CHAPTER 3

3. RESEARCH METHODOLOGY

Research methodology is the way of systematically solving the research problem. It constitutes the blue print for data collection, measurement and analysis of data under which the researcher acquaints himself/herself with the various steps generally adopted to study a research problem, along with the underlying logic behind them.

The present study was designed to evaluate the effectiveness of health promotion intervention in improving the quality of life among physically challenged children in selected schools, Punjab.

This chapter deals with the research approach, research design, variables, setting of the study, population, sample, criteria for sample selection, sampling technique, sample size and sample size calculation, development and description of tool, development and description of intervention, translation and back translation of the tool, content validity of the tool, pilot study, reliability of the tool, ethical considerations, data collection procedure, drop out and its analysis, and data analysis.

3.1 RESEARCH APPROACH

Research approach refers to plans and the procedures for research that span the steps from broad assumptions to detailed methods of data collection, analysis, and interpretation. In this study, a quantitative evaluative research approach was adopted to evaluate the effectiveness of health promotion intervention in improving the quality of life among physically challenged children in selected schools, Punjab.
3.2 RESEARCH DESIGN

Research design is the overall plan for obtaining answers to the research question or for testing the research hypotheses. The research design chosen for the present study was quasi-experimental, pre interventional and post interventional control group design.

3.1 Schematic representation of research design adopted for the study

<table>
<thead>
<tr>
<th>Group</th>
<th>Pre intervention</th>
<th>Intervention</th>
<th>Post intervention</th>
</tr>
</thead>
<tbody>
<tr>
<td>Study</td>
<td>O1</td>
<td>X</td>
<td>O2, X, O3, X1, O4</td>
</tr>
<tr>
<td>Control</td>
<td>O1</td>
<td>-</td>
<td>O2, O3, -</td>
</tr>
</tbody>
</table>

Keys:

O1 – Pre interventional assessment of quality of life in study and control group

O2, O3, O4– Post interventional assessment of quality of life at 12th, 24th, and 36th week respectively in study and control group

X – Provision of health promotion intervention by investigator and qualified physiotherapist to study group

X1 – Reinforcement to practice health promotion intervention by their own to study group.

3.3 VARIABLES

3.3.1 Independent variable

It is the presumed cause that is varied or manipulated by the researcher to test the effects on the dependent variable. In this study, independent variable was health promotion intervention (Health teaching on diet and personal hygiene, and exercise programme).
3.3.2 Dependent variable

It is the presumed effect and it depends on the independent variable. In this study, dependent variable was quality of life among physically challenged children.

3.3.3 Demographic variables

The demographic variables used in this study were age, gender, education, father education, mother education, family income, type of family and residential area.

3.3.4 Clinical variables

The clinical variables used in this study were category of locomotor disability, level of locomotor disability, duration of locomotor disability and mobility aid used.

3.3.5 Extraneous variables

It is the variable that confounds the relationship between the independent and dependent variable that needs to be controlled either in the research design or through statistical procedure. The extraneous variable in this study were medical treatment for health problems and mass media.

3.4 SETTING OF THE STUDY

The study was conducted in Blind and Handicapped Development Society special school, Hoshiarpur (study group) and Vocational Rehabilitation Training Centre, Ludhiana, Punjab (control group).

The Blind and Handicapped Development Society was founded by Mr. Attar Singh & Mrs. Malti who are already blind in the year 2003 with the mission to help, assist & groom the physically challenged souls of Almighty which has been sent on this earth for some mission in the year 2003. The society run the special school for physically challenged children from LKG to senior secondary under Punjab State Education Board. The institute has total 193 physically challenged
children including of visual (120) and locomotor (73) disabilities, from different parts of India but most of them were from Uttar-Pradesh and Bihar states and all the children were residing in hostel.

The Vocational Rehabilitation Training Centre, Ludhiana, Punjab was founded by late Dr. E.M. Johnson during the year 1964 in collaboration with foreign missionaries. The centre has eleven different departments which are all functioning excellently. The Rehabilitation Council of India, Ministry of Social Justice and Empowerment New Delhi have appointed this institute to be as its Zonal Coordination Committee for North Zone for monitoring its various activities and also for conducting various workshops /seminars in the North Zone since 2002. The Executive Director of VRTC, Ludhiana is the Chairperson for the North Zone consisting of six States Punjab, Haryana, Himachal Pradesh, Uttranchal, Chandigarh (U.T.), and Jammu& Kashmir. Research scholars from various universities visit this institution for their research work in the field of disability/education/sociology/medical. The department of special education run the classes from LKG to senior secondary and has an excellent record of academic achievements in respect of the annual examination conducted by the Punjab State Education Board. The institute has total 235 physically challenged children including of visual (145) and locomotor (90) disabilities, from different parts of India and most of them were residing in hostel.

