EFFECTIVENESS OF ICE APPLICATION PRIOR TO INTRAMUSCULAR IMMUNIZATION ON PAIN RESPONSE AMONG UNDER FIVE CHILDREN IN PEDIATRIC OUTPATIENT DEPARTMENT, INSTITUTE OF CHILD HEALTH AND RESEARCH CENTRE, GOVERNMENT RAJAJI HOSPITAL, MADURAI-20

M.Sc (NURSING) DEGREE EXAMINATION

BRANCH – II CHILD HEALTH NURSING

COLLEGE OF NURSING

MADURAI MEDICAL COLLEGE, MADURAI - 20

A dissertation submitted to

THE TAMILNADU Dr. M.G.R. MEDICAL UNIVERSITY,

CHENNAI – 600 032.

In partial fulfillment of requirement for the degree of

MASTER OF SCIENCE IN NURSING

APRIL – 2014

CERTIFICATE

This is to certify that this dissertation titled**, " EFFECTIVENESS OF ICE APPLICATION PRIOR TO INTRAMUSCULAR IMMUNIZATION ON PAIN RESPONSE AMONG UNDER FIVE CHILDREN IN PEDIATRIC OUTPATIENT DEPARTMENT, INSTITUTE OF CHILD HEALTH AND RESEARCH CENTRE, GOVERNMENT RAJAJI HOSPITAL, MADURAI-20."** is a bonafide work done by Mrs. S.Jayashree**,** College of Nursing, Madurai Medical College, Madurai - 20, submitted to the **TAMILNADU DR.M.G.R. MEDICAL UNIVERSITY, Chennai** in partial fulfillment of the university rules and regulations towards the award of the degree of **MASTER OF SCIENCE IN NURSING**, **Branch II, Child Health Nursing** under our guidance and supervision during the academic period from 2012 – 2014.

Mrs. S. POONGUZHALI,
M.Sc (N), M.A, M.B.A, Ph.D,
PRINCIPAL ,
College of Nursing,
Madurai Medical College,
Madurai-20.

Dr.B.SANTHAKUMAR,
MD(F.M)., M.Sc, (F.Sc)., PGDMLE, Dip. ND (F.N),
DEAN,
Madurai Medical College,
Madurai -20.

EFFECTIVENESS OF ICE APPLICATION PRIOR TO INTRAMUSCULAR IMMUNIZATION ON PAIN RESPONSE AMONG UNDER FIVE CHILDREN IN PEDIATRIC OUTPATIENT DEPARTMENT, INSTITUTE OF CHILD HEALTH AND RESEARCH CENTRE, GOVERNMENT RAJAJI HOSPITAL, MADURAI-20.

Approved by Dissertation committee on……

Expert in Nursing Research

Mrs. S. POONGUZHALI M.Sc (N)., M.A., M.B.A, Ph.D., _____

Principal ,

College of nursing,

Madurai medical college, Madurai.

Expert Specialty Guide

Mrs.N.NAGARATHINAM M.Sc (N), _____

Lecturer in Child Health Nursing

College of nursing,

Madurai medical college, Madurai.

Medical Expert

Dr. Dr.G.Mathevan M.D., DCH, _____

Director Incharge,

Institute of Child Health and Research Center

Government Rajaji Hospital, Madurai

A dissertation submitted to

THE TAMILNADU DR.M.G.R. MEDICAL UNIVERSITY,

CHENNAI - 600 032.

In partial fulfillment of the requirement for the degree of

MASTER OF SCIENCE IN NURSING

APRIL - 2014

ACKNOWLEDGEMENT

First of all I praise and thanks to my almighty with reverence and sincerity for his heavenly richest blessing and abundant grace which strengthen me in each and every steps throughout his endeavour.

The success of this study comes through the valuable help, guidance and contributions of my teachers, seniors, friends and other well wishers.

Iam immensely thankful to **Dr.B.Santhakumar, M.Sc (F.Sc), MD (F.M), PGDMLE, Dip. ND (F.N) Dean, Madurai Medical College, Madurai,** for granting me perrmission to conduct the study in this esteemed institution.

Its my proud and privilege to express my sincere gratitude to our honorable **Principal, Mrs.S.Poonguzhali, M.Sc (N), M.A, M.B.A, Ph.D,** College Of Nursing, Madurai Medical College, Madurai for her continuous valuable guidelines and support throughout the period of study. She has also given inspiration, encouragement and scholarly guidance for completion of this study successfully.

I express my heartfull gratitude to **Mrs.N.Nagarathinam, M.Sc(N), Lecturer in Nursing,** College of nursing, Madurai Medical College, Madurai for her dexterous, constructive, critical guidance, logistic support and valuable suggestions to make the study purposeful and constant support to mould this study in a successful way

I wish to extend my wholehearted thanks to **Mrs.R.Jeyasundari, M.Sc. (N)., M.A., M.A., M.A., M.Phil., PGDHA, Faculty in Nursing,** Child Health Nursing Department, College of Nursing, Madurai Medical College, Madurai for her efforts, interest, sincerity, hard work . She was generous enough to spare even extra time to help me, to sort my problem during thesis and who has also given inspiration, encouragement and laid foundation to complete this dissertation in a successful way.

I extend my gratitude to **Mrs.N.Maheswari , M.Sc (N)., M.B.A, Faculty in nursing** Child Health Nursing Department, College of Nursing, Madurai Medical College, Madurai for enlightening ideas, timely motivation and reassurance which kept my working towards the completion of this successful dissertation.

My Sincere thanks to **Dr.G.Mathevan M.D., DCH, Incharge Director of Paediatric Medicine** for his generous support, keen interest, valuable correction, guidance to translate this study into illustration.

I am grateful to **Dr. A. Helen M. Perdita**, **M.Sc (N), Ph.D,** Principal, Madurai Apollo College of Nursing, Madurai, **Mrs. S.M.Agnes Merin, M.Sc (N),** Associate Professor, Matha College of Nursing, Manamadurai, **Mrs. Jyothi Lakshmi, M.Sc (N**), Reader, Sacred Heart College of Nursing, Madurai for their suggestions and tool validity.

I owe to express my grateful thanks to **All Faculties of College of Nursing,** Madurai Medical College, Madurai for their guidance and support for the completion of my study.

I thank whole heartedly **Mr.C.Valarmathi, M.A. B.Ed** and **Mrs.M.Selvarani, M.A, B.Ed,** PG Assistant for the guidance in tamil and English editing

I express my thanks to **Mr.S.Kalaiselven**, **M.A, B.I.L.Sc., Librarian,** College of nursing, Madurai Medical College, Madurai, for his cooperation in collecting the related literature for this study.

I wish to express my sincere thanks to **Mr.Pandi, M.Sc., MPS.,MBA, MPHil,MCS., MPHIL., MCOM., Staitician,Assistant Professor i/c,Department of statistics, Madurai Medical College, Madurai** for extending necessary guidance for statistical analysis.

My heart full thanks to **M.P.N.Jagadha MBA.,** for her care and regard she has rendered for completing my study.

I express my thanks to **Mr**.**R.Rajkumar,Mr.Upendran** and **Mr.Samsutheen,** for their support for the completion of the study I thank for their help and untiring work in the preparation for this study.

I wish to thank my department mates **Mrs.Saranya.P, Mr. N.Chendrya Perumal, Mr. Absar Hussain.J. and Ms.Muthu Meenakshi.N** for their constant physical and psychological support to me in completing this study.

My affectionate thanks to **my lovable parents Mr.R.Shanmugam** and **Mrs.K.T.Vijayalakshmi, Retired Nursing Superintendant.,** who has been the backbone of my career and endeavors. And my son **Mr.A.Vijayasahar**,BE for the care, assistance and support throughout this study which cannot be expressed in words.

Gratitude is extended to all my friends and colleagues who provided encouragement, who listened to, sometimes counselled and always supported me during my studies.

ABSTRACT

Under five children routinely experience pain associated with commonly used invasive procedures. The main objective of the study is to evaluate the Effectiveness of ice application prior to immunization on pain response during intramuscular immunization among the under five children undergoing intramuscular immunization. Modified widenbach's prescriptive theory was used. Quantitative approach with True experimental design - Post test only design was adopted for this study. With the use of simple random sampling technique 30 infants were assigned to experimental group, and 30 were in control group (n=60). Ice application prior to intramuscular immunization was given to the experimental group. In this technique ice pack covered with a lint piece was placed for 30 seconds prior to intramuscular immunization. The intramuscular immunization was given by the usual standard technique for the control group. Consequently, the pain level was measured by FLACC (Face, Legs, Activity, Cry, Consolability) pain scale. Result revealed the control group mean (7.97) is higher than the experimental group mean (3.03) of the under five children. The obtained't' value is 15.59, significant at $p<0.05$ level. There was no significant association between pain level among experimental group and baseline variables. This concludes that the pain response of experimental group is less than the control group. Hence, the ice application prior to intramuscular immunization for under five children had effect on the pain response during intramuscular immunization.

TABLE OF CONTENTS

LIST OF TABLES

LIST OF FIGURES

LIST OF APPENDICES

Introduction

CHAPTER - I

INTRODUCTION

"First love is a kind of vaccination which saves a man from

Catching the complaint of second time"

- **Honore de Balzac**

Pain associated with vaccine injections is a source of distress for individuals of any age as well as for the immunization provider. If not addressed, the pain and anxiety associated with immunizations can be related to fear of future procedures, medical fears, and avoidance behaviors including non-adherence with immunization schedule. It is estimated that up to 25% of adults have needle fears.

The majority of people with needle fears develop them in childhood. Efforts aimed at minimizing pain in childhood have the potential to prevent the development of needle fears and promote consumer satisfaction and trust in health care providers because of more positive experiences for children and their families.

The taxonomy committee of International Association for the Study of Pain (IASP) defines pain as "an unpleasant sensory and emotional experience associated with actual or potential tissue damage."

Pain is subjective; each person feels and expresses pain differently. Every individual learns the meaning of pain through experiences early in life. For children, being distressed during a procedure may have a negative impact on the memory of pain.

The under five children who are exposed to painful experiences develop a sensitization to future pain and may develop altered responses to future pain. The under five children who were exposed to repeated painful stimuli such as venipuncture or heel prick demonstrated an anticipatory response to the pain, rather than developing a tolerance for pain, if exposed to repeated procedures, children may actually develop a conditioned anxiety response that manifests as "pre-procedural anxiety". Approximately 10% of the adult population have needle phobia, a condition that develops in childhood following a negative medical experience involving an injection. Over time, the phobia may become generalized to all medical situations.

Adults who have needle fears or needle phobia tend to avoid preventive medical care for themselves and may avoid immunizations for their children. While the immunization experience can be anxiety-provoking for the child and for the parent, it is also an opportunity for parents and the child (of preschool age and older) to learn coping strategies that will be useful in any stressful situation. There are several evidence-based interventions that can be used before and during the immunization procedure to reduce acute pain and anxiety at the time of vaccine injection. The immunization provider and client or parent should work together to select from the strategy which will work best for the vaccine recipient.

Pain is a global health problem which exists from the birth to the last stage of the life. It's a very unpleasant sensation that cannot be shared with others. Under five children routinely experience pain in the hospitals especially during the vaccination procedure.Immunization is the most aversive of medical procedures for healthy children too.

Studies based on 2005 census, revealed that immunization program could cover about 100% of target children in India. Only about 63% of children received all the vaccines (BCG, DPT, OPV, and Measles). During immunization, the children undergo pain due to the prick. The pain associated with such injections is a source of distress for children. If not addressed, this pain can lead to pre procedural anxiety in the future and fear of needles. Painful procedures are likely to be confounded with anticipatory and concurrent anxiety, usually considered together as possible related distress.

Younger children experience pain similarly and probably more intensely than older children and adults. They are also at risk of adverse long term effects on behavior and development, through inadequate attention towards pain relief in early life. Pain can be assessed using self-report, behavior observation, or physiologic measures, depending on the age of the child and his or her communication capabilities. Accurate pain assessment requires consideration of the plasticity and complexity of children's perception.

Minimizing pain during childhood vaccination can help to prevent distress, development of needle fears and subsequent health care avoidance behaviors. Numerous myths, insufficient knowledge among caregivers, and inadequate application of knowledge contribute to the lack of effective management.Parents are likely to have a substantial impact on child's experience of pain.This involves primarily preparing the parents who have under five children. However, for older children, the procedure must be discussed with the child itself. The underfive period extends from the birth to five years. The Under five children are undertreated for pain for a number of reasons, including professional's misconceptions about

pain; the complexities of pain assessment; and the lack of information regarding currently available pain reduction techniques. A number of fallacies continue to flourish because of incorrect knowledge about pain in under five children, despite these fallacies having been disproved by current research to pediatric pain. Pain is a universal, complex and subjective experience. They spend a lot of time with children who are suffering with pain and suffering than any other health care provider.

The Gate-Control theory of Melzack and Wall (1965) stated that stimulation of larger diameter fibers (e.g., using appropriate pressure or vibration) can close the neural gate so that the central perception of itch and pain is reduced. It is based on the fact that small diameter nerve fibers carry pain stimuli through a gate mechanism but larger diameter nerve fibers going through the same gate can inhibit the transmission of the smaller nerves carrying the pain signal.

Chemicals released as a response to the pain stimuli also influence whether the gate is open or closed for the brain to receive the pain signal. This lead to the theory that the pain signals can be interfered with stimulating the periphery of the pain site, the appropriate signal-carrying nerves at the spinal cord or particular corresponding areas in the brain stem or cerebral cortex. It is generally recognized that the Pain gate can be shut by stimulating nerves responsible for carrying the touch signal (mechanoreceptors) which enables the relief of pain through massage techniques, rubbing, pressure, ice packs, acupuncture, electrical analgesia and also the application of vibration.

Ice therapy also known as cryotherapy is one of the most widely used treatment modalities used for acute pain. It is cheap, easy to use and requires little time to prepare. Ice is a therapeutic agent used in medicine as an integral part of injury treatment and rehabilitation. The use of ice pack is widespread because of their effectiveness, convenience, low cost, and ease of transportation. Ice packs can be made with any form of ice; however, 2 commonly used forms are cubed ice(by freezing water to stony hard ice packs) and crushed ice. Ice is believed to help control pain by inducing local anesthesia around the treatment area. Investigators have also shown that it decreases oedema, nerve conduction velocities, cellular metabolism, and local blood flow.

There are many theories and it is possible that a number of the proposed mechanisms in combination can cause pain reduction. Some of the possible mechanisms include:

1. Decreases the amount of bleeding by vasoconstrictioninto the injury site and so lessens swelling
2. A decreased nerve transmission in pain fibres
3. Cold reduces the activity of free nerve endings
4. Cold raises the pain threshold
5. Cold causes a release of endorphins
6. Cold sensations over-ride the pain sensation - known as the pain gate theory

Considering the anxiety due to painful procedures such as injections as well as the unpleasant feelings the parents and the children get, it was hypothesized that the application of local refrigeration would decrease the pain related to injection procedures

A combination of pharmacological and non-pharmacological interventions can ensure the highest standard of care in the management of pain in children. In under five children, ice application prior to intramuscular injection has drastically reduced pain while doing invasive procedures.

Ice application slows the nerve impulse in the area, which interrupts the pain spasm reaction between the nerves. The cold makes the vein in the tissue contract, reducing pain. Once the cold is removed, the vein overcomes compensate and dilate, and blood rushes into the area, which in turn has an analgesic effect.

A study was conducted on inadequate pain management during routine childhood immunization. The view was to summarize existing knowledge about: the epidemiology of childhood immunization pain; the pain experience of children undergoing immunization; current analgesic practices; barriers to practicing pain management in children; and recommendations for improvements in painmanagement during immunization. The adoption of pain-relieving techniques into clinical practice has been suboptimal. The underutilization of pain management strategies can be attributed to a lack of knowledge about pain and effective pain prevention strategies, and the persistence of attitudes about pain that interfere with optimal clinical practices. The study showed that treating pain during childhood immunization has the potential to reduce distress during the procedure and greatly improve satisfaction with the immunization experience through more positive experiences for children and their

families. Other potential benefits include improved adherence to immunization schedules and reduced squeal of untreated pain.

The investigator herself during her clinical experience and daily life has come across many under five children who were screaming due to pain during intramuscular immunization. Very few studies have been conducted on the application of ice pack prior to intramuscular immunization for assessing the pain responses among under five children during immunization. This experience motivated the investigator to undertake the study to assess the pain responses among under five children during intramuscular immunization.

1.1 NEED FOR THE STUDY

'For all the happiness mankind can gain is not in pleasure but in rest from pain'

- John Dryden.

Pediatric nursing is traditionally involved in professional and competent care of children. One of the most dramatic advances in pediatric nursing is the traumatic care of children. To the child of any age, a visit to the hospital can be at best a frightening event and at worst a traumatizing experience. The children imagine hospital as a place where they get injections. Injections of any kind can hurt when they happen to see a nurse or a doctor with an injection syringe. The emotional disturbance and fear knows no boundary in children who feel threatened by painful procedures.

Injections of any kind can hurt! The word "pain" is derived from the Latin word "Poena" which means punishment, which is in turn derived from the Sanskrit root 'pu', meaning purification. Pain is a common and an ever present sensation for

children and adult. Every child has his or her own perception of pain. Newborn and under five children routinely experience pain associated with commonly used invasive procedures such as blood sampling and intramuscular injection, immunizations, and heel lancing procedure etc ., Pain is a subjective experience, young children respond to pain with behavioral reactions that depend on their age and cognitive processes. Since pain was deemed the fifth vital sign, proper evaluation and management of this symptom has become an essential element of nursing practice. Moreover, pain is a source of concern and distress for new parents and may disturb mother–child bonding. A number of factors influence the pain perceived by the child, including maturation of the nervous system, the child's developmental stage, and previous pain experiences. Under five children develop a memory of pain.

World scenario states that 76% of infants were fully immunized. Indian scenario represents that 431,033 infants were fully immunized in the year of 2011-2012 according to Ministry of Health and Family welfare, India. The immunisation coverage is increased DPT1 coverage is 83%, DPT2 coverage is 72%at 2010 by UNICEF and WHO. Tamilnadu scenario depict that the immunization coverage is increased to 91% by Department of Public health and Preventive Medicine. Despite of this coverage Hib (Haemophilus influenza type b) kills more than 370,000 children under five every year; nearly 20% of these children die in India. 2.95% of deaths were due to Pneumonia. A recent study shows that Hib vaccine could prevent about 1/3 of life-threatening cases of bacterial pneumonia, the leading infectious cause of death in Asian children.

In India 77.2% of rural and 80 % of urban children are immunized with vaccines annually. However the children vaccinated will experience severe to moderate pain. Hence there are many non-pharmacological measures to reduce the level of pain; one of which is ice-application at the injection site prior to intramuscular immunization.

Immunization plays a major role in reducing infant mortality rate. WHO has declared that Year 2012, as a "Year of Intensification of routine Immunization" in South East Region. In the year of 2011, our Government of India has recently launched pentavalent vaccine in Tamil Nadu and Kerala. This Pentavalent has reduced number of pricks from 9+1 (3 each for DPT, HepB and Hib + HepB birth dose). But the pain during immunization is the great source of distress to children as well as Parents.

The pain associated with immunizations is a source of anxiety and distress for the children receiving the immunizations, their parents and the providers who must administer them. The Centre for Disease Control and Prevention schedule recommends immunizations against 14 diseases, which translates in to 14 to 20 separate injections before the age of 2 years, depending on the number of combination vaccines available. Therefore, immunizations are the most frequently occurring painful procedures performed in pediatric settings.

Immunizations have been administered for more than half a century, but the distress they endanger has not been examined with the attention or rigor that might be predicted on the basis of their frequency. Perhaps it should not be surprising that procedures that were developed before the burdens of evidence-based medicine continue to be performed without the scrutiny that newer interventions received.

A true experimental study was done to assess the effectiveness of ice application prior to intramuscular immunization in reduction of pain among children in a selected hospital, Mangalore with 50 samples during the year 2007. Children was selected randomly and ice application were given for the experimental group children for 30 seconds. The existing pattern of injection for the control group. The research approach was post-test only design. The study findings revealed that 85% of the children in the experimental group had mild pain perception level after ice-application and children in the control group had moderate to severe pain .

An experimental study was done on effectiveness of ice application at selected point (L_1-L_4) prior to intra muscular injection in reducing pain among 60 children between 15-18 months attending the immunization clinic. Ice application was given for children under experimental group for 30 seconds prior to intramuscular injection. At the end of this period, intramuscular injection was given and assessment of pain was done immediately for one minute by using observational checklist and Wong and Backer faces pain scale. The study finding revealed that majority (80%) of the children in experimental group had mild pain level after ice application. The mean (8.43) and standard deviation (1.30) of experimental group when computed with mean (16.97) and standard deviation of (1.22) of control group revealed that the calculated 't' value 26.19 was greater than the table value. Thus, the study findings revealed that there was a high statistical significant difference in level of pain among children between experimental and control group at $p<0.001$ level of significance.

Minimizing pain for the under five children during intramuscular immunization can help to prevent distress, development of needle fears and

subsequent health care avoidance behaviors, such as non-adherence with immunization schedules. More positive experiences during immunizations also maintains and promotes trust in the health care providers.

