CHAPTER III

METHODOLOGY

The research methodology includes the strategies to be used in collecting and analyzing data to accomplish the research objectives and to test the research hypothesis. It has crucial implications for the validity and credibility of the study findings. This chapter gives a brief description of the methodology adopted for the study to compare the Physical and Psychosocial well-being of CLHIV in family-based and institutionalized care settings in Karnataka.

The content of the chapter includes the description of the research approach, research design, settings, sampling techniques, development and description of instrument, data collection procedure and plan for data analysis.

Research approach

Research approach mainly depends on the existing problem, the objectives framed for the study, the method of collecting the data and its analysis. It is a vehicle for hypothesis testing or answering research questions involving a plan, structure and strategy.

As this study was attempted to compare the Physical and Psychosocial well-being of CLHIV in family-based and institutionalized care settings, a quantitative cross sectional survey approach was found to be appropriate.
Figure 3: Schematic Representation of Research Design

**RESEARCH DESIGN**
- Cross Sectional Design

**SETTING**
- KR Hospital Mysore
- St. John's Hospital Bangalore
- Indira Gandhi Children’s Hospital

**POPULATION**
- CLHIV and their caretakers

**SAMPLING PROCEDURE**
- Purposive Sampling Technique

**SAMPLE SIZE**
- 190 Family based and 190 institutionalized CLHIV

**INSTRUMENTS**
- Weight and Height
- PedsQL™ 4.0
- SDQ

**DATA ANALYSIS**
- Descriptive and inferential statistics
Research design

Research design is considered as a "blueprint" for research. It is the specification of methods and procedures for acquiring the information needed. It is the over-all operational pattern or framework of the project that stipulates what information is to be collected from which source by what procedures. The selection of research design is an important and essential step in research as it is concerned with the overall framework of conducting the study by giving a plan, structure and strategy of investigation.

Research design used was cross sectional survey design, which aids in obtaining firsthand information, accurate and meaningful data.

Variables

Variables are qualities, properties or characteristics of persons, things or situations that change or vary. It is an abstract entity which takes on different values.

The types of variables identified in the present study were:

- Study variables
- Extraneous variables

Study variables:

Physical and Psychosocial well- being of CLHIV in family-based and institutionalized care settings.
Extraneous variables:

Age, Sex, parental status, number of years in the school, Duration of stay in institution, CD4 count, Clinical staging and Duration of ART years

Settings of the study

Setting is the environment in which the study is conducted. Investigator initially listed down all the hospital attached with an ART center. Among them St. Johns Medical College Hospital Bangalore, Indira Gandhi Children’s hospital Bangalore and K R Hospital Mysore were selected as per the permission granted.

St. John's Medical College Hospital is a tertiary medical service centre with 1200 beds. About 300 children registered in the ART center. The center started functioning from April 2008. They render services to children living in the family and the institutionalized children.

Indira Gandhi Children’s hospital Bangalore is a 230 Bedded hospital which provides medical care to all Paediatric patients. It has a Regional Paediatric ART Centre.

The institutions attached to St. John’s medical college hospital and Indiragandhi Childrens hospital includes Infant Jesus Children’s home and Calvery Chapel Trust.

Krishna Rajendra Hospital (K R Hospital), founded by Sri Krishnarajendra Wodeyar in 1927, is a tertiary referral center and teaching hospital having around 1050 beds attached to the Mysore Medical College in Mysore. The ART center started functioning from April 2004. All children attending ART services are residing in the families.
The Infant Jesus children’s home started in 2001 at Kothanur, Bangalore. There are 105 children living under the love and tender care of the Deena Seva (Servants of the poor) missionary sisters. Among the total habitants only eight are not affected by AIDS. From a newborn baby to sixteen-year-old teens are living in the calm and serene atmosphere of the home. Nearly all the children are from the districts of Karnataka and few from other states such as Tamil Nadu and Andhra Pradesh. Children go to regular school.