The rationale for selecting these schools as a research setting was that these special schools had adequate strength of physically challenged children with locomotor disabilities in Punjab and were convenient for investigator in terms of geographical proximity and economical consideration.

3.5 POPULATION

It is the entire set of individuals having some common characteristics. It encompasses target population and accessible population.
3.5.1 Target population

It is the entire aggregate of cases for which the investigator would like to generalize the findings. The target population for this study was physically challenged children with locomotor disability.

3.5.2 Accessible population

It is aggregate of cases that confirm to designated criteria and that are accessible as subjects for the study. The accessible population for this study refers to physically challenged children with locomotor disability in the age group of 10 to 19 years studying in Blind and Handicapped Development Society special school, Hoshiarpur and Vocational Rehabilitation Training Centre, Ludhiana, Punjab and those were available during data collection.

3.6 SAMPLE

It is the subset of population selected to participate in a research study. It comprised of physically challenged children those fulfilled the inclusion criteria.

3.7 CRITERIA FOR SAMPLE SELECTION

The sample were selected based on the following criteria

3.7.1 Inclusion criteria

1. Physically challenged children who were suffering with mild, moderate and severe level of locomotor disability
2. Physically challenged children who were in the age group of 10 to 19 years
3. Physically challenged children who had I.Q >70 tested by clinical psychologist.
4. Physically challenged children who were available during data collection.
5. Physically challenged children who were able to understand and speak Hindi / Punjabi.
3.7.2 Exclusion criteria

1. Physically challenged children who were suffering with multiple disabilities.
2. Physically challenged children who were not willing to participate in the study.

3.8 SAMPLING TECHNIQUE

It is the process of selecting a portion of the population to represent the entire population. In this study, sample were selected through non-probability purposive sampling technique.

3.9 SAMPLE SIZE AND SAMPLE SIZE CALCULATION

The sample size for the present study was 120 physically challenged children, out of which 60 were in study group and 60 were in control group. The sample size was determined based on the pilot study results and also computed through power analysis.

3.9.1 Sample size calculation

The sample size was estimated by power analysis prior to commencement of the study [181]. The estimated sample size was 50 in each group considering the attrition rate of 20%. The sample size was rounded to 60 in each group.

\[
 n = \frac{2\sigma^2 (Z_{1} + Z_{0})^2}{d^2} \\
 \sigma = \frac{\sigma_1 + \sigma_2}{2}
\]

Where,

\( \sigma_1 \) : Standard deviation in the first group = 16.06

\( \sigma_2 \) : Standard deviation in the second group = 19.52

\( d \) : Mean difference between the samples = 10
With 20% dropout rate (50+10=60 samples) 60 children were taken for the study.

3.10 DEVELOPMENT AND DESCRIPTION OF THE TOOL

Polit and Hungler point out that complete and appropriate answer of a research question largely depends on the selection of appropriate method of data collection so in the present study the data collection tool was selected and developed on the basis of extensive review of literature and with guidance of experts. The tool consisted of three sections:

3.10.1 Section A: Structured questionnaire for demographic and clinical variables of physically challenged children

It consisted of 8 demographic and 4 clinical variables for obtaining personal information from study subjects. The demographic variables include: age, gender, education, father education, mother education, family income, type of family, residential area and clinical variables include: category of locomotor disability, level of locomotor disability, duration of locomotor disability, mobility aid used.

