"EFFECTIVENESS OF HELFER SKIN TAP TECHNIQUE ON PAIN DURING INTRA MUSCULAR INJECTION AMONG CHILDREN ATTENDING IMMUNIZATION CLINIC AT SELECTED HOSPITAL, KOLAR, KARNATAKA"

By

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Research project submitted to

Sri Devaraj Urs College of Nursing,Tamaka,Kolar

In partial fulfillment of the requirement for the degree of

Masters of Science in Nursing

In

Pediatric Nursing

Under the guidance of

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2019

Declaration By The Candidate

I hereby declare that this research project entitled "A study to evaluate the Effectiveness of Helfer Skin Tap technique on Pain during Intra muscular injection among children attending Immunization clinic at selected Hospital, Kolar, Karnataka" is a bonafide and genuine research work carried out by me under the guidance of Prof. Radha M.S, Vice-Principal and HOD, Department of Pediatric Nursing, Sri Devaraj Urs College of Nursing, Tamaka, Kolar.

Signature of the Candidate

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Date:

Place: Tamaka, Kolar

CERTIFICATE BY THE GUIDE

This is to certify that the research project entitled "A study to evaluate the Effectiveness of Helfer Skin Tap technique on Pain during Intra muscular injection among children attending Immunization clinic at selected Hospital, Kolar, Karnataka", is a bonafide and genuine research work done by Mrs.Saritha.V, in partial fulfillment of the requirement for the Degree of Master of Science in Pediatric Nursing.

Prof .Radha M.S

Vice-Principal and HOD

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Tamaka, Kolar.

Date:

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ENDORSEMENT BY THE HEAD OF THE DEPARTMENT/ PRINCIPAL/HEAD OF THE INSTITUTION

This is to certify that the dissertation entitled "A study to evaluate the Effectiveness of Helfer Skin Tap technique on Pain during Intra muscular injection among children attending Immunization clinic at selected Hospital, Kolar, Karnataka", is a bonafide and genuine research work done by Mrs.Saritha.V, under the guidance of Prof.Radha M.S Vice-Principal and HOD Department of Pediatric Nursing, in partial fulfillment of the requirement for the Degree of Master of Science in Pediatric Nursing.

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ACKNOWLEDGEMENT

"Pleasure of love lasts but a moment; Pain of love lasts of lifetime"

Bette Davis

First and foremost I would like to express a deep sense of gratitude to god almighty for his guidance , strength and wisdom, which was best owed upon me at every step through out this endeavor and for the successful completion of this study.

I express my sincere gratitude and whole hearted thanks to main architect of the study **Prof.Radha M.S,** Vice-Principal & HOD, Dept.of Pediatric nursing, for her remarkable teaching abilities and support generous assistance, clues to proceed further have proved a great source of inspiration to me for successful completion of this study.

I am greatly indebted to **Dr.G.Vijayalakshmi**, Principal, Sri Devaraj Urs college of Nursing, for her inspiration , perceptual guidance, valuable suggestions and guidance for successful completion of the study.

I express my sincere thanks to **Mrs.Lavanya Subhashini,** Associate Professor, Dept. of Pediatric Nursing, Sri Devaraj Urs college of Nursing for her constant interaction, for boosting my spirits through ups and downs in helping me to complete the study successfully.

I express my sincere gratitude to **Prof.Zeanath C.J,** HOD, Dept. of Medical Surgical Nursirg, and Chief Nursing Officer and staff of Immunization clinic of R.L Jalappa Hospital and Research center, Kolar for their timely co-operation and support.

It gives me a great pleasure to express my heartful gratitude to **all the HOD's, and Teaching faculty of various departments,** Sri Devaraj Urs College of Nursing, Tamaka,Kolar for their valuable advice and suggestions.

I am greatful to Mr.Ravi Shankar, Asst. Professor, Department of Statistics, Sri Devaraj Medical College, Kolar for his expert guidance, valuable suggestions and assistance in the statistical analysis and interpretation of data.

I express my humble thanks to **Dr. Lakshmaiah** V. Medical Superintendent, Sri R.L Jalappa Hospital and Research Center for granting me permission to conduct the study.

A profound and deep sense of gratitude to the **Librarians** of Sri Devaraj Urs College of Nursing, for their co-operation.

I owe my personal debt of gratitude to all children and their mothers for enthusiastic participation in the study, without their co-operation the study would not have been possible.

I am indeed privileged to show my heartfelt gratitude to my family without whom my study would not have been possible. I wish to acknowledge my beloved parents **Mrs.Rani**, **Mr.Sudhakar Naidu,** my partner, **Mr.Pavan Kumar K.B**, my loving Son **Master. Jashwanth K.P Chowdhary** who had been a source of strength and support through their prayers and encouragement. This accomplishment would not have been possible without them. Thank you.

No words can express my appreciation and indebtedness to many of them whose names have not been mentioned who helped unselfishly and most willingly in the successful completion of the Research Project.

Thank you all.