Assessing and managing an under five year old child with pain is a daily problem for nurses. They are the responsible persons who not only implement the doctor's orders, but also the ones who work closely with patients to facilitate healing processes. So nurses can use simple interventions like ice-application to relieve procedural pain in children and promote comfort for them.

Therefore, from the above findings the researcher felt that it is a need to conduct the present study to assess the effectiveness of ice-application prior to intramuscular immunization in pain responses among under five children.

1.2 STATEMENT OF THE PROBLEM

Study to assess the effectiveness of ice application prior to intramuscular immunization on pain response among under five children in pediatric outpatient Department, Institute of Child health and Research Centre, Government Rajaji Hospital, Madurai-20.

1.3OBJECTIVES

- To assess the pain response during intramuscular Immunization for under five children in the experimental and control group.
- To assess the effectiveness of ice application prior to intramuscular immunization by pain response in the experimental group
- To compare the pain response between experimental group and control group.

- To determine the association between the post test scores of pain response with their selected baseline variables in experimental group.

1.4 HYPOTHESES

H_1 Thereis a significant difference in pain response during intramuscular immunization among experimental and control group.

H_2 There is a significant association between the post test scores of experimental group with their selected demographic variables.

VARIABLES

Independent variable: Ice Application

Dependent variable : Pain response

1.5 OPERATIONAL DEFINITION:

Effectiveness

Refers to the ice application, which helps in reducing pain as evidenced by the significant difference in the pain score of under five children in the experimental group and control group.

Ice- Application

Refers to the application of ice pack covered with a lint piece, over the intramuscular immunization site (antero-lateral aspect of thigh) for thirty seconds prior to the intramuscular immunization.

Pain Response

Refers to the unpleasant sensation experienced by the under five children during intramuscular immunization which is elicited by various expressions like crying, mourning and facial grimaces. This is measured by FLACC (Face, Legs, Activity, Cry and Consolability) pain scale.

Under five children

Refers to children between the age group of less than 5 years who attend the immunization clinic and satisfy the inclusion criteria.

Intramuscular Immunization

Refers to the injection of pentavalent and DPT vaccine given intramuscularly according to the immunization schedule advised by the Ministry Of Health and Family Welfare, Government of India.

1.6 ASSUMPTION

- Children may experience pain during immunization.
- Every child is unique but they may have variations in their pain response

1.7 DELIMITATION

- The study is limited to Under five children receiving Intramuscular immunizations at immunization clinic, outpatient department ,Institute of child Health and Research centre, Government Rajaji hospital, Madurai
- Data collection period limited to 6 weeks.

1.8 PROJECTED OUTCOME

This study will reveal the level of Pain experienced by the under five children who undergo intramuscular immunization at the immunization clinic of the paediatric outpatient department, Government Rajaji Hospital, Madurai. It will give strong evidence that the under five children who receive ice pack application prior to intramuscular immunization will experience reduced levels of pain, compared to those under five children who are immunized by the usual method. In addition, the results will motivate the health care workers to use this non pharmacological and cost effective technique to reduce the pain during Intramuscular immunization for under five children.

Review of Literature

CHAPTER - II

REVIEW OF LITERATURE

A literature review is a body of text that aims to review the critical points of knowledge on a particular topic of research. (American Nurses Association, 2000). The literature review is used in two ways by the research community. The first refers to the activities involved in identifying and searching for information on a topic and the second one is developing an understanding of the state of knowledge on the topic.

This chapter deals with two parts:

Section - A: Review of literature

Section - B: Modified Conceptual framework on Widenbach's Prescriptive theory

SECTION - A

The literature has been organized under following sections:

PART- I: Literature related to assessment of pain during Intramuscular immunization.

PART-II: Literature related to physical interventions on pain during intramuscular immunization.

PART - III: Literature related to psychological interventions on pain during intramuscular immunization.

PART-IV: Literature related to pain response on ice application prior to intramuscular immunization.

2.1 LITERATURE RELATED TO ASSESSMENT OF PAIN DURING INTRAMUSCUALR INJECTION

Rosenbloom.et.al, (2011) conducted a prospective cohort study on Parental Sex and Age: Their Effect on Pain Assessment of Young Children. A total of 61 couples were examined. The investigators provided instructions regarding the use of a visual analogue scale (VAS) to both parents at the same time using a standard information kit. Both parents were asked to rank the child's pain on a 100-mm VAS. The result conclude that there was no significant difference between mothers' VAS (59.1 ± 27.4) compared with father's VAS (57.9 ± 26.3) (P = 0.75).

RashaSrouji, SavithriRatnabalan and Susan schneweiss, (2010) conducted a study on Pain assessment and non-pharmacological management. The researcher concluded that pain perception in children is complex, and is often difficult to assess. A review of pain assessment scales that can be used in children across all ages Neonatal Facial Coding System (NFCS), Neonatal Infant Pain Scale (NIPS) , The Premature Infant Pain Profile (PIPP), Crying Requires Increased Vital Signs Expression Sleeplessness (CRIES), Maximally Discriminate Facial Movement Coding System (MAX) were used for neonates, The Faces Legs Activity Cry Consolability Scale (FLACC), The COMFORT scale used for infants. Observational Pain Scale (OPS), The Toddler-Preschooler Postoperative Pain Scale (TPPPS), were used for toddlers. The Child Facial Coding System (CFCS), Poker Chip Tool, Ouchers scale used for preschoolers. Visual Analogue Scale (VAS), Pediatric Pain Questionnaire was used for Schoolers. The distractions techniques are provided by nurses to manage pain in children is most effective when adapted to the developmental level of the child.

Anna Taddio.et.al., (2009) conducted a systemic review on inadequate pain management during routing childhood immunization: the nerve of it. MEDLINE, Psych INFO, EMBASE, CINAHL and the Cochrane central register for primary research and review articles published from beginning of October 2008 data bases were searched for the study. Result showed that on average younger children exhibit more distress and pain than do older children. More than 90% of toddlers and 50% of primary school children exhibit severe distress during immunization. Individual child factors such as developmental level, temperament may have a considerable effect on children's immunization.

Harrison, D., **Loughnan, P., and Johnston, L. (2006)** conducted a postal survey on current pain assessment and procedural pain management practices in neonatal units in Australia. The survey comprised questions relating to pain assessment scores, pain reduction strategies for minor painful procedures and the use of articulated policies relating to procedural pain management. Surveys were sent to 181 eligible organizations, and 105 of these were returned (58%). Six units (6%) used pain assessment scores on a regular basis, and 16 units (15%) had an articulated policy directing pain management practices during painful procedures. Non-nutritive sucking and various nursing comfort measures were the pain reduction strategies most frequently used during minor painful procedures. Result suggested that twenty-four units (24%) used sucrose or other sweet-tasting solutions during procedures. Breast-feeding during venepuncture, heel lance and intramuscular or subcutaneous injection was infrequently practiced and topical anesthetic agents were rarely used.

Pat Hummel.(2006) state that Neonatal pain assessment has received much attention over the past decade. Behavioural indicators of pain include facial action, body movement and tone, cry, state/sleep, and consolability. Physiological indicators of pain include increased heart rate, respiratory rate, and blood pressure, as well as decreased heart rate variability and oxygen desaturation. Pain assessment in neonates is difficult in neurologically compromised, chemically paralyzed, and non-responsive infants. Multiple pain assessment tools are summarized. Pain assessment and management protocols are delineated.

Elizabeth.A, Stanford.et.al, (2005) conducted a study on ‘‘Ow!’’: Spontaneous Verbal Pain Expression among Young Children during Immunization. Fifty-eight children between the ages of 4 years 8 months and 6 years 3 months (67% female) were videotaped while receiving their routine preschool immunization. Children provided self-report of pain using a 7-point faces pain scale. Fifty-three percent (53%) of children used verbalizations spontaneously to express their pain. The modal verbalization was the interaction ‘‘Ow!,’’ which expressed negative affect and was specific to the experience of pain.

Catherine B. McClellan, Lindsey L. Cohen, and Karen E. Joseph. **(2003)** conducted a study on Infant Distress during Immunization. A multimethod assessment of distress was conducted to investigate infants (N = 37) undergoing routine immunizations. Measures of infant distress included Parent report, nurse report, infant heart rate, and an observational measure of infant distress. Parents rated their infant's distress and pain significantly higher than did nurses. Observational and physiological ratings of infant distress were found to vary significantly by phase, and there were no correlations between adult ratings of pain and distress and physiological

ratings. Findings suggest that infant procedural distress can be assessed in a number of manners. The discordance between these measures emphasizes the need for multimethod assessment of pediatric procedural distress in both research and clinical settings.

2.2 LITERATURE RELATED TO PHYSICAL INTERVENTIONS ON PAIN DURING INTRAMUSCULAR INJECTION

John W. Harrington.et.al.,(2012) conducted a prospective, randomized, placebo-controlled trial study on Effective analgesia using Physical interventions for Infant Immunizations 2- and 4-month-old 230 infants were selected. Infants were assigned into 4 groups (2 x 2) receiving either 2mL of water or 2mL of 24% oral sucrose and then either standard-of-care comfort measures by parents or intervention with the 5 S's (swaddling, side/stomach position, shushing, swinging, and sucking) immediately post vaccination. Results revealed significantly different mean pain scores between study groups with the exception of the 5S's and 5S's with sucrose groups. These 2 groups had lower similar mean scores over time, followed by sucrose alone, then control. The same trend was found with the proportion of children crying as with the mean pain score outcome measure.

Jen-Jiuan Liaw.et.al, (2011) conducted a randomized clinical trial on Non-nutritive Sucking and Oral Sucrose Relieve Neonatal Pain during Intramuscular Injection of Hepatitis Vaccine. 165 (gestational age, ≥36 weeks) infants received IM injections and were randomized to three treatment groups: non-nutritive sucking (NNS), 20% oral sucrose, or routine care. Pain was measured by the Neonatal Facial Coding System, physiological signals by electrocardiogram monitors, and cry duration using a stopwatch. Result shown that Pain was significantly lower among

infants in the Non Nutritive Sucking ($B = -11.27$, $P < 0.001$) and sucrose ($B = -11.75$, $P < 0.001$) groups than that in controls.

Mary-Ellen Hogan. (2011) conducted a single blind, randomized controlled trial study on effectiveness of tactile stimulation (rubbing before 15 seconds and after 15 seconds) when added to a combination of pain reducing interventions in infants undergoing immunization. 120 infant's ages 4-6 months were participated in this study. Result showed that Characteristics did not differ ($p > 0.05$) between those allocated to tactile stimulation and usual care groups. Mean MBPS pain scores did not differ between groups: 8.2 (1.1) vs. 8.0 (1.3), respectively ($p = 0.57$).

Pillai Riddell,RR.et.al., (2011) conducted a systemic review to assess the efficacy of non-pharmacological interventions for infant and child (up to three years) acute pain, excluding breast milk, sucrose, and music. Fifty-one studies, with 3396 participants, were analyzed. They searched CENTRAL in The Cochrane Library (2011, Issue 1), MEDLINE (1966 to April 2011), EMBASE (1980 to April 2011), Psyc INFO (1967 to April 2011), Cumulative Index to Nursing and Allied Health Literature (1982 to 2011), Dissertation Abstracts International (1980 to 2011) and www.clinicaltrials.gov. The result revealed that the largest Standard Mean Deviation for treatment improvement over control conditions on pain reactivity were: non-nutritive sucking-related interventions (preterm: SMD -0.42; neonate: SMD -1.45), kangaroo care (preterm: SMD -1.12), and swaddling/facilitated tucking (preterm: SMD -0.97). For immediate pain-related regulation, the largest SMDs were: non-nutritive sucking-related interventions (preterm: SMD -0.38; neonate: SMD -0.90), kangaroo care (SMD -0.77), swaddling/facilitated tucking (preterm: SMD -0.75), and rocking/holding (neonate: SMD -0.75).

Tisvy Thomas, Asha P Shetty and Praveen V Bagali. (2011) conducted a post only control group study on Role of Breastfeeding in Pain Response During Injectable Immunization among Infants. The samples were 40 infants receiving the 1st, 2nd and 3rd doses of DPT immunization in the age group of 5 – 15 weeks selected by Non probability purposive sampling technique. Breastfeeding was given by the mother in sitting position and the infant in lying position on mother's lap while administering injectable immunization. The immunization was administered 2 minutes after the initiation of breastfeeding. The pain score assessed by using the modified neonatal infant pain scale. The mean pain score 4.7 of the 1st minute in the experimental group was lower than the mean pain score 6.6 in the control group, the mean pain score at 5th minute in the experimental group was 0.55 which is lower than that of the control group score of 1.95.

Barnhill , BT., Holbert, Jackson and Erickson. (2010) conducted a study on using pressure to decrease the pain of intramuscular injections. The subjects were 93 patients who had dorso gluteal intramuscular injections of immune globulin at a county health department. Forty-eight received the pressure treatment and 45 received a standard injection in which no pressure was applied. Mean pain intensity on a 100-mm visual analogue scale, adjusted for differences in injection volume, was 13.6 mm for the experimental group and 21.5 mm for the control group (P=0.03). The findings suggested that simple manual pressure applied for 10 sec. prior to the injection site is a useful technique to decrease injection pain.

Denise Harrison.et.al,(2010) conducted a systemic review on Efficacy of sweet solutions for analgesia in infants between 1 and 12 months of age. Of the 695 studies identified, 14 (Randomized controlled trials) RCTs with 1674 injections met the inclusion criteria. Sucrose or glucose, compared to water or no treatment

decreased crying during or following immunization in 13 of the 14 studies. Infants receiving 30% glucose (three trials, 243 infants) had a decreased relative risk in crying incidence following immunization.

Dilli,D., Kucuk,IG., and Dallar,Y. (2009) conducted a study on Interventions to reduce pain during vaccination in infancy. A consecutive sample of 243 children between age 0 and 48 months were selected. A total of 158 infants were randomly assigned to breast-feeding or no breast-feeding during immunization, and 85 children were randomly assigned to receive 12% sucrose solution, lidocaine - prilocaine cream, or no intervention. All children were evaluated for crying time and pain score using the Neonatal Infant Pain Scale (NIPS) for those under age 12 months and the Children's Hospital of Eastern Ontario Pain Scale (CHEOPS) for those over age 12 months. The study result suggest that Breast-feeding in infants under age 6 months and use of sucrose or lidocaine-prilocaine in children age 6 to 48 months significantly reduced crying time and pain scores compared with controls. No difference in outcome was seen between the sucrose and lidocaine-prilocaine treatment groups.

Ipp.M.et.al, (2009) conducted a Single-center, double-blind, randomized clinical trial study on Order of vaccine injection and infant pain response. Healthy 120 infants 2 to 6 months of age were selected. The Modified Behavioural Pain Scale (MBPS), using videotaped recordings of the procedure. In addition, parents rated pain using a 10-cm visual analogue scale (VAS). Crying (yes/no) was also measured. 60 received the DPTaP-Hib vaccine first and 60 received the PCV (Pneumococcal conjugate vaccine) first. Infant characteristics did not differ between groups. The result suggested that the DPTaP-Hib vaccine caused significantly less pain ($P < .001$) than the PCV, as assessed by the Modified Behavioural Pain Scale, Visual Analogue Scale, and crying.

LovepreetKaur, Sukhwinder Kaur.et.al, (2009) conducted a randomized control trial on Analgesic effect of breast-feeding in infants during immunization Injections. A total of 216 infants receiving DPT and its combinant vaccines were randomly distributed into control and experimental group. Infants in the control group (n=106) were administered vaccine without breast feeding and the infants in experimental group (n=110) were administered vaccine during breast feeding. Pre-vaccination and post-vaccination behaviour of infants was scored on Modified Behavioural Pain Scale. Cry duration was recorded. The net pain scores and duration of cry was compared among the two groups. The result suggest that Significant difference in behavioural response of the infants was observed among the infants, t= 5.5 at df = 214 ($p<0.01$).

Taddio.A.et.al,(2009) conducted a systemic review of randomized trials on experimental and quasi randomized controlled trials on Physical interventions and injection techniques for reducing injection pain during routine childhood immunizations in children 0 to 18 years of age, Nineteen Randomized Controlled Trials involving 2814 infants and children (0-18 years of age) were included in the systematic review using validated child self-reported pain or assessments of child distress or pain made by others (parent, nurse, physician, observer). The study sought to determine the effects of: (1) different formulations of the same vaccine; (2) position of the child during injection; (3) intramuscular versus subcutaneous injection; (4) cooling of the skin at the injection site with ice before injection; (5) stroking the skin or applying pressure close to the injection site before and during injection; (6) order of vaccine injection when 2 vaccines were administered sequentially; (7) simultaneous versus sequential injection of 2 vaccines; (8) vaccine temperature; (9) aspiration before injection; (10) anatomic location of injection; (11) aspects of the

needle (gauge, length, angle of insertion, speed of injection); and (12) combinations of these interventions. All meta-analyses were performed using a fixed-effects model. The study conclude that Pain during immunization can be decreased by: (1) injecting the least painful formulation of a vaccine; (2) having the child sit up (or holding an infant); (3) stroking the skin or applying pressure close to the injection site before and during injection; (4) injecting the least painful vaccine first when 2 vaccines are being administered sequentially during a single office visit; and (5) performing a rapid intramuscular injection without aspiration.

Efe.E.et.al,(2007) conducted a study on the use of breast-feeding for pain relief during neonatal immunization injections. Sixty-six healthy infants for their second, third, or fourth-month immunization with intramuscular diphtheria, tetanus, and pertussis were randomized to be breast-fed before, during, and after the injection or to be given the injection according to routine clinic procedure (no breast-feeding). To assess the pain responses of the neonates during and after immunization, their heart rates, oxygen saturation levels, and length of crying. The crying time was shorter in the experimental (breast-feeding) group (M +/- SD duration, 35.85 +/- 40.11 seconds) than in the control group (M +/- SD duration, 76.24 +/- 49.61 seconds; p = .001). The heart rate and oxygen saturation levels were almost the same in both groups. The study result showed that breast-feeding, maternal holding, and skin-to-skin contact significantly reduced crying in infants receiving an immunization injection for diphtheria, tetanus, and pertussis.

Moshe Ipp, Anna Taddio.et.al, (2007) conducted a randomized controlled trial study on Vaccine-related pain of two injection techniques. The subjects were 113 Healthy infants 4–6 months of age receiving their routine DPTaP-Hib immunization.

Interventions were Standard of care group: slow aspiration prior to injection, slow injection and slow withdrawal. Pragmatic group: no aspiration, rapid injection and rapid withdrawal. The result revealed that the Mean Modified Behavioural Pain Scale scores (95% confidence interval (CI)) were higher ($p<0.001$) for the standard group compared to the pragmatic group, 5.6 (5 to 6.3) vs. 3.3 (2.6 to 3.9).

PragyaPathak, Raman Kalia and BhavneetBharti. (2007) conducted a true experimental study on the Effect of needle gauge (23 G, 25G) on perception of pain intensity among infants receiving D.P.T. vaccination. 320 infants receiving DPT vaccine were vaccinated with 25G (n=161) or 23G (n=159) needle in the two randomized groups. Pre and post-vaccination behaviour of infants was scored on Modified behaviour pain scale (MBPS) and recorded on Video clips. The result revealed that Significant difference in behavioural response to pain was observed among infants in the two groups, $t = 4.25$, $df=318$, ($p<0.01$). The results revealed that 23 G. needle causes less pain as compared to 25 G. needle.

Schechter, NL. (2007) conducted a systemic review on Pain reduction during pediatric immunizations. The limited available data suggest that intramuscular administration of immunizations should occur in the vastuslateralis (anterolateral thigh) for children <18 months of age and in the deltoid (upper arm) for those >36 months of age. Controversy exists in site selection for 18- to 36-month-old children. A number of studies suggest that the ventrogluteal area is the most appropriate for all age groups. Longer needles are usually associated with less pain and less local reaction. During the injection, parental demeanor clearly affects the child's pain behaviors. Excessive parental reassurance, criticism, or apology seems to increase distress, whereas humor and distraction tend to decrease distress. Distraction

techniques vary with the age, temperament, and interests of the child, but their efficacy is well supported in the literature. Sucrose solution instilled directly into the mouth or administered on a pacifier reduces evidence of distress reliably in children <6 months of age and should be used routinely. Although there is no perfect topical anesthetic available at this time, selective use for children who are particularly fearful or who have had negative experiences in the past is highly endorsed. Pressure at the site, applied with either a device or a finger, clearly reduces pain.

Chung, JW.,Ng, WM.,Wong, TK. (2002) conducted an experimental study on the use of manual pressure to reduce pain in intramuscular injections. Seventy-four subjects, participating in an immunization vaccination campaign, were recruited by convenience sampling. They were required to receive two doses of vaccines via intramuscular injections. One was given in a conventional way, i.e. without manual pressure being applied prior to the injection (control condition). The other was given with manual pressure being applied prior to the injection (experimental condition) for 10 seconds. The instrument for measuring the perceived pain intensity was the Pain Intensity Verbal Rating Scale (Cantonese). The mean manual pressure applied was 190.82 mmHg (SD=5.25). Results demonstrated a Subjects with manual pressure applied before injections reported lower pain intensity scores, whilst those without the application of manual pressure before injections reported higher pain intensity scores.