The structured questionnaire had multiple responses, in which the respondents were asked to choose very relevant response. No scores were allotted for the demographic and clinical variables.
3.10.2 Section B: Quality of life questionnaire

It was constructed after reviewing standardized tools such as World Health Organization Quality of life (WHOQOL)-BREF Questionnaire (2004), KIDSCREEN-52 Health related quality of life questionnaire for children and adolescents (2004), Pediatric Quality of Life Enjoyment and Satisfaction Questionnaire (Jean Endicott et al 2006), Pediatric Quality of Life Inventory-PedsQL™ (James W. Varni 1998), SF 36 – Health Status Questionnaire (Ware and Sherbourne 1992), Child Health Questionnaire (1990), Ferrans and Powers Quality of life Index spinal cord injury version-II (1998), Betty R Ferrell & Marcia M. Grant Quality of life scale (1997), EuroQOL five dimensions (EQ-5D) Health – related Quality of life questionnaire (1990), EORTC Core Quality of life Questionnaire - C30 (1997), Ryff Scales of Psychological wellbeing (1995), Psychosocial Wellbeing Inventory (Valeria Negovan 2010), Perceived social support scale (Zimet, Dahlem, & Farley, 1988).

It consisted of 40 questions which had 70 items under three domains of quality of life to find out how much of a problem each one has undergoing during the past one month. The investigator asked /assessed for health problem and rated on 4 point scale (4 - Not at all a problem, 3 - A little bit problem, 2 - Quite a bit problem, 1 - Very much problem) to assess the quality of life among physically challenged children. The three domains of quality of life included:

[A] Physical wellbeing

It comprised of 10 questions which had 40 items from ten sub domains of physical wellbeing. The number of items for each sub domain was as: integumentary problems (5 items), oral problems (6 items), eye problems (4 items), ear problems (3 items), respiratory problems (3 items), gastrointestinal problems (4 items), genitourinary problems (3 items), neuromuscular problems (4 items), musculoskeletal problems (2 items), and other problems (6 items).
[B] Psychological wellbeing

It comprised of 15 questions which had 15 items from four sub domains of psychological wellbeing. The number of items for each sub domain was as: mood state problems (item no. 13, 15, 16, 19, 20, 21), self esteem problems (item no.18, 24), perceived control problems (item no. 23, 25) and life outlook problems (item no. 11, 12, 14, 17, 22).

[C] Social well being

It comprised of 15 questions which had 15 items from four sub domains of social wellbeing. The number of items for each sub domain was as: i.e. social relationship problems (item no. 26, 31), social support problems (item no. 27, 30, 32), engagement/participation in socio-cultural activities problems (item no. 29, 34, 35, 37, 40), and societal attitude problems (item no. 28, 33, 36, 38, 39).

Scoring interpretation

1. Each item was scored against four point’s i.e. 4 if it is not at all a problem, 3 if it is a little bit problem, 2 if it is quite a bit problem, 1 if it is very much problem so the maximum raw score was 280 and minimum raw score was 70.

2. In the physical well-being domain of quality of life all the items were scored in same way as represented in questionnaire but in psychological well-being domain of quality of life item no. 11, 12 and 17 for ease of interpretability were scored reversely and rest of the items were scored in the same way as represented in questionnaire and in social well-being domain of quality of life for ease of interpretability item no. 26 to 35 were scored reversely and the item no.36 to 40 were scored in the same way as represented in questionnaire, so that higher score indicated good quality of life and low score indicated poor quality of life.

3. The total of the items in each category was added to yield a raw total score. The total raw score was ranging between 70 to 280. The raw total score was transformed in to a percentage maximum possible score by using the following formula:
Raw total score - minimum score

_______________________________________ x 100

(Minimum possible score - minimum score)

OR

Raw total score - 70

_______________________________________ X 100

210

4. The percentage maximum possible score was interpreted in terms of quality of life as follows:

\[ \leq 40\% \text{ - Very poor quality of life} \]

\[ 41\% \text{ - 60}\% \text{ - Poor quality of life} \]

\[ 61\% \text{ - 80}\% \text{ - Fair quality of life} \]

\[ \geq 81\% \text{ - Good quality of life} \]

**Criterion measure**

**Quality of life score:** (Maximum score = 280; Minimum score = 70)

<table>
<thead>
<tr>
<th>Range of score</th>
<th>Levels of quality of life</th>
</tr>
</thead>
<tbody>
<tr>
<td>70 - 155 (1 - 40%)</td>
<td>Very poor quality of life</td>
</tr>
<tr>
<td>156 – 197 (41 – 60%)</td>
<td>Poor quality of life</td>
</tr>
<tr>
<td>198 – 239 (61 -80%)</td>
<td>Fair quality of life</td>
</tr>
<tr>
<td>240 - 280 (81 - 100%)</td>
<td>Good quality of life</td>
</tr>
</tbody>
</table>