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ABBREVATIONS

FLACC: Faces, Legs, Activity, Cry and Consolability

AOC: Age of Child

NOV: Number of Vaccines

TOV: Type of vaccines

ROV: Route of vaccines

ABSTRACT

Background of the Study

Routine immunizations are the most frequent painful medical procedure during childhood. The world health organisation estimates that 12 billion injections are given annually and that approximately 5% are childhood vaccinations. Vaccine injections are the most common reason for iatrogenic pain in childhood. With the steadily increasing number of recommended vaccinations, there has been a concomitant increase in concern regarding the adequacy of pain management.

Studies reveal that non pharmacological methods of pain management diminish pain perception by reducing intensity and increasing pain tolerance, reduce pain-related distress, strengthen coping abilities; and give the child and family a sense of control over pain. Traditionally, pain management tends to emphasize the use of pharmacological agents. However, pain is influenced by an array of physical and psychosocial factors, and children differ in their response to pain and to analgesics. Therefore, it is important to have a range of options, including non-pharmacological measures available, in order to manage children pain effectively

Statement of the Problem

"A Study to Evaluate the Effectiveness of Helfer Skin Tap technique on Pain during Intra muscular injection among children attending Immunization clinic at selected Hospital, Kolar, Karnataka"

Objectives of the study

1. To Evaluate the Effectiveness of Helfer Skin Tap technique on Pain by using pain scale.
2. To determine the association with level of pain during Immunization with number of vaccinations, age of child and type of vaccine.

Methods

Quantitative approach with True Experimental Time series (Posttest only with Control group) design was used for this study.

The study was conducted at Immunization Clinic of R.L.Jalappa Hospital and Research Centre, Kolar. The sample consisted of 40 children attending to immunization clinic. The sample were selected and allotted to experimental group and control group by using simple random(computer generated random number assignment) sampling technique and following inclusion criteria.

Data was collected by taking consent was taken from mothers of Children in Experimental group and prepared for vaccination, positioned the child, identified the site and started tapping at Injection site for 3mts before, during and after vaccination. Pain scores were assessed by video recording from the time of initiating the intervention, till completion. Then the video was analyzed by using FLACC Pain Measuring Scale.

For the babies of control group ,routine steps of vaccination were followed and pain scores were assessed, by using FLACC Pain Measuring Scale.

The collected data was analyzed by using descriptive and inferential statistics.

Results:

Majority i.e. 80% (16) children were in the age group of 1-9 months and 20% (04) were in the age group of 10-18 months in Experimental group where as in Control group majority i.e. 70% (14) children were in the age group of 1-9 months and 30% (06) were in the age group of 10-18 months respectively.

With regard to No of Vaccinations i.e. 70% (14) children were Immunized for 01-03 times,15 %(03) were Immunized for 04-06 times, 15 %(03) were Immunized for 07-09 times in Experimental group where as in control group**,** 65% (13**)** were Immunized for 01-03 times,15 %(03) were Immunized for 04-06 times, 20 %(04) were Immunized for 07-09 times respectively.

With regard to type of vaccination 100% (20) of children were vaccinated against Live attenuated Vaccines both in Experimental and Control groups respectively.

With regard to Route of vaccination 100% (20) of children were vaccinated Intra-muscularly both in Experimental and Control groups respectively.

Findings revealed that frequency and percentage distribution of pain scores of children in Experimental and Control groups. 65% (13) children were having moderate pain ,35% (07) of children were having Severe pain in Experimental group, whereas 95% (13) children were having severe pain , 5% (01) of child has no pain in Control group respectively.

Chi- square calculated value is less than table value at 0.05 level of significance for association between Gestational age, Birth weight of child and Order of birth and Feeding performances of Preterm and LBW babies Hence the stated H_{02} was accepted.

Conclusion:

Findings revealed that the Helfer Skin Tap Technique helps in reducing pain in children during Intramuscular injections.

Key terms: Pain, Immunization, Intra-muscular, Immunization clinic, Helfer Skin Tap Technique.

LIST OF CONTENTS

LIST OF TABLES

	children attending to Immunization clinic in Control group	

LIST OF FIGURES

LIST OF ANNEXURES

INTRODUCTION

History will judge us by the difference we make in the everybody lives of children

Nelson Mandela

Pain is an area of active research. Pain is referred to as the fifth vital sign and is the most common discomfort for child patients seeks health care. Subjective in nature, Pain is "whatever the person says it is, whenever he or she says it does[1]."

According to the International Association for the Study of Pain, "Pain is an unpleasant sensory and emotional experience associated with actual or potential

tissue damage. For pediatric patients, medical procedures are often painful, unexpected, and heightened by situational stress and anxiety leading to an overall unpleasant experience. Although the principles of pain evaluation and management apply across the human lifespan, infants and children present unique challenges that necessitate consideration of the child's age, developmental level, cognitive and communication skills, previous pain experiences, and associated beliefs[2].

A child's response to and understanding of pain depends on the child age, state of development and other situational factors. Depending on their developmental stage, children use different coping strategies, such as escape, postponement or avoidance, diversion and imagery to deal with pain[3].