Calvery chappel trust is residential child care programme provide services to almost 100 Children living with HIV/AIDS.

The totals of 380 children were included in the study. 68 family based children were from KR Hospital Mysore, 152 children, out of which 58 family based and 94 institutionalized were from St. Johns Hospital Bangalore and 160 children, out of which 68 family based and 92 institutionalized were from Indiragandhi children’s hospital Bangalore.

**Population**

The population is the entire group of persons or objects that is of interest to the investigator.

Study population comprises of children living with HIV and their care takers.

**Sampling procedure**

The sample is a subset of the population selected by investigator to participate in a research study. Subjects who met the inclusion criteria were selected by purposive sampling technique.

**Sample size**

Sample size was estimated using the following formula:
\[ N = \frac{2S_p^2[Z_{1-\alpha/2} + Z_{1-\beta}]^2}{\mu d^2} \]

\[ S_p^2 = \frac{S_1^2 + S_2^2}{2} \]

In order to find the mean difference of 5 in the Quality of life domains, considering 13.5 and 15.56 SD in Group 1 and Group 2 respectively with 5% level of significance and 80% Power the number required in each arm (ie. family cared-Gp-1 and institutionalized cared children-Gp-2) is 190. So the total sample size will be 380 children.\(^{37}\)

**Inclusion criteria for children**

- Children diagnose with HIV infection
- Children willing to participate in the study
- Children between the age group of 5-16 years

**Inclusion criteria for care takers/parent**

- Care taker who cares for the child for
  - Minimum 15 hours/week
  - Minimum six months

**Data Collection Tools and Techniques**

**Section 1:** Demographic, clinical, immunological information and anthropometric
Measurements

Section 2: Health Related Quality of Life elicited through The Pediatric Quality of Life Inventory (PedsQL™ 4.0) Generic core scale

Section 3: Behavioral and emotional difficulties and pro-social behavior assessed by using Strengths and Difficulties Questionnaire (SDQ)

Description of the instrument

Section 1: Demographic, clinical and immunological information and anthropometric Measurements

This section includes information such as age, sex, recent CD4 count and clinical stage (WHO 2006), parental status, ART status, age of starting ART and duration of schooling. The data was collected from medical charts and by interviewing.

Height and weight were measured at the time of the interview and Z score standard deviations (SD) were calculated based on WHO criteria for anthropometric measurements (WHO 2006). Height-for-age Z-scores between 2 SD around the international average for sex and age are considered healthy (World Health Organization 2007). BAZ-scores less than -1 SD is defined as undernutrition, -1 to 2 SD was normal and above 2 SD was defined as overweight.

Section 2: Health Related Quality of Life elicited through The Pediatric Quality of Life Inventory (PedsQL™ 4.0) Generic core scale
The Pediatric Quality of Life Inventory (PedsQL™ 4.0) was used to measure Health Related Quality of Life (HRQOL). It comprises of parallel child self-reports and caregiver proxy reports. The PedsQL™ 4.0 encompasses physical subscale (8 items), and psychosocial subscale. Psychosocial subscale composed of emotional (5 items), social (5 items), and school functioning (5 items). Developmentally appropriate forms exist for different age groups. This study utilized reports for ages 5 to 7 years (young child), 8 to 12 years (child) and 13 to 17 years (adolescent). Items are scored and transformed to a 0 to 100 scale such that high scores indicate better HRQOL. One standard deviation below the mean has been used as a meaningful cut off point score for an at-risk status for impaired HRQOL in study performed in California (Varni, Burwinkle, Seid, & Skarr, 2003).

Validity and reliability

The PedsQL™ 4.0 has been validated for use among pediatric populations with acute or chronic health conditions (Varni, Seid, & Kurtin, 2001). The PedsQL has also been validated with CLHIV and uninfected children in India, with internal consistency $\alpha > 0.7$ (Banerjee et al., 2010). The PedsQL™ 4.0 was validated for use in Hindi (Das et al., 2010) but not Kannada, the native language of this study participant. Therefore, experienced interpreters performed translation and back translation of the PedsQL™ 4.0 questionnaire to provide Kannada forms.