2.3 LITERATURE RELATED TO PSYCHOLOGICAL INTERVENTIONS ON PAIN DURING INTRAMUSCULAR INJECTION

Nicole M. Racine, Pillairiddell, David flora, Hartley garfiled and Saul Green berg. (2011) conducted a cross sectional analysis on A Longitudinal Examination of Verbal Reassurance during Infant Immunization: Occurrence and

Examination of Emotional Availability as a Potential Moderator. The study was conducted with 606 infants (and their parents) at 4 different ages (*n*=376 at 2 months, *n*=455 at 4 months, *n*=484 at 6 months, and *n*=407 at 12 months). Results showed that Verbal reassurance was positively associated with infant distress across all four ages. Emotional Availability was only negatively related to verbal reassurance at 12 months of age. Emotional Availability was not a significant moderator at any age. Findings demonstrated consistent but small relationships between verbal reassurance and infant pain over the first year of life.

Dustin P. Wallace.et.al, (2010) conducted a randomized controlled unblended study on the effect of a "cough trick" technique on self-reported pain of children receiving routine immunizations. 68 children of prekindergarten (ages 4 –5) or pre–junior high school (ages 11–13) were selected as sample. A single "warm-up" cough of moderate force, followed by a second cough that coincided with needle puncture was given then assesses the pain level by Visual Analogue Scale. The result suggest that the strategy was acceptable, effective, and worth doing (*t*40 _ 3.5; *P* _ .001). Finally, of the 11 nurses who rated their satisfaction with the cough trick, 10 thought that the strategy was both acceptable and effective.

Chambers.CT.et.al., (2009) conducted a systemic review on randomized controlled trials and quasi randomized controlled trials on effect of Psychological interventions for reducing pain and distress during routine childhood immunizations. Twenty Randomised controlled trials involving 1380 infants and children (1 month to 11 years of age) were included in the systematic review. MEDLINE, PsycINFO, EMBASE, CINAHL, and the Cochrane Central Register of Controlled Trials databases were searched. They examined the efficacy of 7 psychological

interventions: (1) breathing exercises; (2) suggestion; (3) child-directed distraction; (4) parent-led distraction; (5) nurse-led distraction; (6) parent coaching; and (7) combined cognitive-behavioural interventions. Result revealed that Breathing exercises were effective in reducing children's self-reported pain (standardized mean difference [SMD], -0.43; P = 0.01) No evidence was found to support suggestion as a psychological intervention for reducing pain associated with paediatric immunization. Child-directed distraction was effective in reducing self-reported pain (SMD, -0.28; P = 0.03). Parent-led distraction was effective in reducing observer-rated distress (SMD, -0.50; P = 0.002), but not other measures of pain or distress. Nurse-led distraction was effective in reducing distress ratings as assessed by the observer (SMD, -0.40; P = 0.005). Combined cognitive-behavioural interventions were effective in reducing children's self-reported pain (SMD, -0.75; P < 0.001).

Lindsay S. Uman, Christine.T. Chambers, Patrick J. McGrath and Stephen Kisely, (2008) conducted a Randomized Controlled Trial on Psychological Interventions for Needle-related Procedural Pain and Distress in Children and Adolescents. The trials included 1,039 participants in treatment conditions and 951 in control conditions. A variety of cognitive-behavioural psychological interventions were given to the trials. The Outcome measures included pain and distress as assessed by self-report, observer report, behavioural/observational measures, and physiological measures. Result shown the largest effect sizes for treatment improvement over control conditions were found for distraction, combined cognitive-behavioural interventions, and hypnosis, with promising but limited evidence for several other psychological interventions.

Patricia.J.Gousie. (2007) conducted a study on The Effects of Live Music on the Distress of Paediatric Patients Receiving Injections. An experimental group of 19 paediatric patients ranging from age 2 to 10 years were randomly selected to receive music therapy during their injections. The experimental group was then compared to a control group of 16 paediatric patients' ages 2 to 10 years who did not receive music therapy. Results implied that with the music the two, four, six, seven, eight, and ten-year-old demonstrated that they were get less behavioural stress during the injection. The three and ten year olds showed no changes and five-year-olds that represent 9 percent of the total subjects, demonstrated to have more distress with the music.

Sparks, L. (2003) conducted a quasi experimental study on compared the effect of two forms of distraction on injection pain in a convenience sample of preschool children. 105 children (53 girls and 52 boys) ages 4 to 6 years needing DiptheriaPertusis Tetanus (DPT) immunizations were selected for the study. Study children were randomly assigned to receive one of three treatments with their DTP injection: touch, bubble-blowing, or standard care. Prior to injection, a measure of medical fear was obtained (Child Medical Fear Scale) and pain was measured through use of the Oucher Scale. Result showed that both forms of distraction touch and bubble-blowing, significantly reduced pain perception. There were no interaction effects of either age or gender.

Cassidy.KL.et al., (2002) conducted a study to evaluate the effectiveness of audiovisual distraction compared with a blank TV screen in the reduction of pain associated with intramuscular immunization. Five-year-old children (N = 62), undergoing diphtheria, polio, tetanus, and pertussis immunization were selected as samples. Intervention is an age-appropriate musical cartoon or a blank TV screen

Subjects were randomly assigned to watch television (TV) (N = 29) or a blank TV screen (control) (N = 33) during immunization, and were videotaped. Immediately after the injection, the children rated their pain. The result showed that there were no significant group differences for any pain or distraction measures. The relative risk estimate for clinically significant pain among the distraction group was 0.64 (range: 0.23-1.80). Higher levels measures of distraction (i.e., greater time looking at the TV screen) related to lower levels of pain on all three pain

French, GM., Painter, EC., and Coury, DL. (1994) conducted a randomized unblended controlled study on the effect of an active distraction technique on pain in preschool children receiving Diphtheria, Pertussis, and Tetanus immunization. One hundred forty-nine children were selected for the study. The intervention is Children were taught to blow out air repeatedly during the injection, as if they were blowing bubbles. The result suggest that Children who were taught to blow out air during their shots had significantly fewer pain behaviors ($P < .04$) and demonstrated a trend toward lower subjectively reported pain ($P = .06$). There was no significant difference in the nurse or parent visual analog scale scores.

2.4 Literature related to pain response on ice application prior to intramuscular immunization.

Children's Hospital of Eastern Ontario (2008) conducted a Quasi- experimental study was undertaken to determine the effect of local refrigeration prior to venipuncture on pain related response in infants. The sample size was 80 infants. Two groups were chosen for the study: the test and control group, in order to test the effect of local coldness in reducing the pain of venipuncture. Physiological

responses (i.e., Blood pressure, pulse, and respiration), behavioral responses (using the Children's Hospital of Eastern Ontario Pain Scale: CHEOPS) were assessed. Result showed no significant difference between the two groups for physiological response (before and after procedure). However behavioral response during and after the procedure (P=0.0011), and subjective responses after the procedure (P=0.0097) where significantly lower (i.e., the test group had lower scores in behavioral and subjective response compared to the control group. The results of this study suggest that the use of local refrigeration prior to venipuncture can be considered an easy and effective intervention of reducing venipuncture related pain.

Trobe University, Australia(2008) conducted a study and aimed to assess whether there was any change in pain associated with an injection into the hallux, if the site of injection was first refrigerated using ice. Twenty participants each received two injections of lignocaine into the hallux. Prior to each injection, participants were randomized to receive either no-ice or a six-minute application of ice over the injection site. The pain outcome was measured on a visual analogue pain scale. The application of ice significantly reduced needle-stick pain, with the median scores for the no-ice and ice injections being 57 and 16 mm, respectively ($P < 0.001$). Nevertheless, 16 out of 20 participants preferred ice prior to the injection. Only four indicated no preference and none indicated a preference for no-ice. Therefore icing the digit prior to injection is an effective and inexpensive method to reduce the discomfort of a local anesthetic injection.

Local hospital, Toronto (2008)conducted a randomized controlled trial was done to determine the effects of ice application on pain relief in children of age group 1-4 years undergoing vaccine injections during the year 2008. Data

were collected from 40 children attending an immunization clinic in a local hospital, Toronto. The subjects included 20 intervention group members and 20 control group members. Ice or cold packs was applied to the intervention group members on the injection site immediately before the procedure (within 1 minute of injection). Pain was measured with a numeric rating scale and measuring vital signs. Children who were provided with ice application had a lower degree of discomfort than children who were not provided with this intervention ($p<0.01$).

Scott Halperin.MD.et.al, (2011) Among children undergoing vaccination, does (1) applicationof a vapocoolant spray or (2) application of ice or a cool/cold pack on the skin before injection of vaccine reduce pain at the time of injection? Background and evidence Vapocoolants: Vapocoolants (skin refrigerants) contain chemicals that produce an instantaneous cooling effect upon contact with the skin. The coldness may, in turn, reduce the sensation of pain during the vaccine injections. Four RCTs82–85 included in the systematic review10 examinedthe use of vapocoolants in 247 infants and children. In three of the RCTs,82,83,85 the effect of a vapocoolant was compared with that of a placebo spray. A meta-analysis of data from two of these RCTs (100 children aged four to six years)82,83 showed a beneficial effect on self-reported pain. Inthe third RCT, which involved 60 infants aged two to sixmonths, there was no difference in the pain associated withvaccine injection.85 In two RCTs that compared vapocoolantspray with typical care (no spray or typical care by the nurse),there was no difference between groups,83,84 although in theabsence of a placebo group, positive results would beexpected. This result reinforced the overall findings.Ice or cool/cold packs: Applying ice or cool/cold packs tothe skin produces a cooling sensation that may reduce thesensation of pain during vaccine injections.

Cool/cold packsare readily available and inexpensive. However, two RCTsinvolving 78 children aged 4 to 18 years86, 87 that were includedin the systematic review10 showed that ice had benefit.On the basis of the results of the systematic reviews,10,12 weconcluded that there was sufficient evidence to recommendfor or against skin-cooling techniques (i.e., vasocoolents, ice,cool/cold packs) to reduce pain in children undergoing vaccineinjections. The evidence for vasocoolents contrasts withthe results of two studies performed in adults undergoing vaccineinjections.48,88 It is possible that children, especiallyyoung children (up to three years old) may perceive coldness, or the cold may cause them to focus their attention on the procedure with lesser pain.

PART - B

2.5 CONCEPTUAL FRAMEWORK

The conceptual framework provides a conceptual perspective regarding the interrelating phenomena. It deals with abstractions (concepts) that are assembled by virtue of their relevance to a common theme. Conceptual models are useful in the research process in clarifying concepts and their associations, in enabling researchers to place a specific problem into appropriate context.

This study was based on the concept of ice application prior to intramuscular immunization, reduces the pain level during intramuscular immunization among the under five children attending immunization clinic. The investigator adopted a Widenbach's prescriptive theory (1969) as the foundation for developing the conceptual framework.

Widenbach's theory is made up of three factors as follows:

- The central purpose
- Prescription
- Realities

Central purpose:

The nurse's central purpose defines that quality of health she desires to effect and she recognizes to be her special responsibility in caring for the patient. In this study the central purpose is to assess the effectiveness of ice application prior to immunization on pain responses among under five children during intramuscular immunization, attending the immunization clinic.

Prescriptions:

Once the nurse identified needs of the patient, she develops a prescription or plan of care. In this study, the investigator planned to provide a ice application prior to immunization for experimental group.

Realities:

The realities are:

- Agent
- Recipient
- Goal
- Framework

THE CONCEPTUAL FRAMEWORK OF THIS NURSING THEORY CONSISTS OF FOLLOWING STEPS

1) Identification of the patients need for help
2) Ministration of the help needed
3) Validation that the action taken was helpful to patient

Identification:

The nurse identifies the patient need. In this study the need was pain during intramuscular injection among the under five children.

Ministration:

Ministering to the patient, the nurses apply a comfort measure, or therapeutic procedure.

Ministration had two components:

Prescription:

The nurse provides care to the patient .Ice application prior to intramuscular immunization was given for the under five children with experimental group. Usual standard technique was given for the control group. The procedure of ice application means ice pack was applied prior to intramuscular immunization in the immunization site for 30 seconds. Usual standard technique was given for control group.

Realities:

Agent : It means who is the practising nurse. In this study the researcher is the agent.

Recipient : The patient's are the recipients of the nurse's action. In this study the under five children were the recipients.

Goal : The goal is the desired outcome the nurse wishes to achieve. In this study the goal is to reduce the pain level of under five children.

Framework : Framework consists of human, environmental, professional and organization facilities. In this study the framework is immunization clinic.

Validation:

After help has been ministered the nurse validates that the actions were indeed helpful. Here the investigator validate by means of post test assessment of pain level measured by FLACC (Face, Legs, Activity, Cry, Consolaility) pain scale both in experimental and control group. The experimental group had relaxed position, relaxed facial expression after ice pack application prior to immunization.. The control group had crying, tensed muscle, stiff joints, and difficult to console.

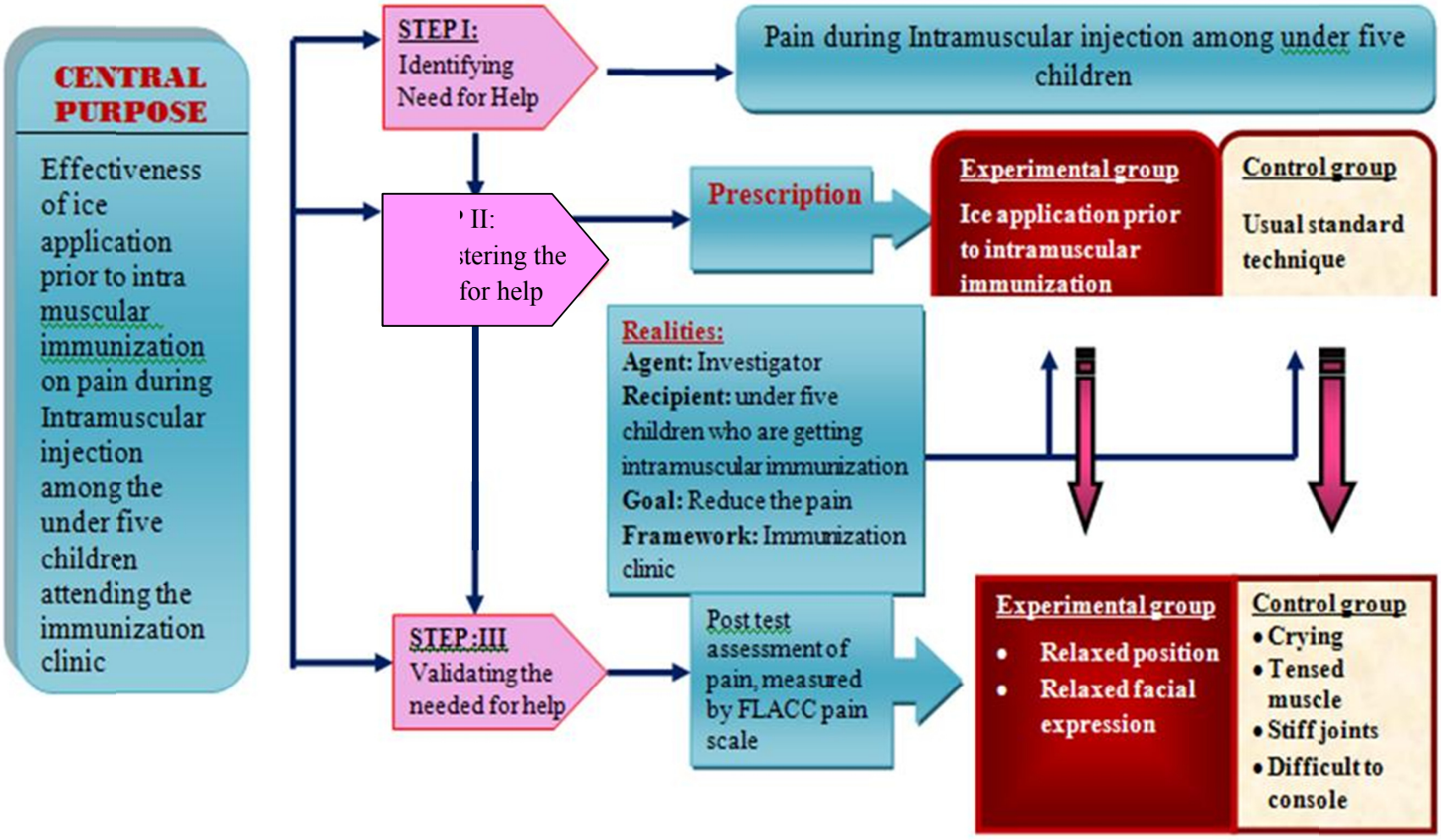


Fig: 1 MODIFIED WIDENBACH'S PRESCRIPTIVE THEORY (1969)

Methodology

CHAPTER - III

METHODOLOGY

This chapter includes research approach, research design, variables, setting, population, sample and sample size, sampling technique, development of the tool, content validity, pilot study, data collection procedure, plan for data analysis, and ethical consideration.

3.1 RESEARCH APPROACH

Quantitative approach was used for the study to evaluate the effectiveness of ice application prior to intramuscular immunization on pain response during intramuscular immunization among under five children, attending immunization clinic of the pediatric outpatient department, Institute of Child Health and Research Centre, Government Rajaji Hospital, Madurai.

3.2 RESEARCH DESIGN

The research design selected for the present study was True Experimental Study – Post test only Design adapted. A true experiment involves Randomization, control and manupulation. The study intended to evaluate the effectiveness of ice application prior to intramuscular immunization on pain response among the under five children attending immunization clinic of the pediatric outpatient department, Institute of Child Health and Research Centre, Government Rajaji Hospital, Madurai.

	GROUP	INTERVENTION	POST TEST
R	Experimental group	X	O1
	Control group	-	O1

R - Randomization

O1 - Post test for both experimental group and control group

X - Intervention to experimental group

(Ice Application Prior to intramuscular Immunization)

3.3 VARIABLES

Variables included in the study were

Independent Variable **:** Ice application

Dependent Variable **:** Pain Response

Baseline Variables **:** Age of the under five child, Sex, birth order, Literacy level of the care giver, type of family, religion, place of residence,Place of birth, Place of venue of immunization, previous knowledge about pain reduction interventions.

3.4 SETTING OF THE STUDY

This study was conducted in the immunization clinic of the pediatric outpatient department, Institute of Child Health and Research Centre, Government Rajaji Hospital, Madurai. Monthly more than 200 children were receiving immunization from the, pediatric outpatient department. Among them, approximately

more than 100 under five children were receiving pentavalent vaccine, and around 50 children receive DPT Booster vaccines.

3.5 POPULATION

Target population:

Under five children receiving intramuscular injection during immunization.

Accessible population:

Under five children receiving intramuscular injection during immunization in the outpatient department, Institute of Child Health and Research Centre, Government Rajaji Hospital, Madurai.

3.6 SAMPLE SIZE

The total sample size was 60; among these 30 were in experimental group, 30 were in control group.

3.7 SAMPLING CRITERIA

The following were the criteria for selection of samples for the study.

Inclusion criteria

- Children in both sexes male and females of age less than five years.
- Under five children who received Pentavalent vaccine &DPT Vaccine.
- Under five children who were in the age group of less than five years

Exclusion criteria

- Under five children of mothers who were not willing to participate.
- Under five children with neurological deficit and congenital deformities.
- Under five children with fever and other distress during immunization process.

3.8 SAMPLING TECHNIQUE

In this study Probability sampling - Simple Random Sampling Technique was used.

3.9 METHOD OF SAMPLE SELECTION

The samples were selected those who were arrive at the inclusion criteria. Simple random sampling technique was used with non-replacement method. The odd and even numbers were given to the samples. From this with the use of lottery method, the odd numbers were considered as control group and even numbers were considered as experimental group.

3.10 RESEARCH TOOL

The tool was developed after extensive review of literature, internet sources and discussion with experts.

3.10.1 DESCRIPTION OF THE TOOL

The tool consists of following two sections;

Section - I:

It consists of 10 items seeking information about Age, Sex Age of the under five child, Sex, birth order, Literacy level of the care giver, type of family, religion, place of residence, Place of birth, Place of venue of immunization, previous knowledge about pain reduction interventions.

Section II:

FLACC pain scale: (Face, Legs, Activity, Cry, Consolobility) standardized scale cum observation checklist.Sandra Merkel, MS, RN, Terri Voepel-Lewis, MS, RN, and ShobhaMalviya, MD, (2003) at S. Mott Children's Hospital, University of Michigan Health System, developed the FLACC scale

3.10.2 SCORING PROCEDURE

The minimum obtainable score for each category of pain response was zero and maximum score 2. The total of maximum pain score was 10**.**

SCORE INTERPRETATION

Based on the score the pain response is graded as follows;

SCORE CATEGORIES

SCORE	-	**INTERPRETATION**
0	-	No pain
1-3	-	Mild pain
4-6	-	Moderate pain
7-10	-	Severe pain

3.11 TESTING OF THE TOOL

VALIDITY

The study was validated by 3 nursing experts, and two medical experts; The Director in-charge of the Institute and Research Centre of Pediatrics and Pediatric Surgeon Suggestions were considered. The nursing experts and the medical expert's consensus, and then the tool were finalized.