**Physical wellbeing score:** (Maximum score = 160; Minimum score = 40)

<table>
<thead>
<tr>
<th>Range of score</th>
<th>Levels of physical wellbeing</th>
</tr>
</thead>
<tbody>
<tr>
<td>40 - 88 (1 - 40%)</td>
<td>Very poor physical wellbeing</td>
</tr>
<tr>
<td>89 – 112 (41 – 60%)</td>
<td>Poor physical wellbeing</td>
</tr>
</tbody>
</table>
113– 136 (61 -80%) Fair physical wellbeing
137 - 160 (81 - 100%) Good physical wellbeing

**Psychological wellbeing score:** (Maximum score = 60; Minimum score = 15)

Range of score Levels of psychological wellbeing
15- 33 (1- 40%) Very poor psychological wellbeing
34 – 42 (41 – 60%) Poor psychological wellbeing
43– 51 (61 -80%) Fair psychological wellbeing
52 - 60 (81 - 100%) Good psychological wellbeing

**Social wellbeing score:** (Maximum score = 60; Minimum score = 15)

Range of score Levels of social wellbeing
15 - 33 (1 - 40%) Very poor social wellbeing
34 – 42 (41 – 60%) Poor social wellbeing
43– 51 (61 -80%) Fair social wellbeing
52 – 60 (81 - 100%) Good social wellbeing

### 3.10.3 Section C: Satisfaction scale

The level of satisfaction of physically challenged children on health promotion intervention was assessed by 5- point rating scale. The 5- point rating scale consists of 10 items totally ranged from 1- 5 (5- very satisfied, 4- satisfied, 3- neither satisfied nor dissatisfied, 2- dissatisfied, 1- very dissatisfied).

**Criterion measure**

**Satisfaction score:** (Maximum score = 50; Minimum score = 10)

Range of score Levels of satisfaction
10 – 18 (1 – 20%) Very Dissatisfied
19 – 26 (21 – 40%) Dissatisfied
27– 34 (41 - 60%) Neither satisfied nor dissatisfied
3.11 DEVELOPMENT AND DESCRIPTION OF INTERVENTION

The health promotion intervention was developed after extensive review of literature and with guidance of experts in the field of medicine, nursing and physiotherapy. It consisted of health teaching on diet, personal hygiene and exercise programme for the duration of 36 weeks.

3.11.1 Health teaching on diet

Health teaching on diet refers to dietary advice planned in consultation with dietician consisted of introduction, definition, types and amount of food stuff should be taken to have a well balanced diet and remain healthy with disability, and risks associated with eating unhealthy diet provided to physically challenged children, their caretakers and teachers after assessing pre interventional level of quality of life of physically challenged children by investigator himself for the duration of 30 minutes by adopting lecture cum discussion as a method of teaching and power point as a visual aid thereafter they were reinforced to practice healthy dietary habits for the duration of 36th weeks.

3.11.2 Health teaching on personal hygiene

It refers to advice on personal care and grooming of an individual’s body consisted of definition, various aspects of personal hygiene i.e. care of skin, hair, mouth, eyes, ears, hands, nails and menstrual hygiene etc, benefits of maintaining good personal hygiene and consequences of poor personal hygiene provided to physically challenged children, their caretakers and teachers after assessing pre interventional level of quality of life of physically challenged children by investigator himself for the duration of 30 minutes by adopting lecture cum discussion as a method of teaching and power point as a visual aid thereafter they were reinforced to practice personal hygiene habits for the duration of 36th weeks.
3.11.3 Exercise programme

It consisted of introduction, definition, three kinds of exercises i.e. range of motion exercises, stretching exercises and strengthening exercises, and advantage of doing regular exercises. To perform these exercises intensively the sample of study group were divided into two groups (30 in each). For each sample, range of motion (10 minutes), stretching (10 minutes) and strengthening (10 minutes) exercises were administered by a qualified physiotherapist and assisted by investigator for 30 minutes/day thrice in a week for the duration of 24 weeks thereafter for the next 12 weeks they were reinforced to practice these exercises by their own. A practice diary was maintained to confirm regular practice of health promotion intervention.