Section 3: Behavioral and emotional difficulties and pro-social behavior assessed by using Strengths and Difficulties Questionnaire (SDQ)

The Strengths and Difficulties Questionnaire (SDQ) is an internationally well validated brief behavioral screening tool for children 3–16 years old, to assess behavioral and emotional
difficulties and pro-social behavior. The SDQ has versions for parent/caregiver, teacher, and self-report. This study utilized only caregiver reports. The SDQ is composed of five sub-scales of five items each (emotional symptoms, conduct problems, hyperactivity/inattention, peer relationships, and pro-social behavior). Items are scored on a 3-point scale, from 0 (Not true) to 2 (Certainly true). The Pro-social score is the sum of its five items. The Total Difficulties summary score is the sum of all items of the other four scales. It ranges from 0 to 40, with higher values signifying more difficulties. Scores are categorized according to need for intervention such as in the total scores 0-15 low need 16-19 some need and 20-40 high need. (Goodman, Meltzer, & Bailey, 1998). It has been validated in Indian populations (Bele, Bodhare, Valsangkar & Saraf, 2013) and was available in Kannada. Cronbach's alphas for the total difficulties score were 0.77 for the parent SDQ and 0.81 for the teacher SDQ.65

Pilot Study

Pilot study was conducted from March 2013 to May 2013. Written informed consent was obtained from each participating caregiver. Written assent was taken from all participating children. Investigator introduced to the guardian, care taker or child. Samples were selected by using purposive sapling method from the ART centers of Indira Gandhi Children’s hospital Bangalore, K R Hospital Mysore and St.Johns Hospital Bangalore. Total of 40 samples were collected 20 institutionalized and 20 family based Children Living with HIV. Baseline data was collected through interview schedule, Physical well-being was assessed by measuring the weight and height psychosocial well-being was assessed through PedsQL™ 4.0 and strength and difficulty questionnaire (SDQ). Pilot study helped to get clarity about methodology of the study, analysis to be used and the feasibility of the tool. The study was found to be feasible and the plan for data analysis workable.
Data collection Procedures

IERB clearance was obtained from Sri Ramachandra University and Ethical Review Board and St.John’s Medical College Hospital. Informed consent was obtained from the guardian of the child and Director of Institution for institutionalized children. Recruitment of child participants began by describing the study and answering questions individually. Participants 8-16 years of age gave written consent, while children between 5-7 years gave verbal assent. All questionnaires were administered face to-face, independently and confidentially, in either English or Kannada, the local language, depending on the child’s preference. The interviews took approximately 30 minutes for each child and 30 minutes for the care giver.

Plan for data analysis

Data analysis is the systematic organization and synthesis of the research data and the testing of research hypothesis using the data.

The data obtained would be analyzed using both descriptive and inferential statistics based on the objectives and hypotheses of the study under the following headings:

Section 1: Description of baseline variables

Section 2: Physical and Psychosocial well-being of family based CLHIV

Section 3: Physical and Psychosocial well-being of institutionalized CLHIV

Section 4: Comparison of Physical and Psychosocial well-being of family based and institutionalized CLHIV
Section 5: Correlation between physical and psychosocial well-being of family based and institutionalized CLHIV

Section 6: Association between baseline variables and physical and psychosocial well-being of family based and institutionalized CLHIV

The analyzed data would be presented in the form of tables and figures.

Summary

This chapter has dealt with the research methodology used in the present study. It included the research approach, research design, variables under study, setting of the study, population, sample, sampling technique, sampling criteria, tool construction, validity, reliability of the tool, pilot study, data collection process, problems faced and plan for data analysis.