RELIABILITY

The reliability of the tool was tested using Crohnbach's Alpha method with a sample size of 10 samples, 5 samples in each experimental and control group. The internal consistency reliability coefficients for FLACC (Face, Legs, activity, Cry, Consolability) pain scale were found to be high, with Crohnbach's alpha value r = 0.75.

$$\alpha = \frac{N \cdot \bar{c}}{\bar{v} + (N-1) \cdot \bar{c}}$$

Here N is equal to the number of items, c-bar is the average inter-item covariance among the items and v-bar equals the average variance.

Hence, the tool was considered highly reliable for proceeding with the main study.

3.12 ETHICAL CONSIDERATION

A formal permission was obtained from The Director of the Institute and Research centre of Pediatrics, Government Rajaji Hospital, Madurai. Ethical consideration was acquired from the Ethical committee, Madurai Medical College,

Madurai. Information was given to all the subjects' mothers about purpose of the study. Written informed consent was obtained from the subjects' Mothers. Subjects have had the complete freedom to withdraw the study to their reason. No physical or psychological discomfort was made to the samples.

3.13 PILOT STUDY

A formal permission was obtained from The Director of the Institute of Child health and Research centre, Madurai to conduct the pilot study. Pilot study was conducted at the immunization clinic of the Pediatric outpatient department. The pilot study was conducted by the investigator from 16.09.2013 to 21.09.2013 A brief self introduction was given by the investigated to the mothers. The purpose of the study explained to the mother and consent got from the Mothers. 10 Under five children were selected, those who are coming under the inclusion criteria with the use of Simple Random Sampling technique. Lottery method was used and five under five children for each control and experimental group was selected.

Interview method was used to collect the baseline variables. Usual standard technique was given to the control group. Then the investigator assessed the pain score with the use of FLACC (Face, Legs, Activity, Cry, and Consolobility) pain scale. For the experimental group first the site of injection was selected. Frozen Ice pack covered with a lint piece cloth was applied over the lateral part of the thigh for 30seconds prior to the intramuscular immunization. Then the child was immunized. The investigator assessed the pain score for the experimental group with the use of FLACC (Face, Legs, Activity, Cry, and Consolobility) pain scale. For the control group the child was immunized and assessed to the pain score.

3.13.1 FINDINGS OF THE PILOT STUDY

Pilot study suggests that in control group 80% of the under five children had severe pain during immunization, 20% of under five children had moderate pain and majority of the under five children in experimental group 80% had moderate pain, 20% had mild pain during immunization. Finding of the pilot study revealed that the sample were ample enough for the main study; Tool was adequate; Study was feasible and practicable to conduct the main study in the immunization clinic of the outpatient department, Institute of Child Health and Research Centre, Government Rajaji Hospital, Madurai.

3.14 DATA COLLECTION PROCEDURE

The main study was conducted from 1.10.2013 to 15.11.2013. The formal permission was obtained from the Director, Institute of Child Health and Research Centre, Government Rajaji Hospital Madurai. A brief self-introduction was given to the mothers. In the immunization clinic, the samples were selected as those who satisfied the inclusion criteria. With the use of lottery method, the samples were chosen. Odd and even numbers were given to the samples. The odd numbers were considered as control group and even numbers were considered as experimental group. The purpose of the study was explained to the mother and assured of confidentiality of the data collected. Both verbal and written consent was obtained from the mother. Interview method was used to collect the base line variables. The investigator was given usual standard technique for the control group whereas; ice pack application was given for 30 seconds for the experimental group prior to the immunization. Followed by, pain score measured by FLACC (Face, Legs, Activity, Cry, and Consolability) pain scale.

Immunization was given every day in the immunization clinic, pediatric outpatient department, Institute of Child Health and Research Centre, Government Rajaji Hospital, Madurai and each day samples were collected as per the children attending the immunization clinic. The samples were selected as experimental and control groups by lottery method. Baseline variables were collected by interview method. Ice pack application was given for the experimental group. The investigator selected the injection site (antero- lateral aspect of mid thigh) and applied ice pack covered with a lint piece cloth, for 30 seconds prior to immunization which interrupts the pain spasms causing numbness and reduces the pain. According to the age of the child Pentavalent vaccine or DPT vaccine was administered. Ice pack covered with a lint piece was placed in the anterolateral aspect of the thigh for 30 seconds. Followed by, the pain score was measured by FLACC (Face, Legs, Activity, Cry, Consolablity) pain scale. Usual standard technique was given for the control group. The appropriate injection site (antero- lateral aspect of midthigh) was selected. According to the age either Pentavalent vaccine or DPT vaccine was administered. Subsequently, pain level was measured by FLACC (Face, Legs, Activity, Cry, Consolablity) Pain scale.

Each day around 12-14 children attended the immunization clinic for immunization. Among them 10-12 children come exclusively for intramuscular immunization. Lottery method was used and Odd and even numbers were given to the children and the samples were selected.For the experimental group ice application for 30 seconds prior to intramuscular immunization for the under five children. The pain scale was assessed using FLACC Pain Scale.

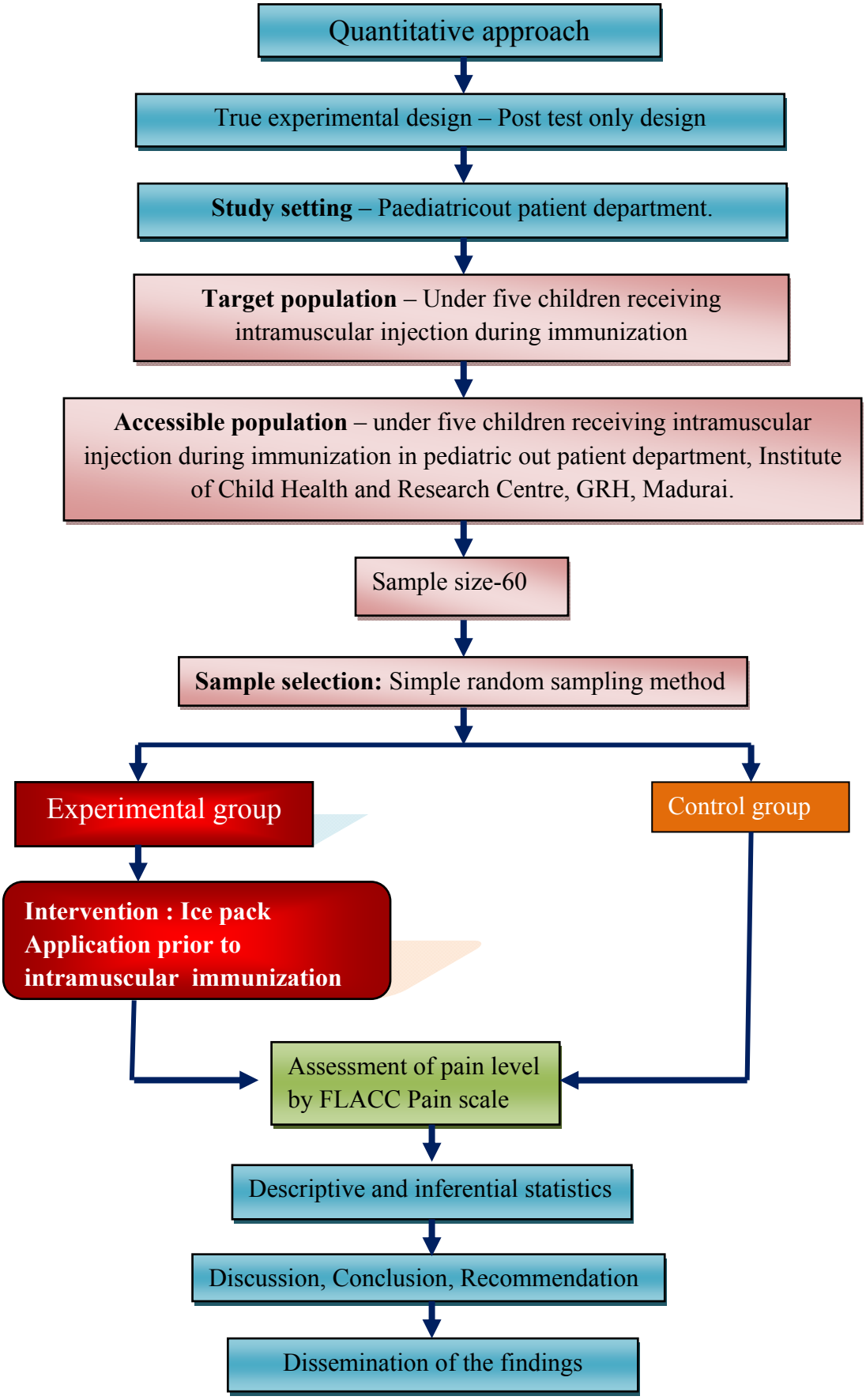
3.15 PLAN FOR DATA ANALYSIS

Data were analyzed using both descriptive and inferential statistics. Tests used in this study were frequency and percentage distribution, standard deviation, mean, Chi square test, and Paired‘t’ test. Base line variables were analyzed by frequency and percentage distribution. Mean, Standard deviation were used to analyze the pain level of under five children both in experimental and in the control group. Paired‘t’ test was used to evaluate the effectiveness of ice pack application prior to immunization on intramuscular injection pain. Chi square test was used to find the association between the pain level of under five children in experimental group and base line variables.

3.16 PROTECTION OF HUMAN RIGHTS

The proposed study was conducted after the approval of dissertation committee of College of nursing, Madurai medical college, Madurai. In order to protect the human approval obtained from the ethical committee during the month of September 2013 from the Ethical Committee, Madurai medical college, Madurai. In addition the permission was obtained from, Director, Institute of Child Health and Research Centre, Government Rajaji Hospital Madurai. Both verbal and written consent was obtained from all the study subjects and the data collection was kept confidential. The possible benefit of participating in the study was explained to all the subjects. Reassurance was given to the study subjects, that confidentiality and privacy was maintained throughout the study.

3.17 SCHEMATIC REPRESENTATION OF RESEARCH STUDY



Data Analysis And Interpretation

CHAPTER - IV

DATA ANALYSIS AND INTERPRETATION

Analysis is the process of organizing and synthesizing the data so as to answer research questions and test hypothesis. (Suresh K. Sharma).

This chapter deals with the analysis and interpretation of data collected from the 60 under five children those who were undergoing intramuscular injection during immunization. The data have been analyzed and presented under the following headings.

SECTION: A

Base line characteristics of the experimental and control group

This analysis has been done to find out the frequency and percentage distribution of demographic variables such as Age, Sex, birth order, Literacy level of the care giver, type of family, religion, place of residence, Place of birth, Place of venue of immunization, previous knowledge about pain reduction interventions. in experimental and control group.

SECTION: B

Assessment of pain level of under five children during Intramuscular immunization with usual standard technique and application of ice pack prior to immunization.

Pain has been analyzed in four degrees (No pain, Mild pain, Moderate pain, severe pain) for the experimental and control group during Immunization in frequency and percentage.

SECTION: C

Compare the pain level of under five children receiving intramuscular injection in both experimental and control group.

Comparison of degree of pain in experimental and control group has been done by mean score and its significance by statistical test

SECTION: D

Association between pain levels of under five children among experimental group with selected base line variables

Base line variables of experimental group have been analyzed in association with pain level during intra muscular injection.

SECTION - A

BASE LINE CHARACTERISTICS OF EXPERIMENTAL AND CONTROL GROUP

TABLE 1

Frequency and percentage distribution of Base line variable of under five children in experimental and control group n=60.

S. NO	Demographic Variable	Experimental group		Control group	
		f	%	f	%
1.	Age of the child				
	a. Birth to 12 months	27	90	26	87
	b. 13- 36 months	3	10	3	10
	c. 37- 60 months	0	0	1	3
2.	Sex of the child				
	a. Male	16	53	18	60
	b. Female	14	47	12	40
3.	Type of family				
	a. Nuclear family	15	50	15	50
	b. Joint family	15	50	15	50
	c. Separated family	0	0	0	0
4.	Religion				
	a. Hindu	24	80	24	80
	b. Christian	2	7	6	20
	c. Muslim	4	13	0	0
	d. Others	0	0	0	0
5.	Caregivers literacy level				
	a. Illiterate	3	10	2	7
	b. Primary education	1	3	5	17
	c. High school	11	37	10	33
	d. Higher secondary	3	10	9	30
	e. Graduate and above	12	40	4	13

S. NO	Demographic Variable	Experimental group		Control group	
		f	%	f	%
6.	Birth Order				
	a. First Child	21	70	18	60
	b. Second Child	7	23	10	33
	c. Third and above	2	7	2	7
7.	Place of Residence				
	a. Urban	23	77	20	67
	b. Rural	7	23	10	33
	c. Semi urban	0	0	0	0
8.	Place of Birth				
	a. Health sub centre	0	0	0	0
	b. Primary Health Centre	0	0	0	0
	c. Government Hospital	24	80	24	80
	d. Private Hospital	6	20	6	20
9.	Place of previous venue of immunization				
	a. Health sub centre	0	0	0	0
	b. Primary health centre	0	0	0	0
	c. Government Hospital	26	87	28	93
	d. Private Hospital	4	13	2	7
10.	Previous Knowledge about pain reduction intervention				
	a. Yes	0	0	0	0
	b. No	30	100	30	100

The above table represent that, the age group among experimental group were 27(90%) in the age group of birth to 12 months, 3(10%) were in the age group of 13-36 months, and between 37-60 months there were no children. In control group 26(87%) were in the age group of birth to 12 months,3(10%) were in the age group of13 to 36 months, 1(3%) were in the age group of 37-60 months.

With the view of sex among the experimental group16 (53%) were male children and 14(47%) were female children. In the control group 18(60%) were male children and12 (40%) were female children.

With regard to the type of family among theexperimental group half of them 15(50%) were from nuclear family and the rest of15 (50%) were from joint family, and none were from the separated family. In the control group also half of them 15(50%) were from nuclear family and the rest of15 (50%) were from joint family, and none were from the separated families.

In respect to religion among the experimental group 24(80%) were Hindus, 2 (7%) were Christians,4(13%) were Muslims, and none from the other community. In the control group 24(80%) were hindus,6(20%) were Christians, and none were from Muslims and other community.

In the aspect of caregivers literacy level among the experimental group 3(10%) were illiterates, 1(3%) had primary school education, 11(37%) had high school education, 3(10%) were among higher secondary, 12(40%) were among graduates and above. In the control group 2(7%) were illiterates,5(17%) had primary school education,10(33%) had high school education, 9(30%) were among higher secondary, 4(13%) were among graduates and above.

Based on the birth order, In the experimental group 21(70%) were the first child,7(23%)were second child,2(7%) were from third and above. In the control group 18(60%) were the first child, 10(33%) were second child, 2(7%) were from third and above.

In respect to the place of residence among the experimental group, 23(77%) were urban residence, 7(23%) rural residence, and none from semi urban. In the control group20 (67%) were urban residence, 10(33%) rural residence, and none from semi urban.

In accordance with the place of birth, in the experimental group none were born in the health sub centre nor in the primary health center, 24(80%) at government hospital, 6(20%) from private hospital. In the control group also none were born at the health sub center nor the primary health centre, 24(80%) were born at the government hospital, 6(20%) at the private hospital.

As per the place of previous venue of immunization in the experimental group none were immunized at the health sub centre or the primary health centre, 26(87%) were immunized at the government hospital, 4(13%) at the private hospitals. In the control group also none were immunized at the health sub centre nor the primary health centre, 28(93%) at government hospital, 2(7%) at private hospitals.

According to the Previous Knowledge about pain reduction interventions, both the experimental and the control group had 30(100%) predicted no knowledge about Previous Knowledge about pain reduction intervention.

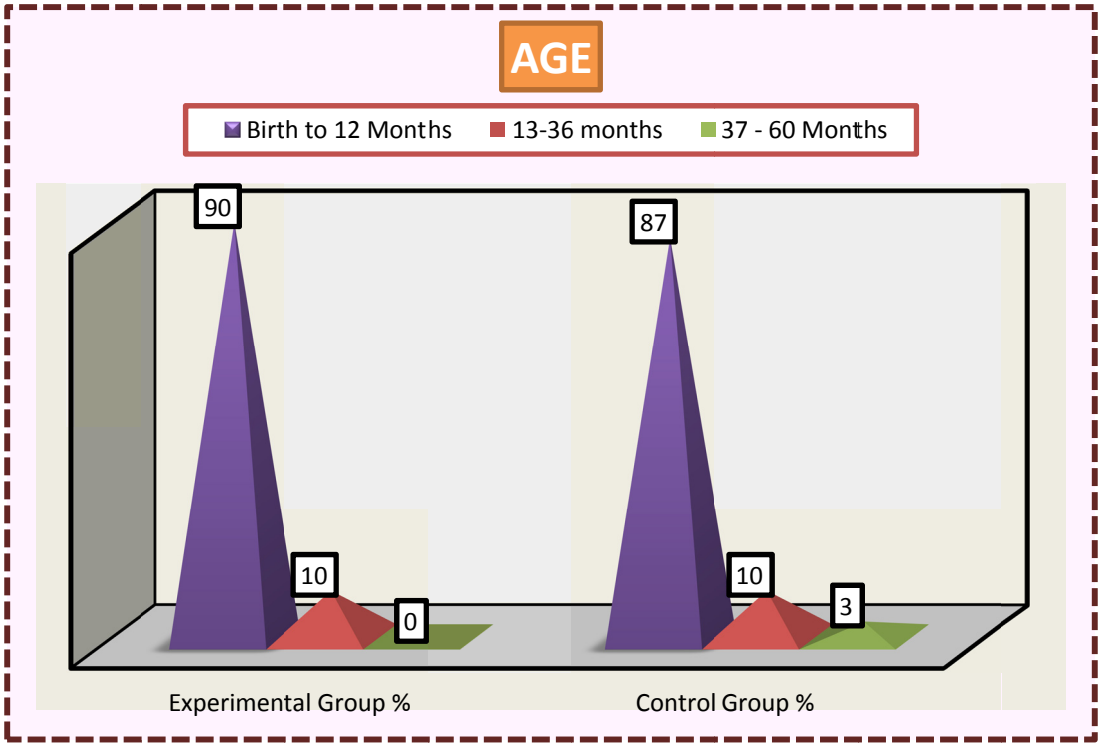


Fig-2.Cluster conical diagram represents the percentage distribution of age among experimental and control group

The age group among experimental group were 27(90%) in the age group of birth to 12 months, 3(10%) were in the age group of 13-36 months, and between 37-60 months there were no children. In control group 26(87%) were in the age group of birth to 12 months,3(10%) were in the age group of13 to 36 months, 1(3%) were in the age group of 37-60 months.

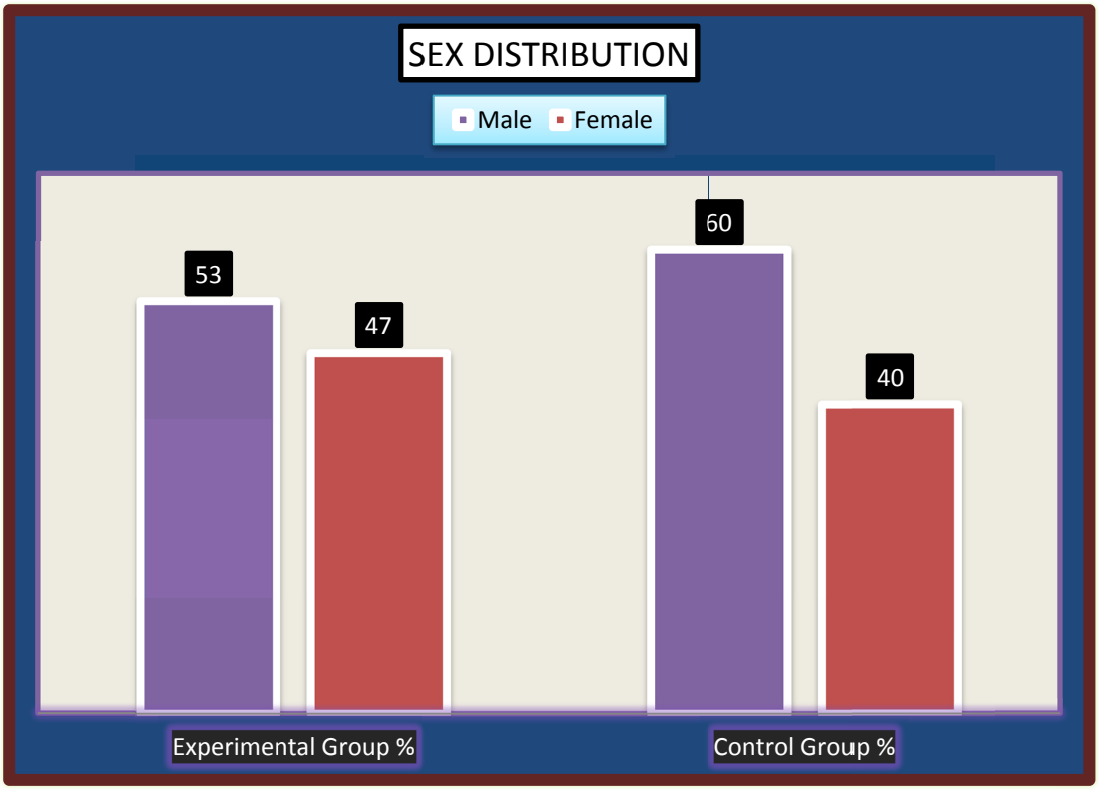


Fig-3Bar diagram shows the percentage. distribution of sex

With the view of sex distribution among the experimental group16 (53%) were male children and 14(47%) were female children. In the control group 18(60%) were male children and12 (40%) were female children.

