Post-

Immediate Post-test

Follow Up

After 3 months and one year of the intervention

Data Analysis and Interpretation

Fig. 4: Schematic diagram of research methodology

ENROLLMENT

Assessed for eligibility/screening of elderly
MMSE (11-23 Score)
n=100

Allocation of villages

ALLOCATION

Allocated to intervention group

Allocated to control group

PRE-TEST

- Informed written consent
- Socio demographic information of elderly

- Cognitive functions and Quality of life of elderly

Intervention (NLCSP) for 7 weeks in groups

No Intervention

POST-TEST

Post-test 1
Elderly= 50

Immediate

Post-test 1
Elderly= 50

Post-test 2
Elderly= 50

3rd Month

Post-test 2
Elderly= 50

Post-test 3
Elderly= 47

1 year

Post-test 3
Elderly=45

Analysis

Fig. 5: Detail of schedule data collection of study for phase II

DESCRIPTION OF THE TOOLS

In this study standardized tools were used for assessing the decline in cognitive functions and quality of life. Tool consists of four sections:

1. Socio-demographic/Baseline Proforma

2. Semi-Structured Interview Schedule for Focused Group Discussion

3. Mini-Mental Status Examination (MMSE)

4. Quality of Life in Alzheimer's Disease (QOL-AD)

Section A: Socio-demographic variables such as age, gender, literacy status, occupational status, financial dependency status, marital status, type of family, having any sickness, availability of caregiver, previous exposure to any kind of cognitive stimulation program.

Section B: Semi-structured interview schedule for exploration of problems faced by elderly and their caregivers due to decline in cognitive functions (Focused Group Discussion) has been used in the qualitative phase of the study. Separate discussion has been done with elderly and with their caregivers for a time period of 35-40 minutes. The FGD was structured as follows:

Stages	Activities	Framework of FGD	Duration (min)
I	Introduction	Researcher (Moderator) done briefing of session	2
II	Questions	Participants	30
III	Group discussion	Moderator	4
IV	Conclusion	Participants	2
V	Debriefing	Moderator	2

Section C: Mini-Mental State Examination for measuring cognitive functions. It is a brief and standardized questionnaire with total of 30 items which has been used for the screening of cognitive impairment. It includes following criterion measures such as orientation, registration, attention and calculation, recall, language and praxis. It is also very popular to evaluate the severity of cognitive decline. Its Hindi version is also available and has been used in the present study (Tiwari and Tripathi,2011). Scoring in the instrument ranges from 0-to 30. The test-retest reliability of MMSE is found to be 0.8-0.95 and for the study, it was done by using Cronbach's alpha 0.81 and Split-half (odd-even) correlation 0.85 method, and the tool was found highly reliable.

MMSE score with its percentage

Cognitive status scoring	Score	Percentage
No Cognitive impairment	24−30	67%−100%
Mild Cognitive impairment	18−23	34%−66%
Severe Cognitive impairment	0−17	< 33%

Section D: Quality of Life in Alzheimer's Disease (QOL-AD) Scale. It is also one of the standardized scales which was developed by Logsdon et al., in 2016. This tool has 13-items that cover components/criterion measures such as physical health, mood, energy, memory, living situations, family, friends, marriage, money, chores, fun, self, and life as a whole. The Hindi version of the tool is also available. Permission for using this tool was obtained on 26th June 2019, by Mapi trust organisation. Test-retest reliability of the tool is 0.75 and internal consistency is 0.79. For the study, it was calculated by Cronbach's alpha 0.79 and by Split-half (odd-even) correlation 0.72 method.

Scoring instructions for QOL-AD:

Scores allocated to each item are as follows:

Excellent 4	Good 3	Fair 2	Poor 1

Overall points ranging from 13 to 52. Higher the level of score better is the quality of life. The categories for the score are Good (40−52), Average (27−39), and Poor (13−26).