3.12 TRANSLATION AND BACK TRANSLATION OF THE TOOL

The Hindi version of quality of life questionnaire was used for the study. The tool was translated into Hindi and the Hindi tool was translated back into English by the experts to improve the validity of the tool and again the tool was given for content validity. Based on content validity expert’s valuable suggestions, the tool was modified and used for the study. Reliability was assessed for the Hindi version of the tool.

3.13 CONTENT VALIDITY OF THE TOOL

The content validity of tool and intervention was established by submitting the proposed draft and obtaining valuable opinion and suggestions along with content validity certificate from the experts in the field of pediatrics, orthopedics, physiotherapy, and pediatric nursing. As per guidance and suggestion of experts relevant amendments were made in the tool and intervention.

3.14 PILOT STUDY

Pilot study was conducted in month of January 2013 for the duration of one month at Navchetna Special School, Hoshiarpur (study group) and Blind and Handicapped Development Society Special School, Hoshiarpur (control group)
among 20 physically challenged children (study group - 10 and control group – 10) selected through non-probability purposive sampling technique guided by inclusion and exclusion criteria. Prior to data collection informed assent/ consent form was obtained from study sample and their parents after explaining the study purpose and assuring for confidentiality and anonymity of collected data. The pre interventional assessment of quality of life was done for both the study and control group. After pre interventional assessment the study group received the health teaching on diet and maintenance of personal hygiene provided by investigator and study subjects were reinforced to practice these healthy life habits for the duration of 4 weeks. For each sample, range of motion (10 minutes), stretching (10 minutes) and strengthening (10 minutes) exercises were administered by a qualified physiotherapist and assisted by investigator for 30 minutes/day thrice in a week for the duration of 4 weeks. A practice diary was maintained to confirm regular practice of health promotion intervention. The post interventional assessment of quality of life was conducted at the end of 4th week for both the groups by using the same questionnaire. The collected data was tabulated and analyzed in accordance with objectives of the study and results showed that that there was statistically significant difference in quality of life among physically challenged children between study and control group at p <0.05 level of significance.

The findings of pilot study revealed that, it was feasible to conduct the main study in selected settings. There was no ambiguity in the tool and the tool was found feasible and practicable to proceed with main study.

3.15 RELIABILITY OF THE TOOL

After pilot study, reliability of tool was established by inter- rater/ inter - observer method and it was found r = 0.87, hence the tool was considered reliable and valid and this was used further to proceed for main study.

The reliability of intervention was assessed by intervention fidelity checklist which was validated by many experts and it consisted of study design, treatment and its delivery, treatment/ intervention receipt, treatment enactment, and treatment delivery The intervention fidelity score for the present study was 90%.
hence the intervention was reliable and considered to be effective for physically challenged children in study group.

3.16 ETHICAL CONSIDERATIONS

The investigator has followed the ethical principles preceding the investigation. The investigator has adhered to the following actions in order to protect the ethical rights of the physically challenged children.

3.16.1 Human rights
1. Formal approval was obtained from the institutional review board and institutional ethical committee of SRM University Kattankulathur, Tamil Nadu, India. The proposal was approved by the members in the ethical committee of SRM University.
2. Official written permission was obtained from the directors of selected schools to conduct the study.
3. Content validity of tool and intervention was obtained from various experts in the field of pediatrics, orthopedics, physiotherapy, and pediatric nursing.

3.16.2 Beneficence and Non-maleficence
1. Health teaching on diet was planned in consultation with dietician and was provided to physically challenged children, their caretakers and teachers in local language by adopting lecture cum discussion as a method of teaching and power point as a visual aid.
2. Health teaching on personal hygiene was planned in consultation with paediatrician and was provided to physically challenged children, their caretakers and teachers in local language by adopting lecture cum discussion as a method of teaching and power point as a visual aid.
3. Exercise programme was administered by qualified physiotherapist and assisted by investigator.

3.16.3 Dignity
1. Both written and oral information about the study were given in local language to physically challenged children and their parents who participated in the present
study. Separate informed consent/assent forms were used for study group and control group. Written assent/consent was obtained from physically challenged children and their parents in study group and control group.

2. The study objectives, type of data, nature of commitments, participation and procedure were explained in the consent/assent form.

3. Physically challenged children were asked to participate voluntarily in the study and they were informed that they have a right to withdraw at any time during the course of the study.