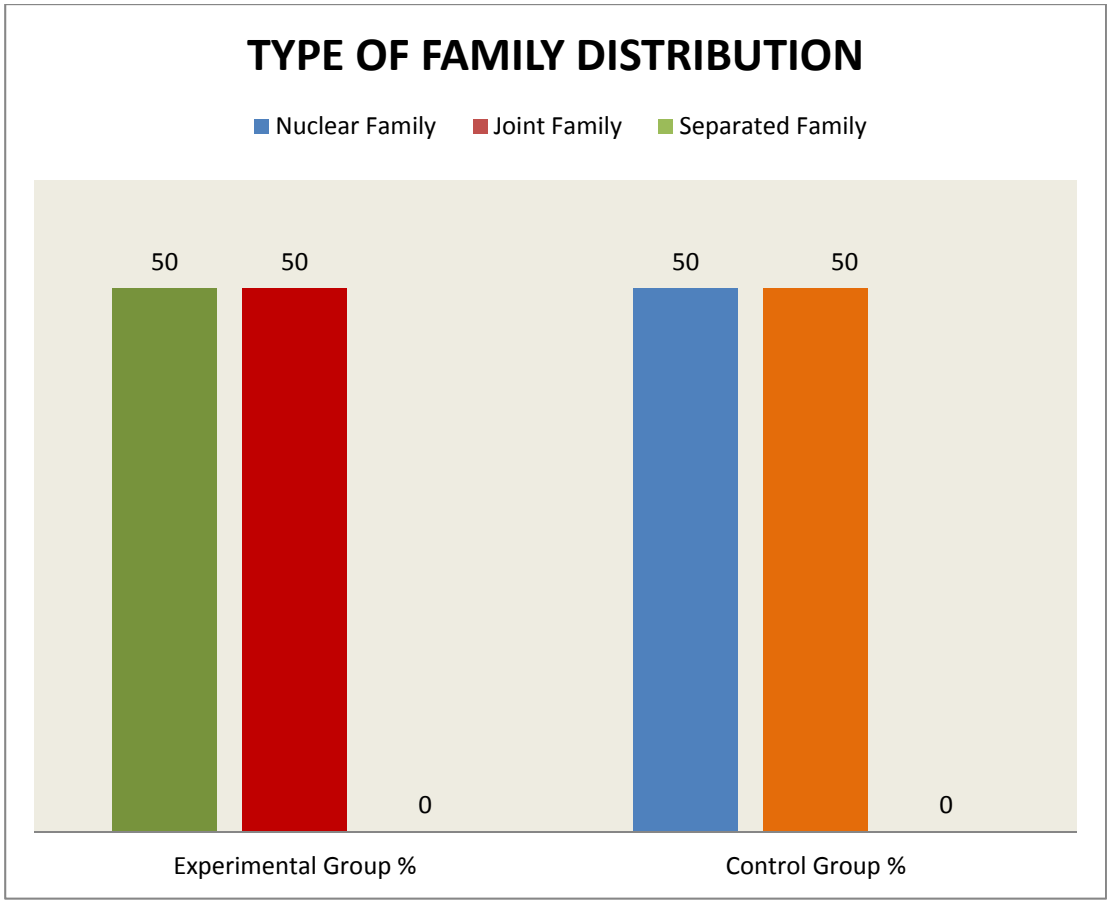


Fig-4 Bar diagram depicts the percentage distribution of type of Family.

With regard to the type of family among theexperimental group half of them 15(50%) were from nuclear family and the rest of15 (50%) were from joint family, and none were from the separated family. In the control group also half of them 15(50%) were from nuclear family and the rest of15 (50%) were from joint family, and none were from the separated families.

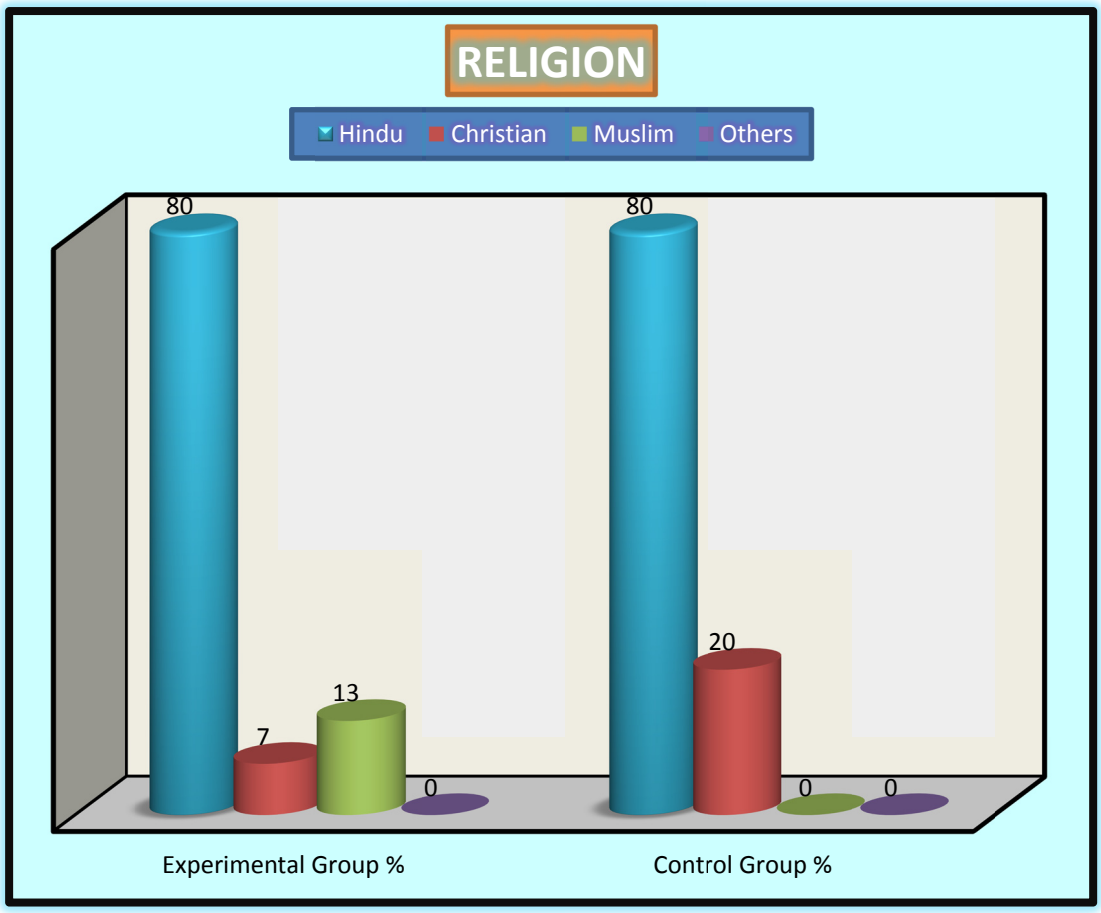


Fig-5 clustered cylindrical diagram represents the percentage distribution of the religion

Religion distribution among the experimental group were, 24(80%) were hindus,2(7%) were Christians,4(13%) were Muslims, and none from the other community. In the control group 24(80%) were Hindus, 6(20%) were Christians, and none were from Muslims and other community.

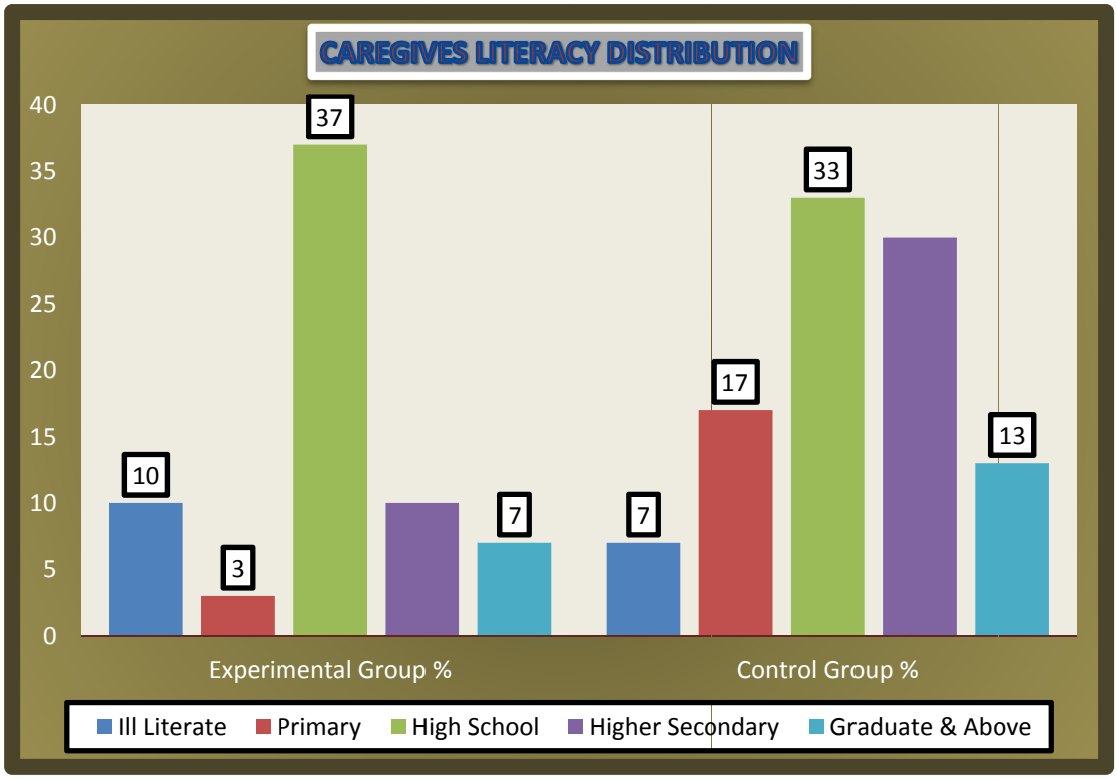


Fig-6 Bar diagram represents the literacy level of the caregivers.

In the aspect of caregivers literacy level among the experimental group 3(10%) hadno formal education, 1(3%) had primary school education, 11(37%) had high school education, 3(10%) were among higher secondary, 12(40%) were among graduates and above. In the control group 2(7%) were illiterates, 5(17%) had primary school education,10(33%) had high school education, 9(30%) were among higher secondary, 4(13%) were among graduates and above.

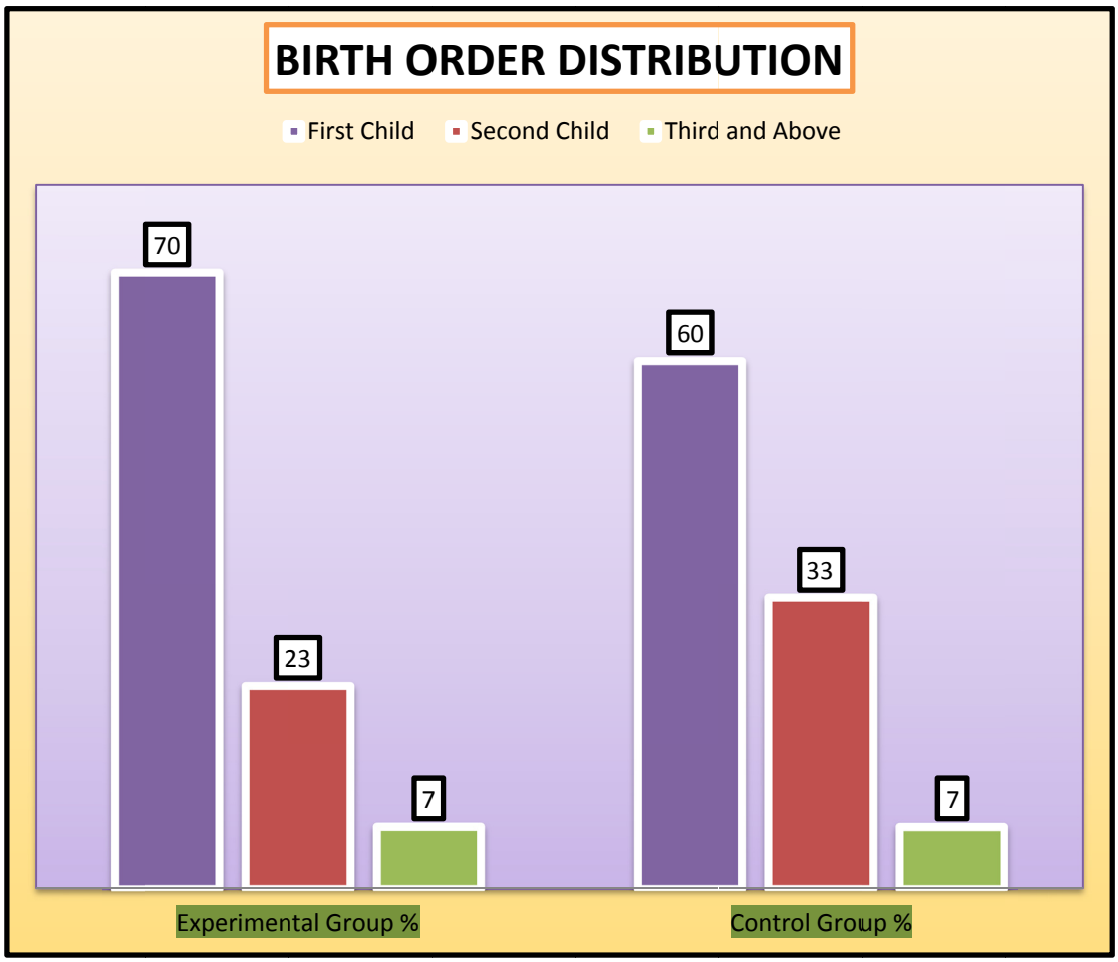


Fig-7 Bar diagram showing the percentage distribution of birth order

Based on the birth order distribution, in the experimental group 21(70%) were the first child, 7(23%) were second child, 2 (7%) were from third and above. In the control group 18(60%) were the first child, 10(33%) were second child, 2(7%) were from third and above.

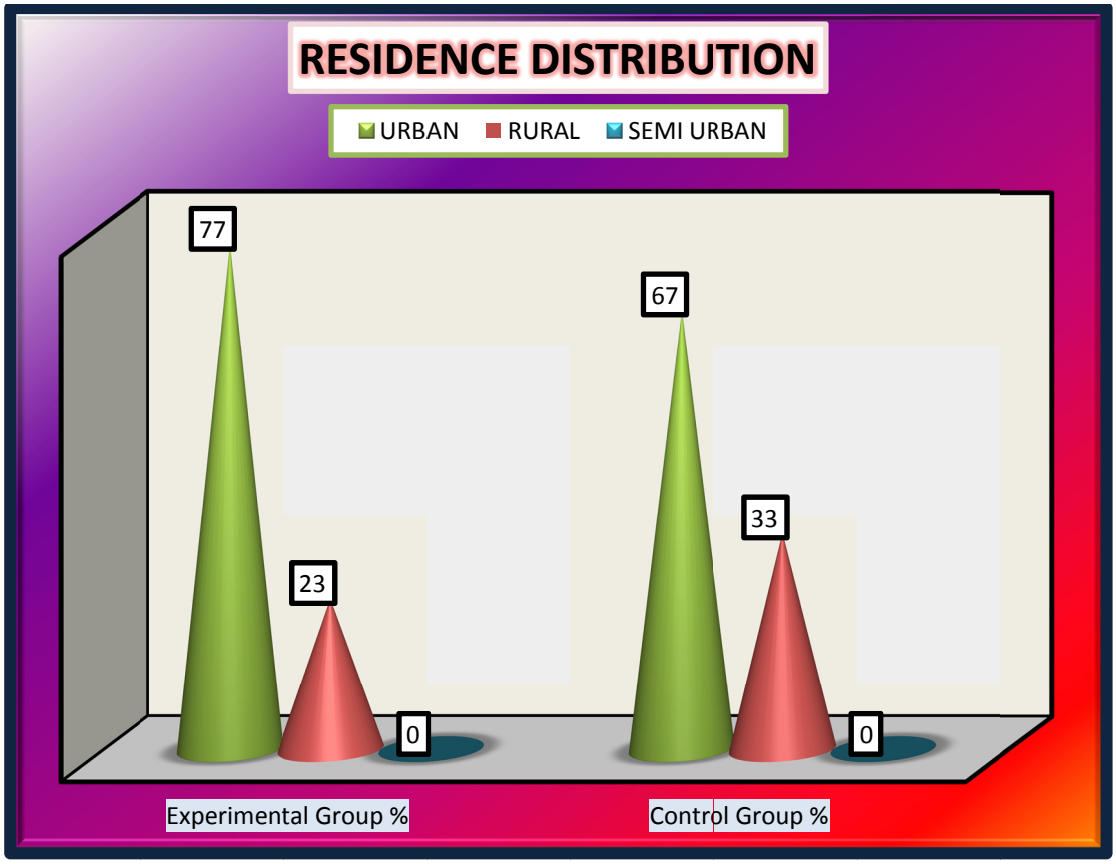


Fig-8 Conical diagram shows the percentage distribution of place of residence

In respect to the place of residence among the experimental group, 23(77%) were urban residence, 7(23%) rural residence, and none from semi urban. In the control group20 (67%) were urban residence, 10(33%) rural residence, and none from semi urban.

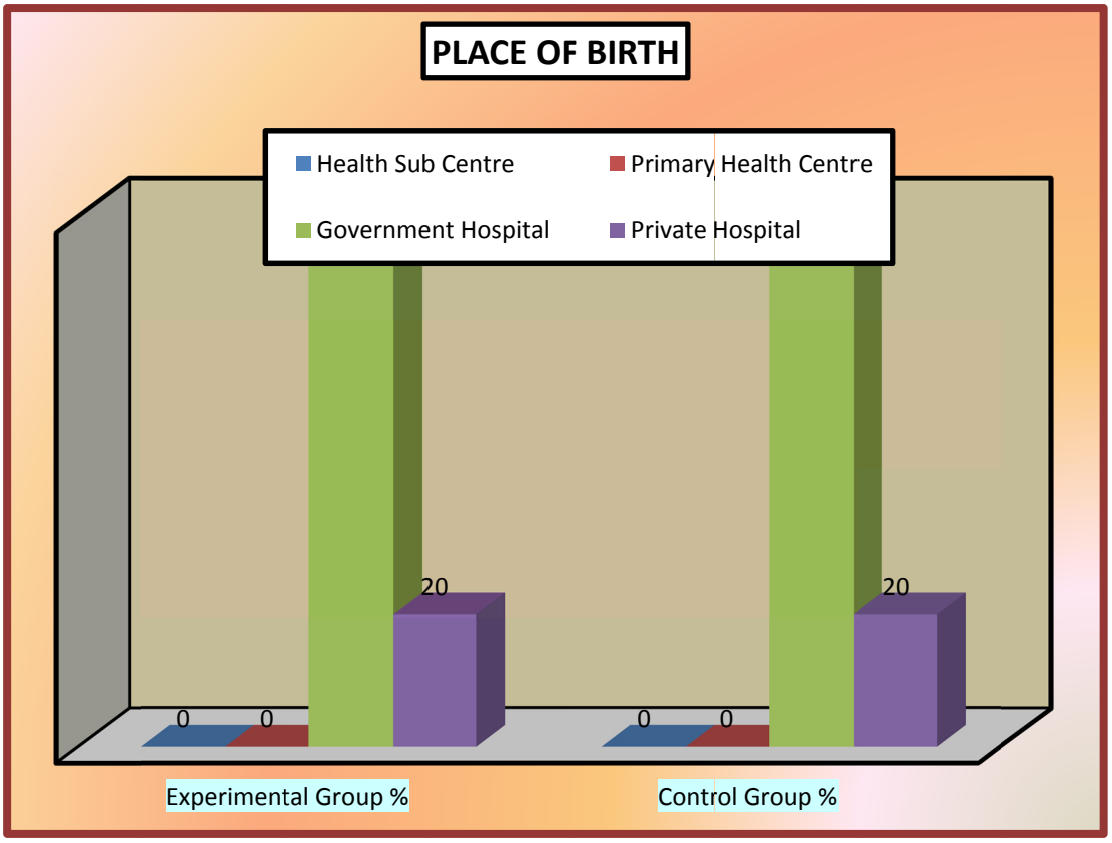


Fig-9 Cluster bar diagram represents the percentage distribution of place of birth

In accordance with the place of birth, in the experimental group none were born in the health sub centre nor in the primary health center, 24(80%) at government hospital, 6(20%) from private hospital. In the control group also none were born at the health sub center nor the primary health centre,24(80%) were born at the government hospital, 6(20%) at the private hospital.