QOL-AD-tool score with its percentage

Quality of Life	Score	Percentage
Good	40−52	67%−100%
Average	27−39	34%−66%
Poor	13−26	< 33%

Section E: Development of Intervention

Nurse-Led Cognitive Stimulation Program was the group-based intervention used in the study. This program was developed by referring to previous research studies, guideline from NICE, UK and discussion with various experts in field. Also, the investigator has attended certified training sessions from the Shanti Home Rehabilitation center of Greater Noida. The certificate has been attached in the Appendix-III. It is a systemically planned, intervention of a total 14 sessions which is multi-component in nature including physical, psychological as well social components with various tasks, games, and activities (please refer to Appendix-VIII for a detailed description). Each session of 75 minutes duration, conducted biweekly, for 7 weeks and has been delivered in groups of elderly. Each session has a unique theme and activities discussion with aims to refine and build the cognitive functions and quality of life in senior citizens. The investigator also developed a booklet containing information on various activities of this program, and the content validity of

the booklet on "Nurse-Led Cognitive Stimulation Program" was established by giving it to the experts from the field, and their valuable recommendations were incorporated in the booklet (Appendix-X). As program is multi-component in its nature with unique theme for each session and these themes are scheduled by focusing on components of cognitive functions and QOL. Each day one home task was also given to keep the continuity and recall of the program. The timing of the session was planned based on elderly's convenience. The session was moderated and delivered with adequate information from the researcher. Reliability of this program was assessed using program fidelity checklist and the obtained score was 85% validating its reliability and effectiveness. The development of intervention has been given in figure no 6.

Fig. 6. Development of Nurse-Led Cognitive Stimulation Program
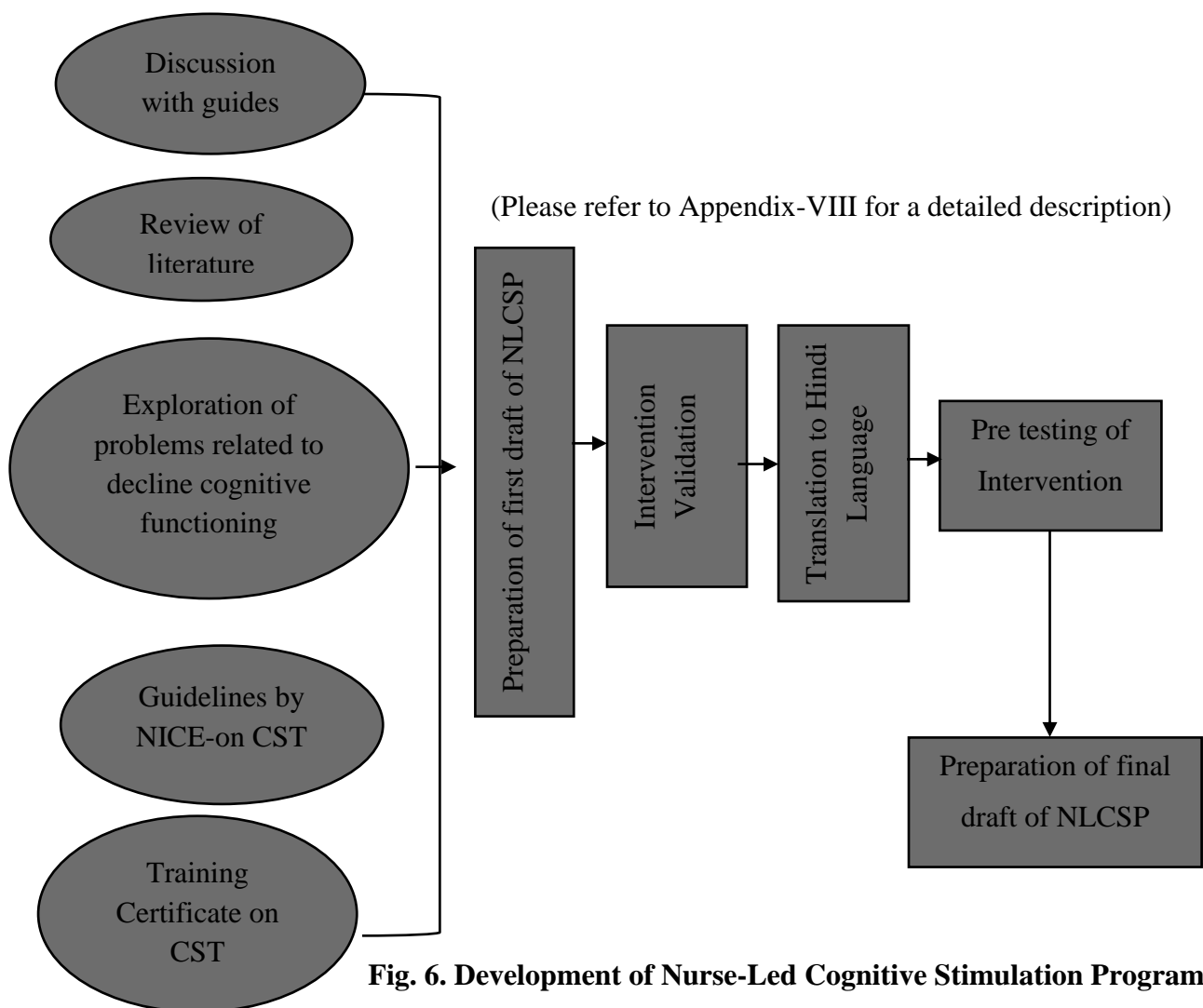
VALIDITY OF TOOLS