4. Pilot study was executed to check the feasibility and time required for the study.

3.16.4 Confidentiality

1. Physically challenged children and their parents were reassured that health related information and research report will be kept confidential.

3.16.5 Justice

1. At the end of the study, for the physically challenged children in control group health promotion intervention was provided for the duration of one week and they were given instructional manual on health promotion intervention for their self reference.

2. The level of satisfaction of physically challenged children on health promotion intervention was assessed in study group.

3.17 DATA COLLECTION PROCEDURE

The main study was conducted from April 2013 to March 2014 at Blind and Handicapped Development Society Special School, Hoshiarpur (study group) and Vocational Rehabilitation Training Centre, Ludhiana (control group). The following steps were followed for data collection.

1. The official written permission was obtained from the directors of both selected special schools after introducing himself and explaining about the study purpose, type of data, nature of commitments, participation and procedure.
2. Physically challenged children were identified as per inclusion and exclusion criteria by asking teachers and reviewing disability certificates.

3. The total 120 physically challenged children (60 from each special school) were selected through non-probability purposive sampling technique.

4. The written informed assent/consent was obtained from study sample and their parents after introducing himself and explaining about the study purpose, type of data, nature of commitments, participation and procedure.

5. The pre interventional assessment of quality of life was done for both the study and control group in a separate room through structured questionnaire for demographic and clinical variables and quality of life questionnaire. The time spent for data collection from each sample was 25 - 30 minutes.

6. Health promotion intervention was provided to physically challenged children in study group by qualified physiotherapist and investigator for the duration of 36 weeks as per plan of intervention but control group received routine care. A practice diary was maintained to confirm regular practice of health promotion intervention.

7. The post interventional assessment of quality of life was done for both the groups at 12\textsuperscript{th} week (post interventional I), 24\textsuperscript{th} week (post interventional II), and 36\textsuperscript{th} week (post interventional III) by using the same questionnaire for the duration of same time in same kind of environment.

8. The sample of control group did not receive the health promotion intervention during the course of study; however, on completion of the study, they also received health promotion intervention for the duration of one week and instructional manual on health promotion intervention was distributed to them.

3.18 DROP OUT AND IT’S ANALYSIS

There was no dropout of any study participants during the course of study so drop out analysis was not done.
3.19 DATA ANALYSIS

The collected data was tabulated and analyzed in accordance with the objectives of study by using Statistical Package for the Social Sciences version 16 software (SPSS Inc., Chicago, IL, USA) and Instat. The Student’s independent t-test was used to compare values between the study and control groups. Pearson chi-square test was used for comparison of values between the study and control group and association between mean difference score of quality of life and selected demographic and clinical variables. Repeated measures of analysis of variance was used to compare difference between pre interventional and post interventional values within the study and control group. A P-value less than 0.05 was considered to be statistically significant. Simple bar diagram, multiple bar diagram and box plot were used to represent the data.

Chapterization

Chapter III: It dealt with research approach, research design, variables, setting of the study, population, sample, criteria for sample selection, sampling technique, sample size and sample size calculation, development and description of tool, development and description of intervention, translation and back translation of the tool, content validity of the tool, pilot study, reliability of the tool, ethical considerations, data collection procedure, drop out and its analysis, and data analysis.

Chapter IV: It deals with observation and findings.
Research Approach and Research design

Quantitative evaluative approach; Quasi- experimental, pre interventional and post interventional control group design

Setting of the study

Blind and Handicapped development society special school, Mahilpur and Vocational Rehabilitation and Training Centre, Ludhiana

Population

Physically challenged children with locomotor disability in the age group of 10 to 19 years studying in selected special schools, Punjab

Sampling technique and sample size

Purposive sampling technique
Subjects (N=120)

Study group (n=60)  Control group (n=60)

Method of data collection

Pre interventional assessment of quality of life was done at baseline through structured quality of life questionnaire for the study and control group

Study group (n=60)  Control group (n=60)
Health promotion intervention (36 wks)  Routine self care

Post interventional assessment of quality of life was done at 12th week, 24th week, and 36th week by using the same questionnaire for the study and control groups

Data analysis

Descriptive and inferential statistics

FIG 3.1: SCHEMATIC REPRESENTATION OF THE RESEARCH METHODOLOGY