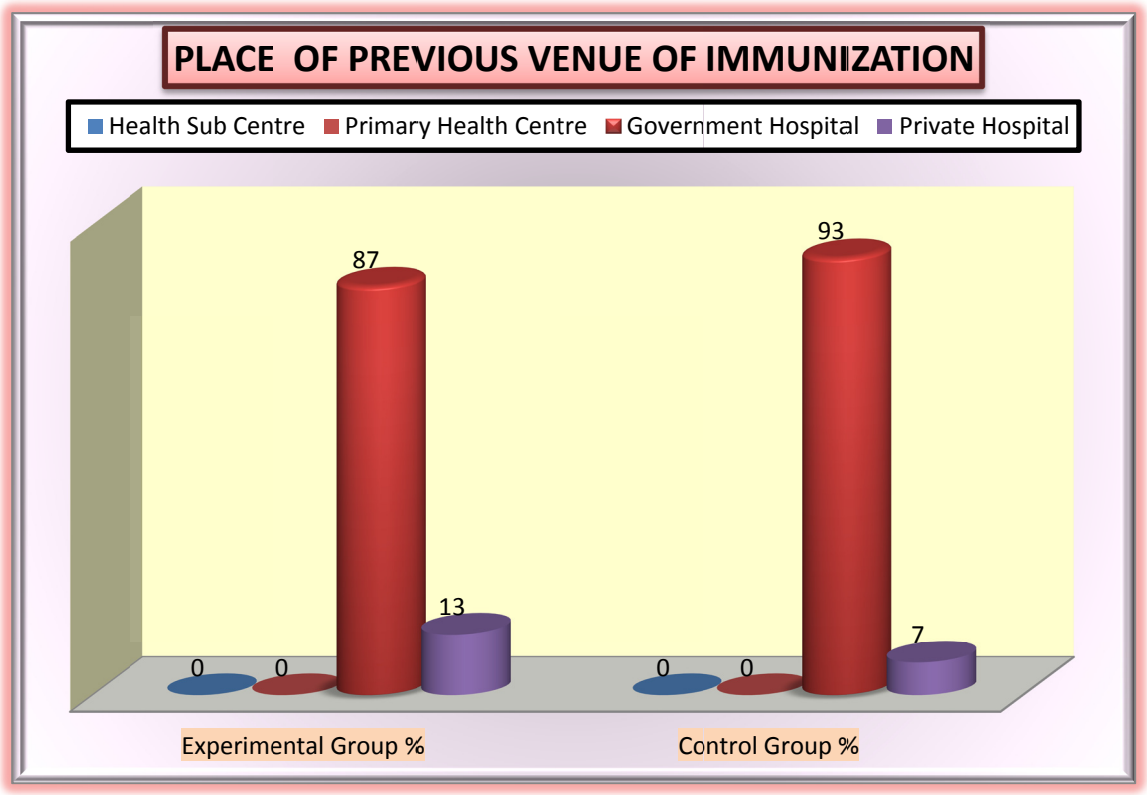


Fig-10 Clustered cylindrical diagram shows the previous venue of immunization

As per the place of previous venue of immunization in the experimental group none were immunized at the health sub centre or the primary health centre, 26(87%) were immunized at the government hospital, 4(13%) at the private hospitals. In the control group also none were immunized at the health sub centre nor the primary health centre, 28(93%) at government hospital, 2(7%) at private hospitals

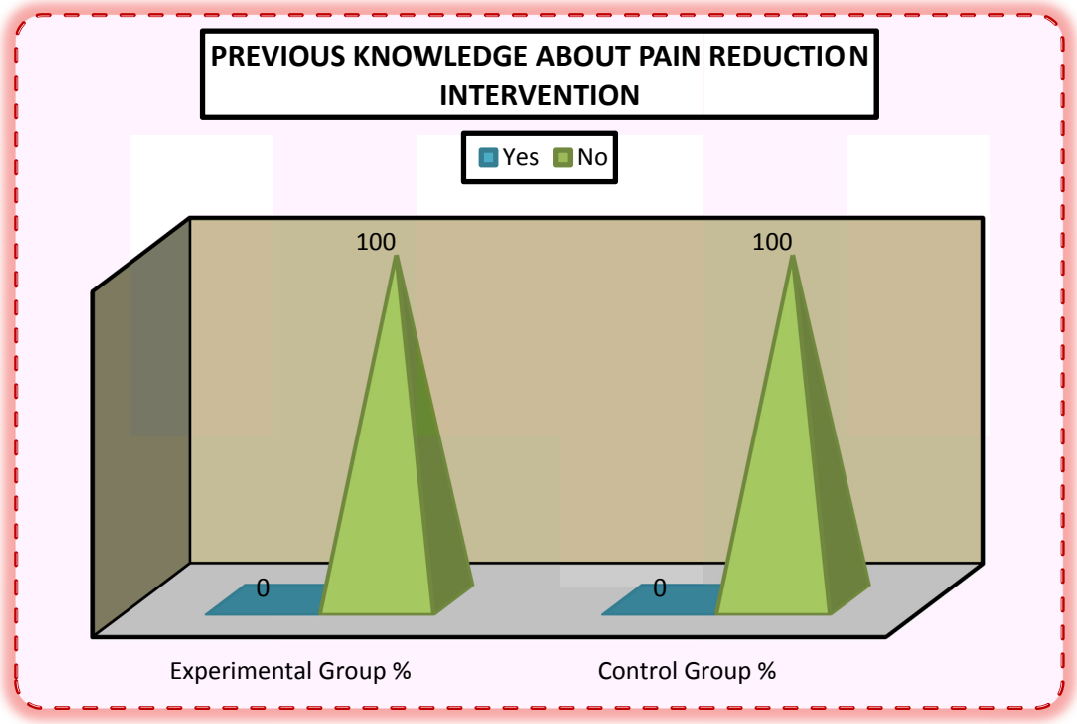


Fig-11 Conical diagram represents the previous knowledge about pain reduction intervention

According to the Previous Knowledge about pain reduction interventions, both the experimental and the control group had 30(100%) predicted no knowledge about Previous pain reduction intervention.

SECTION - B

PAIN LEVEL OF DURING INTRAMUSCULAR INJECTION AMONG EXPERIMENTAL AND CONTROL GROUP

TABLE-2

Frequency and percentage data of under five children receiving intramuscular injection among experimental and control group n=60

LEVEL OF PAIN	EXPERIMENTAL		CONTROL	
	GROUP	n=30	GROUP	n=30
	f	%	f	%
No PAIN	0	0	0	0
Mild Pain	26	87	0	0
Moderate Pain	4	13	5	17
Severe Pain	0	0	25	83

This table represents majority of the under five children 87% (26) had mild pain, 13% (4) had moderate pain during immunization in experimental group. And 83% (25) of the under five children had severe pain while receiving immunization, 17% (5) of under five children had moderate pain in control group.

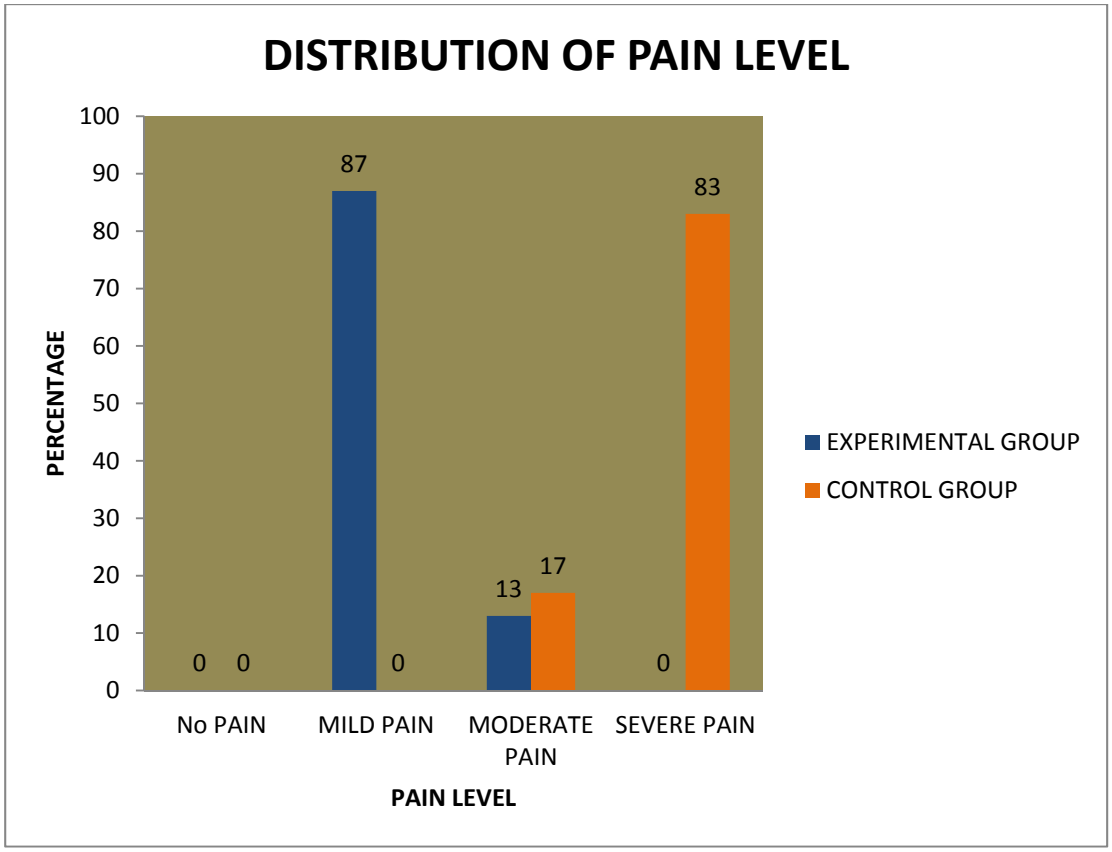


Fig-12 `Clustered bar diagram shows the percentage distribution of pain response

In the distribution of pain level among the experimental group 87% had mild pain and 13% experienced moderate pain during the immunization. On contrast among the control group 83% had severe pain and 17% experienced moderate pain.

TABLE - 3

MEAN PAIN SCORE AND STANDARD DEVIATION OF UNDER FIVE CHILDREN RECEIVING INTRAMUSCULAR INJECTION AMONG EXPERIMENTAL AND CONTROL GROUP

n=60

GROUP	Total score			Effectiveness of mean %
	Mean	SD	Mean%	
Experimental group	3.03	0.89	30	50
Control group	7.97	1.4	80	

The above tableshows thatmean and standard deviation score of under five children with pain level. The mean score of pain level among the experimental group is 3.03 and in the control group is 7.97 whereas thestandard deviation among the experimental group is 0.89, in the control group is 1.4, the mean percentage level in the control group is 80% was higher than the mean percentage 30% in experimental group.

SECTION: C

COMPARISON OF PAIN LEVEL IN EXPERIMENTAL AND CONTROL GROUP.

TABLE - 4

Unpaired "t"-test to assess the effectiveness of ice application prior to immunization

S. No	GROUP	Total score			't' value
		Mean	SD	Mean%	
1.	Experimental group	3.03	0.89	30	15.59 * P< 0.05
2.	Control group	7.97	1.4	80	

*P< 0.05 - significant

The above table represents that mean score of experimental and control group during intramuscular injection. The control group mean (7.97) is higher than the experimental group mean (3.03) of the under five children. The obtained' value is 15.59, significant at p<0.05 level. This concludes that experimental group experienced less pain than control group. Hence, the ice application prior to intramuscular immunization had effect on reducing the pain during intramuscular injection.

SECTION: D

ASSOCIATION BETWEEN PAIN LEVEL OF UNDER FIVE CHILDREN AMONG EXPERIMENTAL GROUP AND SELECTED BASE LINE VARIABLES

TABLE – 5

n=60

VARIABLES		F	P %	Mild		Moderate		Severe		χ	P Value	df
				F	%	F	%	F	%			
Age	Birth to 12 Months	27	90	25	83	2	7	0	0	6.51.	0.003 p<0.05	2
	13 - 36 Months	3	10	1	3	2	7	0	0			
	37 - 60 Months	0	0	0	0	0	0	0	0			
Sex	Male	16	53	13	43.33	3.00	10.00	0.00	0.00	4.05	0.042 p<0.05	1
	Female	14	47	13.00	43.33	1.00	3.33	0.00	0.00			
Type of family distribution	Nuclear Family	15	50	14	47	1	3	0	0	6.39	0.003 p<0.05	2
	Joint Family	15	50	12	40	3	10	0	0			
	Separated Family	0	0	0	0	0	0	0	0			
Relgion	Hindu	24	80	21.00	70.00	3.00	10.00	0.00	0.00	10.37.	.003 p<0.05	4
	Christian	2	7	1.00	3.33	1.00	3.33	0.00	0.00			
	Muslim	4	13	4.00	13.33	0.00	0.00	0.00	0.00			
	Others	0	0	0.00	0.00	0.00	0.00	0.00	0.00			
Caregives literacy distribution	Ill Literate	3	10	3	10	0	0	0	0	17.53.	0.005 p<0.05	8
	Primary	1	3	1	3	0	0	0	0			
	High School	11	37	11	37	0	0	0	0			
	Higher Secondary	3	10	2	7	1	3	0	0			
	Graduate & Above	**12**	40	9	30	3	10	0	0			

VARIABLES		F	P %	Mild		Moderate		Severe		χ	P Value	df
				F	%	F	%	F	%			
Birth order	First Child	21	70	19	63	2	7	0	0	10.57	.009 p<0.05	4
	Second Child	7	23	6	20	1	3	0	0			
	Third and Above	2	7	2	7	0	0	0	0			
Residence	URBAN	23	77	20	67	3	10	0	0	4.31	0.003 p<0.05	1
	RURAL	7	23	6	20	1	3	0	0			
	SEMI URBAN	0	0	0	0	0	0	0	0			
Place of birth	Health Sub Centre	0	0	0	0	0	0	0	0	11.31.	0.001 p<0.05	4
	Primary Health Centre	0	0	0	0	0	0	0	0			
	Government Hospital	24	80	21	70	3	10	0	0			
	Private Hospital	6	20	5	17	1	3	0	0			
Place if of previous venue of immunization	Health Sub Centre	0	0	0	0	0	0	0	0	10.71.	0.003 p<0.05	4
	Primary Health Centre	0	0	0	0	0	0	0	0			
	Government Hospital	26	87	23	77	3	10	0	0			
	Private Hospital	4	13	3	10	1	3	0	0			
Previous knowledge about pain reduction intervention	Yes	0	0	0	0	0	0	0	0	4.37.	o.oo7 p<0.05	1
	No	30	100	26	87	4	13	0	0			

This table depicts that there is no significant association between the pain level of under five children and demographic variables such as age of the under five child, Sex, birth order, Literacy level of the care giver, type of family, religion, place of residence, Place of birth, Place of venue of immunization, previous knowledge about pain reduction interventions among experimental group.

Discussion

CHAPTER - V

DISCUSSION

Each child in the under five age receives 8 shots of intramuscular immunization consisting of BCG, Pentavalent, Hepatitis B, and measles. All these are undoubtedly very painful for the child, the problem should no longer be set aside since more, and more vaccinations are being added to the schedule, effectively turning our children to human pincushions.

The pain perception is an inherent quality of life that occurs early in development. Since many researchers believe that pain in under five children actually have profound. There are several available options to accomplish the objective of minimizingpain during vaccination, which needs serious consideration of all concerned. Of them ice application prior to intramuscular immunization during vaccination have been shown to provide comfort to children and reduce pain. The ice application prior to intramuscular immunization help to control pain by inducing local anesthesia in the intramuscular immunization site. It also decreases edema, nerve conduction velocities, cellular metabolism, and local blood flow.

The focus of this study is to evaluate the effectiveness of ice application prior to intramuscular immunization on pain reduction among the under five children attending immunization clinic at pediatric outpatient department of Institute of child health and research centre, Madurai. 60 samples were selected for this study. FLACC (Face, Leg Movement, Activity, Cry, and Consolobility) pain scale was used to assess the pain level.

BASELINE CHARACTERISTIC OF EXPERIMENTAL AND CONTROL GROUP

Majority of the under five children in the experimental group (90%) were in the age group of birth to 12 months, (87%)in the control group. Regarding the sex of the under five children, (60%) males in control group, and in experimental group about (53%) were males. With regard to the type of family equal distribution was found in both the experimental and control group. In religion most of the experimental group and the control group (80%) were Hindus. Based on the literacy levels in the experimental group (40%) were graduates and above, (33%).Based on the birth order of the first child, in the experimental group was (70%), in the control group was (60%).according to the place of residence children from urban in the experimental group were (77%), and (67%) in the control group. Regarding the place of birth both in the experimental and control group (90%) were born in the government hospitals. The place of previous venue of immunization, in experimental group was (87%) and in the control group was (93%). In the experimental and control group (100%), had noprevious Knowledge about pain reduction interventions

The baseline variable of age in this study is consistent with the study done by Anna Taddio.et al.,(2009)conducted a systemic review on inadequate pain management during routine childhood immunization. Result showed that on average younger children exhibit more distress and pain than do older children. More than 90% of infants and 50% of primary school children exhibit severe distress during immunization.

FINDINGS BASED ON THE OBJECTIVES

The first objective was to assess the pain response during intramuscular Immunization for under five children in the experimental and control group.

In this study the pain response of under five children receiving intramuscular immunization with the standard technique assessed by FLACC (Face, Legs, Activity, Cry, Consolability) pain scale.

The present study reveals that 83% (25%) of the under five children had severe pain while receiving intramuscular immunization, 17% (5) of under five children had moderate pain among the control group.

The present study findings was consistent with the study done by Elizabeth A. Stanford.et al.,(2005)conducts a study on ‘‘Ow!’’: Spontaneous Verbal Pain Expression among Young Children during Immunization. Fifty-eight children between the ages of 4 years 8 months and 6 years 3 months (67% female) were videotaped while receiving their routine preschool immunization. Children provided self-report of pain using a 7-point faces pain scale. Fifty-three percent of children used verbalizations spontaneously to express their pain. The modal verbalization was the interjection ‘‘Ow!’’ which expressed negative affect and was specific to the experience of pain.

This study alsoconsistent with the study done by Barnhill.BJ.etal,(2010) conducted a study on using pressure to decrease the pain of intramuscular immunizations. The subjects were 93 patients who had dorsogluteal immunizations of immune globulin at a county health department. Forty-eight received the pressure treatment and 45 received a standard intramuscular immunization in which no pressure was applied. Mean pain intensity on a 100-mm visual analogue scale,

adjusted for differences in intramuscular immunization volume, was 13.6 mm for the experimental group and 21.5 mm for the control group (P=0.03). The findings suggest that simple manual pressure applied for 10 sec. prior to the intramuscular immunization site is a useful technique to decrease intramuscular immunization pain.

The second objective was to assess the effectiveness of ice application prior to intramuscular immunization by pain response in the experimental group

The pain response of under five children during intramuscular immunization with ice application prior to immunization was assessed by FLACC (Face, Legs, Activity, Cry, and Consolobility) pain scale. With the use of this technique majority of the under five children 87% (26) had mild, 13% (4) had moderate pain during immunization in experimental group. During ice application prior to intramuscular immunization most of the under five childrencrying time was reduced. The under five children who received immunization stopped crying when they were consoled by their mother.

Scott Halperin MD.et.al (2011) Among children undergoing vaccination, does (1) applicationof a vapocoolant spray or (2) application of ice or a cool/cold pack on the skin before intramuscular immunization of vaccine reduce pain at the time of intramuscular immunization? Background and evidence Vapocoolants: Vapocoolants (skin refrigerants) contain chemicals that produce an instantaneous cooling effect upon contact with the skin. The coldness may, in turn, reduce the sensation of pain during the immunizations. Four RCTs82–85 included in the systematic review10 examinedthe use of vapocoolants in 247 infants and children. In three of the RCTs, 82, 83, 85 the effect of a vapocoolant was compared with that of a placebo spray. A

meta-analysis of data from two of these RCTs (100 children aged four to six years)82,83 showed a beneficial effect on self-reported pain. Inthe third RCT, which involved 60 infants aged two to sixmonths, there was no difference in the pain associated with immunization.85 In two RCTs that compared vapocoolantspray with typical care (no spray or typical care by the nurse),there was no difference between groups,83,84 although in theabsence of a placebo group, positive results would beexpected. This result reinforced the overall findings.Ice or cool/cold packs: Applying ice or cool/cold packs tothe skin produces a cooling sensation that may reduce thesensation of pain during immunizations. Cool/cold packsare readily available and inexpensive. However, two RCTsinvolving 78 children aged 4 to 18 years86, 87 that were includedin the systematic review10 showed that ice had benefit.On the basis of the results of the systematic reviews,10,12 weconcluded that there was sufficient evidence to recommendfor or against skin-cooling techniques (i.e., vasocoolents, ice,cool/cold packs) to reduce pain in children undergoing immunizations. The evidence for vasocoolents contrasts withthe results of two studies performed in adults undergoing immunizations.48,88 It is possible that children, especiallyyoung children (up to three years old) may perceive coldness, or the cold may cause them to focus their attention on the procedure with lesser pain.

The third objective of the study was to compare the pain response between experimental group and control group.

Experimental group pain scores were 87% (26) had mild pain, 13% (4) had moderate pain, where as in control group 83% (25) of the under five children had severe pain during immunization, 17% (5) had moderate pain.

The control group mean (7.97) is higher than the experimental group mean (3.03) of the under five children. The obtained‘t’ value is 15.59, at $p<0.05$ level of significance.The study concludes that experimental group experienced less pain than control group. Hence, the ice application prior to intramuscular immunization had effect on pain response during intramuscular immunization.