Content validity: MMSE and QOL-AD are both standardized tools applied in the study. However, items measuring the background factors, focused group discussion tool (semi-structured interview schedule), and Nurse Led Cognitive Stimulation Program were validated by nine experts from various fields, such as nursing, psychiatry, psychology, and psychiatric social worker. Content validity index of items was calculated, based on the response from experts. There was more than 72.8% of agreement regarding items on content validity index. Recommendations by experts were considered and modification has been done for tools as well as for intervention.

Language validity: Language validity was obtained from concerned language specialists in English and Hindi.

RELIABILITY OF THE TOOLS

It is the degree of stability of the tool to measure the attributes that tool is assumed to measure. In present study, it was done by using Split half (odd-even) and Cronbach's Alpha formula for both the tools by administering it to 10 elderly people (5 in each group) of the selected villages. The reliability quotient of the Mini Mental State Examination tool was (r=0.81 and 0.85) tool is found highly reliable, and for the Quality of life-AD reliability score was (r=0.79 and 0.72). Hence both tools were reliable.

ETHICAL PERMISSION

1. Ethical clearance was taken from the Ethics Committee SRHU, Jolly Grant, Dehradun. Approval was granted vide Ethics Committee Letter No. SRHU/HIM/E-1/2019/Z. Dated 26 August 2019.

2. Written administrative permission was taken from The Block Development Officer and Welfare Officer of district Panipat, Haryana as well as from the sarpanch of the selected villages.

3. Informed consent in writing was taken from each study participant.

4. Participants were assured of no harm and were permitted to leave the study at any time they wished.

5. Anonymity and confidentiality of study samples were maintained throughout the study.

PILOT STUDY

Polit & Hungler (2004) stated that it is a smaller version or trial run of the proposed study to check the techniques and methods to be used in a large scale, or in more rigorous study. Its purpose is to refine the study and to prevent an expensive failure. These are also termed as feasibility studies.

In this investigation, pilot study was done on a total of 10% of the main study participants and was conducted in the selected sub-division/block Samalkha of district Panipat from which again two villages (Manana and Chulkana) were randomly selected and allocated as study and non-study groups. Pilot study was started in December 2019 after taking permission from concerned authorities and informed consent from the study participants. Trial out was done on 10 elderlies to certain the feasibility of the study. The sample consisted of 5 participants in the control group and 5 in experimental group. Door-to-door home visit was done to screen the elderly by using Mini Mental State Examination of Hindi version. Focused Group Discussion was done as planned for first phase of study on elderly and their caregivers to explore the problems faced by them due to decline in cognitive functioning. Quality of life was measured by using the tool QOL-AD. The average time taken for gathering data from each sample was 10-15 minutes. Planned

Nurse-Led Intervention Program was taught for 7 weeks to elderly in study group, and post-test and follow up were conducted at immediate, three months and six-months. In conclusion, the study was found to be feasible in terms of accessibility of study participants, time, distance, co-operation from the elderly and their caregivers, along with their financial capability and the material provided.