These findings were consistent with the study done in 2008 ina local hospital, Toronto. A randomized controlled trial was done to determine the effects of ice application on pain relief in children of age group 1-4 years undergoing vaccine intramuscular immunizations . Data were collected from 40 children attending an immunization clinic. The subjects included 20 intervention group members and 20 control group members. Ice or cold packs was applied to the intervention group members on the intramuscular immunization site immediately before the procedure (within 1 minute of intramuscular immunization). Pain was measured with a numeric rating scale and measuring vital signs. Children who were provided with ice application had a lower degree of discomfort than children who were not provided with this intervention ($p<0.01$).

The fourth objective of the study was to determine the association between the post test scores of pain response and the selected baseline variables in experimental group.

There is no significant association between the post test scores of pain response of under five children in the experimental group and selected Baseline variables such as age of the under five child, Sex, birth order, Literacy level of the care giver, type of family, religion, place of residence, Place of birth, Place of venue of immunization, previous knowledge about pain reduction interventions.

This result was consistent with the study done by Moshe Ipp (2004) conducted a study on effects of age, gender and holding on pain response during infant immunization. 106 infants aged 2 to 6 months were positioned either supine (SUP) on the examination table or held (HLD) by a parent during routine immunization. There was no difference between the supine on the examination table and held by parent infants in duration of crying, facial grimacing or visual analogue scale (VAS) pain scores. Similarly age and gender did not affect pain response.

This findings was also consistent with the study done by Ronald L Blunt (2008) conducted a prospective, randomized controlled study on Effect of pragmatic technique of vitamin k intramuscular immunization on newborn pain response. The study result suggest that there is no significant association between pain level of neonates and gestational ages (p value = 0.582), birth weights (p value = 0.432).

Thus the H_1: There will be a significant difference in the pain response between ice application prior to intramuscular immunization and the standard technique during intramuscular immunization was proved.

Thus the H_2: There will be significant association between post test scores of pain response of under five children among experimental group during intramuscular immunization with selected base line variables. Hence this hypothesis rejected.

Summary, Conclusion & Recommendations

CHAPTER- VI

SUMMARY, CONCLUSION AND RECOMMENDATIONS

This chapter dealt about the summary of the study findings, conclusion, Implication, and Recommendation**.**

6.1 SUMMARY OF THE STUDY

Pain response associated with intramuscular immunization is a source of distress for individuals of any age as well as for the immunization provider. If not addressed, the pain and anxiety associated with immunizations can be related to fear of future procedures, medical fears, and avoidance behaviors including non-adherence with immunization schedules. Pain is subjective; each person feels and expresses pain differently. Every individual learns the meaning of pain through experiences early in life. For children, being distressed during a procedure may have a negative impact on the memory of pain. Research indicates that under five children who are exposed to painful experiences develop a sensitization to future pain and may develop altered responses to future pain.

The investigator conducted a study to evaluate the effectiveness of ice application on pain response during intramuscular immunization among Under five children attending immunization clinic, of the outpatient department of Institute of Child Health and research center, Madurai.

The objectives of the study were,

- To assess the pain response during intramuscular Immunization for under five children in the experimental and control group.

- To assess the effectiveness of ice application prior to intramuscular immunization by pain response in the experimental group.
- To compare the pain response between experimental group and control group.
- To determine the association between the post test scores of pain response and the selected baseline variables in experimental group.

The following hypotheses were tested:

H_1 There is a significant difference in pain response during intramuscular immunization among experimental and control group.

H_2 There is a significant association between the post test scores of experimental group and selected demographic variables.

The setting of the study was at the immunization clinic, outpatient department, Institute of child health and research centre,GovernmentRajaji Hospital, Madurai. The research approach used in the study was a quantitative approach and design was True experimental - Post test only control design. The sampling technique was Simple random sampling technique. The total sample size was 60; among that 30 were in experimental group, 30 were in control group. Standardized FLACC (Face, Legs, Activity, Cry, and Consolability) pain scale used for measurement of pain response. The content validity and reliability was obtained prior from the study. Subsequently, a pilot study was conducted and it found that, the tool was feasible and practicable. A modified Widenbach's prescriptive theory (1969) was formulated which provided a useful means in assessing the pain response during intramuscular immunization among under five children. The data collection was done for a period of six weeks from 01.10.2013 to 15.11.2013.Ice application prior to intramuscular immunization was given to experimental group for 30 seconds. First the injection site was

selected.Then, before administering the injection, an icepack covered with lint cloth piece was placed in the antero lateral aspect of the thigh that is at the site of immunization for the experimental group. Then the appropriate intramuscular immunization was given. The pain score was assessed by FLACC pain scale (Face, Legs, Activity, Cry, Consolobility) for the experimental group. The total time duration of Ice application prior to intramuscular immunization for each sample of the experimental group was 30 seconds.For the control group the usual technique was used to give immunization. Then the pain score was assessed by FLACC pain scale (Face, Legs, Activity, Cry, and Consolobility). The data were analyzed by descriptive and inferential statistics.

MAJOR FINDINGS OF THE STUDY

- In the experimental group majority of them 90 %(27) were in the age group of Birth to 12 months, in control group majority of them 87 %(26) were in the age group of Birth to 12 months.
- With regard to, sex in experimental group more than half of them 50%(16) were males and 47%(14) were females. Where as in control group majority of them 60%were males and 40 %(12) were females.
- In both groups half of theunder five children were 50 %(15) were from nuclear family and 50% (15) from the joint family.
- Majority of the under five children belongs to Hindus 80% (24) born in experimental group and control group.
- Based on the caregivers literacy level, among the experimental group 40 %(12) were graduates, 33 %(9) were educated up to high school.

- Majority of the under five children were first child 70 %(21) in experimental group and 60% (18) in control group.
- With the aspect of place of residence, majority of the under five children in the experimental group 77 %(23), and 67 %(20) of the control group, resided at the urban area.
- Regarding the place of birth, majority of the under five children both in the experimental and in the control group 80 %(24) were born in the Government Hospital.
- With the view of place of previous venue of immunization, in the experimental group 87 %(26) and in the control group 93 %(28) were immunized at the Government Hospitals. .
- There was no previous knowledge about pain response interventions among the complete 100% in the experimental and the control group.
- Regarding the pain level, in the experimental group majority of the under five children 87 %(26) had mild pain, 13 %(4) had moderate pain during intramuscular immunisation. Among the control group 83%(25) of the under five children had severe pain while receiving immunisation, 17%(5) of under five children had moderate pain.
- The control group mean (7.97) is higher than the experimental group mean (3.03) of the under five children. The obtained‘t’ value is 15.59, at $p<0.05$ level of significance. This study concludes that experimental group experienced less pain than the control group. So, the Ice application prior to intramuscular immunization had effect on the pain response during intramuscular injection for under five children.

- Statistically there was no significant association found between the post test scores of pain response during intramuscular immunization among experimental group and selected baseline variables.

6.2 CONCLUSION

Based on this study, the researcher concludes that ice application prior intramuscular immunization is an effective intervention to assess the pain response among under five children in pediatric outpatient department, Institute of Child Health and Research Center, Government RajajiHospital ,Madurai-20.

6.3 IMPLICATIONS OF THE STUDY

The study has implications in nursing practice, nursing education, nursing research and nursing administration.

6.3.1 NURSING PRACTICE

- Pain assessment is a basis to pain response. The nurses must be trained to assess the pain response of children according to their age.
- Nurses should practice the non pharmacological measures to assess the pain response during intramuscular immunization.
- Nurses can utilize the evidence based practice in improving the quality and standard of care.
- Nurses must be trained in the aspect of Ice application prior to intramuscular immunization and the technique to be implemented in day to day practice.

- Physical interventions and injection techniques to assess the pain response during intramuscular immunization offer an advantage over other techniques because they can be easily incorporated into clinical practice without added cost or time.

6.3.2 NURSING EDUCATION

- Pain is the fifth vital sign. So pain assessment scales and non pharmacological measures for pain response should be included in the nursing curriculum.
- Nurse educators should formulate procedures regarding non pharmacologic measures on pain response.
- Orientation programmes for the nurses as regards the importance of non pharmacological measures on pain response.
- Updating the knowledge of the staff by proper and relevant in-service education programs to emphasize ice application prior to intramuscular immunization as an intervention for pain reponse among under five children receiving intramuscular immunization.

6.3.3 NURSING ADMINISTRATION

- Nursing administrators can develop nursing practice standards, protocols and manuals of pain assessment and pain management in children of various ages, in which effectiveness of Ice application prior to intramuscular immunization can be included as an important strategy to assess the pain response among under five children.
- The nurse administrator should plan for continuing service education regarding non pharmacologic strategies for pain response during intramuscular immunization.

- Nurses play a major role in immunization. So, efforts has to be made to enhance the capabilities of the nurses through the in- service education programmes on the new paradigm of assess the effectiveness of ice application prior to intramuscular immunization on pain response among under five children, and other non pharmacologic strategy on pain.

6.3.4 NURSING RESEARCH

- Immunization is an important and universal experience for children and Ice application prior to intramuscular immunization is an effective means for pain response in children associated with intramuscular immunization pain. Further research in this area will help the nurse to find out other non pharmacological intervention to assess the pain response of intramuscular immunization pain.
- The nurse researcher should motivate the clinical nurses to apply the research findings in practice. And follow the evidence based practice in order to bring a quality nursing care.

6.4 RECOMMENDATIONS

- ✓ The study can be replicated with large samples in different settings to validate and generalise the findings.
- ✓ The study can be conducted on the other age groups and can compare with other interventions such as application of manual pressure over the injection site, pragmatic technique.
- ✓ Studies can be conducted regarding the knowledge and practice of Ice application prior to intramuscular immunization among health team members.

- ✓ Studies can be conducted to assess the parental emotional response during children's painful procedures
- ✓ Similar studies can be conducted with adult and old age people.

Bibliography

BIBLIOGRAPHY

BOOK REFERENCE

1. Anna Sidey, David Widds. (2005).*Text book of Community Children's Nursing.* (2nd ed.). London : Elsevier publications.

2. Basavanthappa.B.T. (2006).*Community health nursing.* (2nd ed.). New Delhi: Jaypee publications.

3. Basavanthappa, B.T. (1998).*Nursing research* (3rded.). New Delhi: Jaypee Brothers.

4. Denise F. Polit,& Cheryl Tetano Beck. (2004). *Nursing Research Principles and Methods*. (7thed.). Philadelphia: Lippincott.

5. Dianne Watkins. (2003).*Community health nursing*. (2nd ed.).Philadelphia: BailliereTindall.

6. Dorothy R. Marlow.,& Barbara C. Redding. (1998). *Textbook of pediatric Nursing,* (6thed.). Philadelphia: Saunders.

7. Elizabeth Diem. (2006).*Community health nursing projects*. (1st ed.).Philadelphia: Lippincott Williams and Wilkins.

8. Fawcett Jacqueline.(1989).*Analysis and evaluation of conceptual Model of Nursing*. Philadelphia: F.A. Davis.

9. Geri LoBiondo-Wood.& Judith Haber.(2006).*Nursing Research*. **(**6th ed.). St. Louis: Mosby Publications.

10. Ghai O.P. (2004). *Essential pediatrics*.(6thed.) New Delhi: CBS publisher.

11. Gupta, S.P. (1991). *Statistical Methods*. (3rd ed.). New Delhi: Sultan Chand.

12. Henry M.Seiddel. (2009). *Primary care of the New born*. (4th ed.). Elsevier: Philadelphia.

13. Jeanne.M.Sorrell.(2005).*Community based nursing practice*.(1sted.). Philadelphia: F.A David's company .

14. Kamalam,S(2004).*Community health nursing.* (1sted.). NewDelhi:Jaypee publication.

15. KasturiSundarRao.(2007). *Community Health nursing.* (4th ed.).Chennai:BI Publications.

16. Kothari.C.R.(1988). *Research Methodology Methods and Techniques*. New Delhi: Whiey Eastern Ltd.

17. Marcia Stanhope (2000).*Community health and public health nursing*. (6thed.). Missouri:Mosby publications .

18. Mary.A.Nies.(2001).*Community Heath nursing*.(3rd ed.). Philadelphia: W.B.Saunders Publication.

19. McMillan,J.H.,&Schumacher.(1989).*Research in education conceptual introduction*. (1st ed.). New York: Harper collies.

20. Nancy Burns.& Susan K Grove.(2007).*Understanding Nursing Research***.** **(**4th ed.). St.Louis: Saunders Publications.

21. Nicki L.Potts.(2009).*Text book of Paediatrics*.(11th ed.).New Delhi:Jaypee publications.

22. Park K. (2010).*Preventive and social medicine*. (21st ed.). New Delhi: Banarsidas publication.

23. ParulDatta.(2009).*Paediatric Nursing.* (2nd ed.). New Delhi: Jaypee publications.

24. Piyush Gupta. (2010).*Text book of community medicine*. (3rd ed.).New Delhi: CBS publications.

25.Polit.,Beck.,&Hungler,P.(2001).*Essentials of Nursing Research*.(4th ed.).Philadelphia: Lippincott Raven Publishers.

26. Rose Marie Linda. (2008).*Foundations of Nursing Research.* (5th ed.). New Delhi: Pearson Prentice Hall.

27. Sally Huband, Ethel Trigg. (2000). *Practices in children's nursing*.(1st ed.). Edinburgh: Churchill Livingstone.

28. SeshuBabu.V.V.R.(2001). *Review in community medicine*. (2nd ed.). Hyderabad: Paras publications.

29. Sodashy.,&Yalfe,B.J. (1993). *Nursing theory analysis application and evaluation*, (2nded.). Boston: Little Brown.

30. Sunderlal,Adarsh.(2011). *Text book of community medicine.* (3rd ed.) New Delhi: CBS publications.

31. SurajGupte.(2009).*Text book of Pediatrics*.(11thed.).NewDelhi:Jaypee publications.

32. Suryakantha,AH.(2010).*Community medicine*.(2nd ed.).New Delhi:Jaypee publication.

33. Val Hyde.(2002).*Community nursing and health care.*(1st ed.).New Delhi: Jaypee publications.

34. VidyaRatan.(2002). *Preventive and social medicine*. (9th ed.). New Delhi: Jaypee Publications.

35. Viswanathan.J.Desai.(2006).*Achar's Text book of Paediatrics.*(3rd ed.).New Delhi: Orient longman publications.

JOURNAL REFERENCE

1. Achema, G., Oyeleye, B. A. (2011). Pain relief strategies for infants taking DPT immunization in health centres.*African Journal of Midwifery & Women's Health, 5*(3), 193-195

2. Abdel Razek, A.,Az El-Dein, N. (2009). Effect of breast-feeding on pain relief during infant immunization injections. *International Journal Nursing Practice*, 15*,* 99–104.

3. Barnhill, BJ., Holbert ,MD., Jackson, NM. (2010) Using pressure to decrease the pain of intramuscular injections. *Journal of Pain Symptom Management,* 12(1), 52–58.

4. Canadian Task Force on Preventive Health Care New grades for recommendations from the Canadian Task Force on Preventive Health Care. (2003) *CMAJ* .Vol169. 207–8.

5. Cassidy, KL., McGrath, PJ. (2001). A randomized double-blind, placebo-controlled trial of the EMLA patch for the reduction of pain associated with

intramuscular injection in four to six-year-old children. *Paediatrics,* 90*,* 1329–36.

6. Cassidy, KL., Reid, GJ., McGrath, PJ. (2002). Watch needle, watch TV: audiovisual distraction in preschool immunization. *Pain Medicine,* 3*,*108–18.

7. Chambers, CT., Taddio, A., Uman, LS.,HELPinKIDS Team. (2009). Psychological interventions for reducing pain and distress during routine childhood immunizations: a systematic review. *Clinical Therapy* ,31(2), 77–103.

8. Chung, JW., Ng ,WM., Wong ,TK. An experimental study on the use of manual pressure to reduce pain in intramuscular injections. *Journal of Clinical Nursing,*11*,* 457–461.

9. Cohen, LL.,MacLaren, JE., Fortson, BL. (2006). Randomized clinical trial of distraction for infant immunization pain. *Pain ,*125,165–171.

10. Cramer-Berness, LJ., Friedman, AG.(2005). Behavioral interventions for infant immunizations. *Child Health Care* ,34, 95–111.

11. Dilli, D., Küçük, IG.,Dallar, Y. (2009). Interventions to reduce pain during vaccination in infancy. *Journal of Pediatrics,*154(3), 385–390.

12. Dustin P., Keith D. (2010).The "Cough Trick:" A Brief strategy to Manage Pediatric Pain From Immunization Injections.*Pediatrics: The journal of American academy of paediatrics*,*125,* 367-373.

13. Efe E, Ozer ZC. (2007). The use of breast-feeding for pain relief during neonatal immunization injections. *Applied Nursing Research*, 20(1), 10–12

14. Evelyn Cohen, MD., Ericka kraussroth. (2003). Effecctive pain reduction for multiple immunization injections in Young infants. *Archieves of paediatric adolescent Journal, 157,* 1115-1120.

15. French,GM., Painter EC, Coury DL.(1994). Blowing away shot pain: a technique for pain management during immunization. *Pediatrics,*93, 384–388.

16. Hatfield, LA. (2008). Analgesic properties of oral sucrose during routine immunizations at 2 and 4 months of age. *Pediatrics*,121*,* 327–34.

17. Hagan, JF., Jr., Coleman.WL., Foy JM. et al. (2011).The assessment and management of acute pain in infants, children, and adolescents. *Pediatrics*,108(3),793–797.

18. Helfer, Joanne Kieffer. (2000). Painless Injections: Helfer Skin Tap Technique .*Nurse Educator, 25* (6), 272-273

19. Ipp, M., Taddio, A., &Goldbach, M. (2004). Effects of age, gender and holding on pain response during infant immunization. *Canadian Journal of Clinical Pharmacology,*11, 2–7.

20. Ipp M, Cohen E, &Goldbach M, et al.(2007). Effect of choice of measles–mumps–rubella vaccine on immediate vaccination pain in infants. *Archieves Pediatric Adolescent,98* (12),1153-1158.

21. Ipp, M. Taddio, A. and Sam, J.(2007). Vaccine-related pain: randomized controlled trial of two injection techniques. *Archieves Diseases in Children,* 92*,* 1105–8.

22. Ipp, M. Parkin, PC.and Lear, N. (2009). Order of vaccine injection determines infant pain response. *Archieves Diseases in Children*, 163,469–72

23. Jose Rose Mary, Sulochana. (2011). Effectiveness of skintap on pain during immunization response.*International journal of nursing education.4*(1).56-57.

24. Lacey,CM., Finkelstein,M.,&Thygeson,MV. (2008). The impact of positioning on fear during immunizations: supine versus sitting up. *Journal of Pediatric Nurse,* 23*,* 195–200.

25. Love preetkaur, Shukwinderkaur. (2009). Analgesic effect of Breast feeding in infants during immunization: a randomized controlled trial. *Nursing and midwifery Journal, 5*(4).142-154.

26. Merkel ,SI., Voepel-Lewis, T., Shayevitz ,JR. (1997). The FLACC: a behavioral scale for scoring postoperative pain in young children. *Pediatric Nursing,*23*,* 293–297.

27. Meyerhoff, AS., Weniger, BG., & Jacobs, RJ. (2001). Economic value to parents of reducing pain and emotional distress of childhood vaccine injections. *Pediatric Infectious Disease Journal,* 20,57–62.

28. Parvez, E., Stinson, J., Boon, H. (2010). Mothers' beliefs about analgesia during childhood immunization.*Paediatric Child Health* ,15*,*289–293.

29. RashaSrouji, SavithriRatnabalan. (2011). Pain in children: Assessment and management of non pharmacological measures in children and infants. *International journal of paediatrics,5,* 213- 225.

30. Riddell ,RR., Stevens, BJ., Cohen ,LL. (2007). Predicting maternal and behavioral measures of infant pain: the relative contribution of maternal factors. *Pain,* 133*,* 138–149.

31. Rosen bloom,MD., Goldman Michael. (2011). Parental sex and age: the effect of pain assessment in young infans. *Paediatric emergency care,27*(4). 266-269.

32. Schechter,NL., Zempsky, WT., &Cohen, LL. (2007). Pain reduction during paediatric immunizations: evidence-based review and recommendations. *Pediatrics*,119*,* 1184–1198

33. Shah V, Taddio A, Rieder MJ. HELPinKIDS Team. (2009). Effectiveness and tolerability of pharmacologic and combined interventions for reducing injection pain during routine childhood immunizations: systematic review and meta-analyses. *Clinical Therapy* ,31(2). 104– 147.

34. Sparks, L. Taking the "ouch" out of injections for children. Using distraction to decrease pain. *MCN American Journal of Maternal Child Nursing,* 26, 72–8.

35. Sr. Serena. (2009). Rhythmic sin tapping: An effective measure to reduce pain during intramuscular injection. *Indian nursing Journal, 5,*12-15.

36. Taddio A, Manley J. (2007). Routine immunization practices: use of topical anesthetics and oral analgesics. *Pediatrics,*120,637–643.

37. Taddio A, Chambers CT. (2009). Inadequate pain management during childhood immunizations.*Clinical Therapy*,31(2), 152–167.