DATA COLLECTION PROCEDURE

This present investigation was done in selected villages Risalu and Sewah of selected subdivision/block Panipat of district Panipat, Haryana. Research data collection was started in October 2020, and was gathered for a time period of 1 year and 6 months. Before the data gathering process, formal permission from the Authority (District Officer) was sought and obtained. Study was conducted in two phases. Multi-stage random sampling was used to recruit samples from the population. Physical examination of the elderly has been done to identify any health issues before recruitment. In the first qualitative phase, after cognitive screening of elderly FGD was done by taking written informed consent. It was conducted in groups of elderly and their caregivers to explore problems related with declined cognitive functioning. FGD data were collected by using semi-structured interview schedule with open ended questions in the Hindi and native language of elderly. Number of interviews depended on the saturation of information obtained among participants. Interviews were audio-recorded and were also written by two note takers. Following this there was development of intervention on the basis of literature review and certified training. In the second phase of the study total of 100 elderlies (50 in experimental and 50 in control group) were selected after cognitive screening according to sample selection criteria. Standardized tools were used to collect data for the quantitative phase. Before the data collection, the researcher introduced self to the study participants and also described the study purpose for collecting information. A good

rapport was developed with the participants, and they were also assured that their information will be kept private and will only be used for the study purposes. Informed consent was taken in written form from the participants.

After taking the consent, investigator collected the data from the participants in interview format. The time given to each respondent was average 10-15 minutes. Following this, the planned Nurse-Led Cognitive Stimulation Program was taught to the intervention group for seven weeks by making groups of elderly. It was assured that each participant was able to receive and do the activities of the intervention independently. The investigator also provided each one of them with a booklet on "Nurse-Led Cognitive Stimulation Program" having intervention-based activities in words and pictorial form. The elderly was asked to practice the sessions and home work on certain intervention-based activities was given to keep the continuity and recall of the program. Then first post-test was done in both groups after giving seven-week group wise intervention only in the experimental group.

Reminder phone calls and regular visits to the home of the elderly in experimental group were done by the investigator with an aim to remind elderly about their continuation of the program practice. After delivering intervention an immediate post-test has done in both the groups. Following this, two follow-ups after 3 months and 1 year of the intervention for consolidating the effectiveness of Nurse-Led Cognitive Stimulation Program (NLCSP). Then the instruments were edited for their completion. As data in the present study were collected in two phases and it is summarized phase wise clearly as following:

Phase I: A focused group discussion was done in this phase to explore the problems of elderly and their caregiver related to decline cognitive functioning by using semi-structured interview schedule in each group. The investigator played the role of moderator

and ensured privacy and ease the participants by serving refreshments, introducing each other, and involving them in conversations. On-going discussions were held till a consensus on the themes was reached. The audio-taped interviews were listened word to word and were transcribed in to verbatim in the regional language and also translated in English to generate themes and sub-themes.

Phase II: This phase begins with a brief introduction and after written consent demographic questionnaire was used to collect the background information and MMSE and QOL-AD tools to measure study variables. Post the baseline investigations planned Nurse Led Cognitive Stimulation Program was delivered till 7 weeks total 14 session each of 75 minutes in groups of elderly in study group**.** After the completion of cognitive stimulation, program investigator carried out the post-test in both the groups by using same tools. Also, a booklet in word and pictorial form was given to practice the sessions also were followed by phone calls to clarify their doubts. Then follow up was done at 3 months and 1 year after the intervention to evaluate the sustainability of the program.In this study few difficulties were faced by researcher as related to COVID restrictions and traditional boundaries face veiling by females in village.

DATA ANALYSIS AND INTERPRETATION

In study it was done accordingly to the objectives mentioned for the study. For the first phase of qualitative data analysis, audio-recorded interviews were transcribed. Thematic analysis (coding, categorizing, themes) was carried out by using an inductive approach. Finally, similar categories were grouped to form sub-themes followed by themes to explore the participant's experience. Further, for quantitative phase descriptive and inferential statistics were used that were frequency (f) and percentage distribution that presents the categorical data. Chi-square test and Fisher's exact test were used for calculating the homogeneity of data. Quantitative data were expressed as mean±standard

deviation, paired and unpaired t-test, F test ANOVA (F) were used for testing significance at the level of significance p<0.05.

Summary: This chapter dealt with the used approach of research and research design, along with variables, study setting, population, sample, sample size, inclusion and exclusion criteria, sampling techniques, description of tools, content validity, pretesting of tools, reliability, pilot study, plan for data collection, and analysis.