38. Taddio,A., Ilersich,AL., Ipp,M.,&HELPin KIDS Team. (2009). Physical interventions and injection techniques for reducing injection pain during

routine childhood immunizations: systematic review of randomized controlled trials and quasi-randomized controlled trials. *Clinical Therapy* .31(2).48–76.

39. Tivsy Thomas, Shetty,P. (2011). Role of Breast feeding in pain response during injectable immunization among infants.*The Nursing Journal of India,3*(2). 14-21.

40. Uman,LS., Chambers,CT., McGrath P. (2008) A systematic review of randomized controlled trials examining psychological interventions for needle-related procedural pain and distress in children and adolescents: an abbreviated Cochrane review. *Journal of Paediatric Psychology,*33, 842–854.

NET REFERENCES

Retrieved from

1. http://tnhealth.org/dph
2. http://mohfw.org/nhp
3. http://who.int/wer
4. http://tnhsp.org
5. http://childinfo.org/immunization/html
6. http://www.journals.nurseeducatoronline/painless-helfer-skintap.10
7. http://www.who.int/immunization-monitoring/data/en
8. http://www.who.int/sea/rc65
9. http://bccentrefordisesecontrol.org
10. http://www.toronto.ca/health/immunization_children/pdf/howtoreducepain.pdf
11. http://www.who.int.epi/303
12. http://www.whoindia.org
13. http://www.whovaccine/doc
14. http://jpo/sagepub.com
15. http://www.iapimmunization.com
16. http://www.abmprotocol.com
17. http://www.SciRP.org/journal/wjv
18. http://www.archpaediatrics.com

Appendices

APPENDIX – I (A)

RESEARCH TOOL

SECTION: I

DEMOGRAPHIC VARIBLES: **SAMPLE ☐:**

1. Age of the child ☐
   a. Birth -12 months.
   b. 13-36 months.
   c. 37-60 months.
2. Sex of the child ☐
   a. Male
   b. Female
3. Type of family ☐
   a. Nuclear family
   b. Joint family
   c. Separated family
4. Religion ☐
   a. Hindu
   b. Christian
   c. Muslim
   d. Others.
5. Caregivers literacy level ☐
   a. No formal education
   b. Primary education
   c. High school
   d. Higher secondary
   e. Graduate and above.
6. Birth order ☐
   a. First child.
   b. Second child
   c. Third and above

7. Place of residence ☐
    a. Urban
    b. Rural.
    c. Semi urban.
8. Place of birth ☐
    a. Health sub centre
    b. Primary health centre
    c. Government Hospital
    d. Private Hospital
9. Place of previous venue of immunization ☐
    a. Health sub centre
    b. Primary health centre.
    c. Government Hospital
    d. Private hospital.
10. Previous Knowledge about pain reduction interventions ☐
    a. Yes
    b. No

SECTION – II

STANDARDIZED FLACC PAIN SCALE

Put a tick (✓) mark on suitable

S.No	CATEGORY	SCORE	CHILD SCORE
I	FACE		
	No particular expression or smile	0	
	Occasional grimace or frown, withdrawn, disinterested	1	
	Frequent to constant quivering chin, clenched jaw	2	
II	LEGS		
	Normal position or relaxed	0	
	Uneasy, restless, tense	1	
	Kicking, or legs drawn up	2	
III	ACTIVITY		
	Lying quietly, normal position, moves easily	0	
	Squirming, shifting back and forth, tense	1	
	Arched, rigid or jerking	2	
IV	CRY		
	No cry(awake or asleep)	0	
	Moans or whimpers; occasional complaint	1	
	Crying steadily, screams or sobs, frequent complaints	2	
V	CONSOLABILITY		
	Content, relaxed	0	
	Reassured by occasional touching, hugging or being talked to, distractible	1	
	Difficult to console or comfort	2	

SECTION - II

SCORING PROCEDURE

The minimum obtainable score for each category of pain response was zero and maximum score 2. The total of maximum pain score was 10.

SCORE INTERPRETATION

Based on the score the pain response is graded as follows:

Score Categories

SCORE	INTERPRETATION
0	NO PAIN
1-3	MILD PAIN
4-6	MODERATE PAIN
7-10	SEVERE PAIN

APPENDIX – I (B)

பகுதி - அ

தன்னிலை விபரக்குறிப்பு

1. குழந்தையின் வயது ☐
   அ. பிறந்தது முதல் -- 12 மாதம் வரை
   ஆ. 13 - 36 மாதங்கள்
   இ. 37-60 மாதங்கள்
2. குழந்தையின் பாலினம் ☐
   அ. ஆண்
   ஆ. பெண்
3. குடும்ப வகை ☐
   அ. தனிக்குடும்பம்
   ஆ. கூட்டுக்குடும்பம்
   இ. பிரிக்கப்பட்ட குடும்பம்
4. மதம் ☐
   அ. இந்து
   ஆ. கிறிஸ்தவர்
   இ. முஸ்லீம்
   ஈ. மற்றவை
5. கவனிப்பாளரின் கல்வித்தகுதி ☐
   அ. முறையான கல்வி
   ஆ. தொடக்க கல்வி
   இ. உயர்நிலைக்கல்வி
   ஈ. மேல்நிலைக்கல்வி
   உ. பட்டப்படிப்பு மற்றும் அதற்கு மேல்
6. பிறப்பு வரிசை ☐
   அ. முதல் குழந்தை
   ஆ, இரண்டாவது குழந்தை
   இ. மூன்று மற்றும் அதற்கு மேல்
7. வசிப்பிடம் ☐
   அ. நகரம்
   ஆ. கிராமம்
   இ. நகர்ப்புற பகுதி

8. பிறந்த இடம் ☐

அ. துணை சுகாதார நிலையம்

ஆ. ஆரம்ப சுகாதார நிலையம்

இ. அரசு மருத்துவமனை

ஈ. தனியார் மருத்துவமனை

9. முந்தைய தடுப்பூசி போடப்பட்ட இடம் ☐

அ. துணை சுகாதார நிலையம்

ஆ. ஆரம்ப சுகாதார நிலையம்

இ. அரசு மருத்துவமனை

ஈ. தனியார் மருத்துவமனை

10. முந்தைய தடுப்பூசி போடும் போது வலியை குறைக்கும் முறைகளை பற்றிய அனுபவம் ☐

அ. ஆம்

ஆ, இல்லை

பகுதி - ஆ

தரநிலையான FLACC வலி (முகம், கால்கள், நடவடிக்கை, அழுகை, மற்றும் தேற்றக்கூடிய செயல்) அளவுகோல்.

வ. எண்.	பிரிவு	மதிப்பெண்	குழந்தையின் மதிப்பெண்
1.	**முகம்**		
	தெளிவான முகத்தோற்றம் அல்லது சிரிப்பு இன்மை	0	
	எப்பொழுதாவது முகநெளிப்பு, திரும்ப மீள்தல்	1	
	தாடை அடிக்கடி உதறுதல், தாடை இறுக மூடியிருத்தல்	2	
2.	**கால்கள்**		
	வழக்கமான நிலையிலுருத்தல் அல்லது தளர்ந்த நிலையிலுத்தல்	0	
	அதையில்லாத, கஷ்டமான, இறுக்கப் பட்ட நிலையிலுருத்தல்	1	
	உதைத்தல் அல்லது கால்களை இழுத்துக் கொள்ளுதல்	2	
3.	**நடவடிக்கை**		
	அமைதியாக படுத்துக்கொண்டிருத்தல், வழக்கமான நிலையிலிருத்தல்	0	
	நெளிதல், இறுக்கப்பட்ட நிலையில் முன்னும், பின்னுமாக நகர்தல்	1	
	வளைந்து காணப்படுதல், இறுக்கமான அல்லது திடீரென உதறுதல்	2	
4.	**அழுகை**		
	அழாமல் இருத்தல்	0	
	எப்பொழுதாவது முணகுதல்	1	
	கீச்சென்று சப்தமிட்டு அழுதல், தேம்பி அழுதல்	2	
5.	**தேற்றக்கூடிய செயல்**		
	தளர்ந்திருத்தல், தேற்றக்கூடிய நிலையிலிருத்தல்	0	
	தொடுதலினாலும், அணைத்தலினாலும் அல்லது பேசி விளையாடுவதினாலும் திரும்ப உறுதிபடுத்துதல்	1	
	தேற்றக்கூடியது கடினமான செயல்	2	

APPENDIX – II

Ref. No. 9101/E4/3/2013 **Govt Rajaji Hospital,**
Madurai-20. Dated: 20.09.2013

Institutional Review Board I independent Ethics Committee,
Dr. N. Mohan, MS., F.LC.S F.A.I.S.,
Dean, Madurai Medical College &
Govt Rajaji Hospital, Madurai 625020. **Convener.**

Sub: Establishment-Govt. Rajaji Hospital. Madurai-20-
Ethics committee-Meeting Minutes- for August 2013
Approved list -regarding.

The Ethics Committee meeting of the Govt. Rajaji Hospital, Madurai was held on 08.08,2013, Wednesday at 10.00 am to 12.00.pm at the Anesthesia Seminar Hail, Govt. Rajaji Hospital, Madurai. The following members of the committee have attended the meeting.

I Dr. V, Nagarajan, M.D., D.M (Neuro) Ph: 0452-2629629 Cell.No 9843052029	Professor of Neurology (Retired) D.No.72, Vakkil New Street, Simmakkal, Madurai -1	Chairman
2. Dr.Mohan Prasad. MS M.Ch Cell,No.9843050822 (Oncology)	Professor & H.O.D of Surgical Oncology(Retired) D.No.72, West Avani Moola Street. Madurai -1	Member Secretary
3. Dr. I. Jeyaraj, M.S... (Anatomy) Cell.No 9566211947	Director & Professor Institute of Anatomy /V,P Madurai Medical College	Member
4. Dr. Parameswari M.D (Pharmacology) Cell.No.9994026056	Director of Pharmacology Madurai Medical College	Member
5. Dr.S. Vadivel Murugan, MD., (Gen.Medicine) Cell.No 9566543048	Professor of Medicine Madurai Medical College	Member
6. Dr.S. Meenakshi Sundaram, MS (Gen.Surgery) Cell.No 9842138031	Professor & H.O.D of Surgery i/c Madurai Medical College	Member
7. Miss, Mercy Immaculate Rubalatha, MA., Med,, Cell. No. 9367792650	50/5, Corporation Officer's quarters, Gandhi Museum Road, Thamukam, Madurai-20	Member
8. Thiru. .Pala. .Ramasamy , BA.,B.L.,Cell.No 9842165127	Advocate, D.No,72.Palam Station Road, Sellur, Madurai -2	Member
9. Thiru. P.K.M. Chelliah,B.A Cell.No 9894349599	Businessman, 21 Jawahar Street. Gandhi Nagar, Madurai-20	Member

The following Projects were approved by the committee

S.No	Name of P.G	Course	Name of the Project	Remarks
1.	S.Jayashree	M.Sc Nursing in Child health (Pediatric Nursing) Govt. Rajaji Hospital, Madurai	Study to assess the effectiveness of ice application prior to intramuscular immunization on pain response among under five children in pediatric outpatient Department, Institute of Child health and Research Centre, Government Rajaji Hospital, Madurai-20.	Approved

Please note that the investigator should adhere the following: She / He should get a detailed informed consent from the patients/participants and maintain it confidentially.

1.She / he should carry out the work without detrimental to regular activities as well as without extra expenditure to the institution or to Government,

2. She/he should inform the institution Ethical Committee, in case of any change of study procedure, site and investigation or guide.

3. She / He should not deviate the area of the work for which applied for Ethical clearance, She / He should inform the JEC immediately, in case of any adverse events or Serious adverse reactions.

4, She / He should abide to the rules and regulations of the institution,

5. She / He should complete the work within the specific period and if any Extension of time is required He / She should apply for permission again and do the work,

6. She / He should submit the summary of the work to the Ethical Committee on Completion of the work.

7. She / He should not claim any funds from the institution while doing the work or on completion.

8. She / He should understand that the members of IEC have the right to monitor the work with prior intimation.

Member Secretary **Chairman**
Ethical Committee

DEAN/Convenor
Govt. Rajaji Hospital,
Madurai- 20.

20/9/13

To
The above Applicants
-thro. Head of the Department concerned

APPENDIX – III

LETTER SEEKING PERMISSION FOR CONDUCTING THE STUDY

From

Mrs. S.Jayashree

M.Sc (N) I year student (Br— II Child Health Nursing)

College of Nursing

Madurai Medical College. Madurai - 20

To

The Director.

Institute of Child Health and Research Centre,

Government Rajai Hospital

Madurai Medical College.

Madurai.

Through The Proper Channel

Respected Sir.

Sub : College of Nursing. Madurai Medical College. Madurai — M.Sc.(N) 1 year Child Health Nursing Student - Permission for conduct dissertation study Institute of Child Health and Research Centre, GRH, request-regarding

****

As per the Indian Nursing Council and the Tamilnadu Dr. M.G.R. Medical University curriculum requirement all branches of M.Sc Nursing candidates are required to conduct a dissertation study for the partial fulfillment of the P.G Degree course in their respective departments.

I have selected a study topic "**A Study to assess the effectiveness of ice application prior to intramuscular immunization on pain responses among under five children in pediatric outpatient Department, Institute of Child health and Research Centre, Government Rajaji Hospital, Madurai-20**." for my dissertation study; I would like to select patients from the above department.

I assure that I will not interfere with the routine activities of the department.

Hence I kindly request you to consider my requisition and permit me to conduct the study.

Thanking you,

Date:

R. JEYASUNDARI M.Sc., (N) M.Phil., PGDHA., M.A., (Pub. Admin) (Socio) M.A., (JMC) Clinical Lecturer / Tutor in Nursing COLLEGE OF NURSING MADURAI MEDICAL COLLEGE Madurai-625 020.

DIRECTOR INSTITUTE OF CHILD HEALTH & RESEARCH CENTRE GOVT. RAJAJI HOSPITAL MADURAI-625020

Yours obediently,

(S Javashree)

CERTIFICATE OF TAMIL EDITING

TO WHOM SO EVER IT MAY CONCERN

This is to certify that the dissertation by **S.JAYASHREE** II year M.Sc(N) student, college of Nursing, Madurai Medical College, Madurai, who has undertaken the study field on Dissertation entitled "**EFFECTIVENESS OF ICE APPLICATION PRIOR TO INTRAMUSCULAR IMMUNIZATION ON PAIN RESPONSES AMONG UNDER FIVE CHILDREN IN PEDIATRIC OUTPATIENT DEPARTMENT, INSTITUTE OF CHILD HEALTH AND RESEARCH CENTRE, GOVERNMENT RAJAJI HOSPITAL, MADURAI-20.**" has been edited for Tamil language appropriateness.

Date.....

Name தி. ஜனார்த்தனி M.A, B.Ed.,

Signature

Designation முதுகலை பட்டதாரி தமிழ் ஆசிரியர்
மெளண்ட்ரோட் மெட்ரிகுலேஷன் மேல்நிலைப்பள்ளி

CERTIFICATE OF ENGLISH EDITING

TO WHOM SO EVER IT MAY CONCERN

This is to certify that the dissertation by **S.JAYASHREE** II year M.Sc(N) student, college of Nursing, Madurai Medical College, Madurai, who has undertaken the study field on Dissertation entitled "**EFFECTIVENESS OF ICE APPLICATION PRIOR TO INTRAMUSCULAR IMMUNIZATION ON PAIN RESPONSES AMONG UNDER FIVE CHILDREN IN PEDIATRIC OUTPATIENT DEPARTMENT, INSTITUTE OF CHILD HEALTH AND RESEARCH CENTRE, GOVERNMENT RAJAJI HOSPITAL, MADURAI-20.**" has been edited for English language appropriateness.

Name M. SELVARANI
M.A.B.Ed, M.Phil.

Signature M. Selvarani 7/2/14

Designation P. Gr. ASST (ENGLISH)

Institution : ILANGO CORP. HR. SEC. SCHOOL
SHENOY NAGAR
MDU-20

APPENDIX – E

ஒப்புதல் அறிக்கை

எனக்கு இந்த ஆய்வைப்பற்றிய முழு விவரம் விளக்கமாக எடுத்துரைக்கப்பட்டது. இந்த ஆய்வில் பங்குபெறுவதில் உள்ள நன்மைகள் மற்றும் தீமைகள் பற்றி நான் புரிந்துக்கொண்டேன். நான் இந்த ஆய்வில் தானாகவே முன்வந்து பங்கு பெறுகிறேன். மேலும் எனக்கு இந்த ஆய்வில் இருந்து எந்த நேரமும் விலகிக்கொள்ள முழு அனுமதி வழங்கபட்டுள்ளது. என் குழந்தையின் சிகிச்சை ஆவணங்களைப் பார்வையிட்டு அதில் உள்ள விவரங்களை ஆய்வில் பயன்படுத்திக் கொள்ள அனுமதி அளிக்கிறேன். என்னுடைய பெயர் மற்றும் அடையாளங்கள் ரகசியமாக வைத்துக்கொள்ளபடும் என்றும் எனக்கு உறுதியாளிக்கப்பட்டுள்ளது.

இப்படிக்கு,

CONTENT VALIDITY CERTIFICATE

This is to certify that the content & tool,

SECTION A - Demographic Data

SECTION B - FLACC Pain rating Scale

Prepared for data collection by S.Jayashree, II year M.Sc (N) student, college of Nursing, Madurai Medical College, Madurai, who has undertaken the study field on thesis entitled "*A study to assess the effectiveness of ice application prior to intramuscular immunization on pain responses among under five children in pediatric outpatient department at Government Rajaji Hospital, Madurai-20.*" has been validated by me.

Date: 11.9.13.

Madurai.

11/9/13

Signature of the Expert

DR. N. KARUPPARAJU
M.S. (GEN) : D.L.O., M.Ch., (Paed)
Assistant Professor
Govt Rajaji Hospital /
Madurai Medical College /
Regd. No : 43434.

CONTENT VALIDITY CERTIFICATE

This is to certify that the content & tool,

SECTION A - Demographic Data

SECTION B - FLACC Pain rating Scale

Prepared for data collection by S.Jayashree, II year M.Sc (N) student, college of Nursing, Madurai Medical College, Madurai, who has undertaken the study field on thesis entitled "***A study to assess the effectiveness of ice application prior to intramuscular immunization on pain responses among under five children in pediatric outpatient department at Government Rajaji Hospital, Madurai-20.***" has been validated by me.

INSTITUTE OF CHILD HEALTH & RESEARCH CENTER
11 SEP 2013
MADURAI.
GOVT. RAJAJI HOSPITAL

Date:

10/9/13

Signature of the Expert

DIRECTOR I/C
INSTITUTE OF CHILD HEALTH &
RESEARCH CENTRE
GOVT. RAJAJI HOSPITAL
MADURAI - 625 020

CONTENT VALIDITY CERTIFICATE

This is to certify that the content & tool,

SECTION A - Demographic Data

SECTION B - FLACC Pain rating Scale

(Enclosed)

Prepared for data collection by S.Jayashree, II year M.Sc (N) student, college of Nursing, Madurai Medical College, Madurai, who has undertaken the study field on thesis entitled "***A study to assess the effectiveness of ice application prior to intramuscular immunization on pain responses among under five children in pediatric outpatient department at Government Rajaji Hospital, Madurai-20.***" has been validated by me.

Date: 13/9/13.

R. Jothilakshmi,
Signature of the Expert Reader,
Sacred Heart nursing
college, madurai-20.

CONTENT VALIDITY CERTIFICATE

This is to certify that the content & tool,

SECTION A - Demographic Data

SECTION B - FLACC Pain rating Scale

Prepared for data collection by S.Jayashree, II year M.Sc (N) student, college of Nursing, Madurai Medical College, Madurai, who has undertaken the study field on thesis entitled "*A study to assess the effectiveness of ice application prior to intramuscular immunization on pain responses among under five children in pediatric outpatient department at Government Rajaji Hospital, Madurai-20.*" has been validated by me.

Mana madurai

Date: 12/9/13.

Signature of the Expert

Asso. Professor

Matha College of NSG

Vaan puram

Madurai

CONTENT VALIDATION CERTIFICATE

I hereby certify that I have validated the research study of S.Jayashree II year M.Sc Nursing Student of College of Nursing, Madurai Medical College, Madurai who is undertaking the following study:

"Effectiveness of Ice Application Prior To Intramuscular Immunization On Pain Responses Among Under five Children In Pediatric Outpatient Department At Government Rajaji Hospital, Madurai- 20"

30/8/13

Place:

Signature of the Expert

Date:

Designation and Address

Dr. A. Helen M. Perdita.
Principal
Madurai Apollo CON
Madurai - 22.

THE STUDY SETTING OF THE INVESTIGATOR

THE INVESTIGATOR COLLETING DEMOGRAPHIC VARIALE

ICE PACK FOR INTERVENTION

THE INVESTIGATOR APPLYING ICE PACK PRIOR TO INTRA MUSCULAR IMMUNIZATION FOR 30 SECONDS

THE MEDICAL OFFICER GIVING INTRA MUSCULAR IMMUNIZATION (PENTAVALENT) FOR THE UNDER FILE CHILD

THE INVESTIGATOR ACCESSING THE PAIN RESPONSES WITH IN FLACC PAIN SCALE