Pediatric pain management is a challenging task and requires utmost care and concern specially non-pharmacological measures from nursing management point of view. The practice of pediatric pain management has made great progress in the last decade with the development and validation of pain assessment tools specific to pediatric patients. Prior to that, adequate assessment and treatment of pediatric pain lagged behind that of adult analgesia due to a lack of clinical knowledge, insufficient pediatric research, and the fear of opioid side effects and addiction. The guidelines

provided by organizations such as the American Pain Society (APS) and the Agency for Health Care Research and Quality (ARQ), as well as mandates issued by the Joint Commission on Accreditation of Healthcare Organizations (JCAHO) led to the inclusion of pediatric analgesic trials to provide evidence-based pain management guidelines in children of all ages. Almost all the major children's hospitals now have dedicated pain services to provide evaluation and immediate treatment of pain in any child. A multimodal approach to preventing and treating pain is usually used[4].

Pain management is an important aspect of child care and nurses play a significant role in the acute care setting in providing pain assessment and treatment. The use of non-pharmacological pain relief techniques has been found to be effective with less side effects and complications associated with them (Rakel and Barr, 2010).

Pain in infants and children is difficult to assess hence it has led to the creation of numerous age-specific pain management tools and scores. Health care workers need to be skilled in detecting the symptoms and signs of pain in different age groups and determine whether these symptoms are caused by pain or other factors[6].

Effective care in pediatrics requires special attention to the developmental stage of the child. Current research does not adequately discuss the effectiveness of pain management strategies in children at various ages. The experience of pain and coping strategies from developmental perspective is also limited. Thus the researcher's aim is to address potential sources of pain measurement, and responses to pain control and distraction based on pediatric developmental stages[5].

NEED FOR STUDY

Pain is the most common symptom reported to health care providers, is a driving force of health care utilization and lost productivity, and exacts a substantial toll on the afflicted, their loved ones, and society in general. Pain is a prevalent symptom not only in primary medical care and specialty pain clinics, but also in mental health and substance dependence treatment settings[6].

Routine immunizations are the most frequent painful medical procedure during childhood. The world health organisation estimates that 12 billion injections

are given annually and that approximately 5% are childhood vaccinations. Vaccine injections are the most common reason for iatrogenic pain in childhood. With the steadily increasing number of recommended vaccinations, there has been a concomitant increase in concern regarding the adequacy of pain management[7].

A fundamental principle of responsible medical care is not 'do not hurt' but 'do no harm' since pain is harmful to children, the caregivers are committed in preventing harm to their patients. Pain is a major source of distress for children and their families as well as health care providers. Thus, HCPs should be aware of these issues and employ techniques to reduce anxiety and pain during vaccinations, an act that may promote adherence to the vaccination schedule[7].

Health care professionals are responsible for eliminating pain suffering in children when possible. To accomplish this, health care professionals need to expand their knowledge , use appropriate assessment tools and techniques, anticipate painful experiences and intervene accordingly, use a multimodal approach to pain management, use a multidisciplinary approach when possible, involve families and advocate for the use of effective pain management in children. A standardized but flexible approach is necessary to assess the child's pain. Pain assessment is a continuous process[8].

Finally, the improvement of pain assessment in the clinical assessment in the clinical setting can be viewed as a patient care quality issue, and continuous quality improvement methods can be effectively to incorporate pain assessment as an integral component of every child's health care[9].

Studies reveal that nondrug methods of pain management do the following, diminish pain perception by reducing intensity and increasing pain

tolerance, reduce pain-related distress, strengthen coping abilities; and give the child and family a sense of control over pain. Traditionally, pain management tends to emphasize the use of pharmacological agents. However, pain is influenced by an array of physical and psychosocial factors, and children differ in their response to pain and to analgesics. Therefore, it is important to have a range of options, including non-pharmacological therapies available, in order to manage children pain effectively[10].

CHAPTER--2

OBJECTIVES

This chapter deals with the statement of the problem, objectives of the study, operational definitions, hypothesis, conceptual framework which provides a frame of reference of reference of study.

STATEMENT OF THE PROBLEM

"A Study to Evaluate the Effectiveness of Helfer Skin Tap technique on Pain during Intra muscular injection among children attending Immunization clinic at selected Hospital, Kolar, Karnataka"

OBJECTIVES OF THE STUDY

1. To Evaluate the Effectiveness of Helfer Skin Tap technique on Pain by using pain scale.

2. To determine the association with level of pain during Immunization with number of vaccinations, age of child and type of vaccine.

HYPOTHESES

Ho_1 : There will be no significant difference in level of pain among children between experimental and control group.

Ho_2 : There will be no significant association between level of pain with selected socio demographic variables.

OPERATIONAL DEFINITIONS

1. Effectiveness: In this study it refers to the level of reduction of pain after using Helfer skin tap technique during Intra muscular injection.

2. Pain: In this study Pain refers to an unpleasant subjective sensation caused by the intramuscular injection which is measured by FLACC (Face, Legs, Activity, Cry, Consolobility) Pain scale and interpreted as mild, moderate and severe pain.

3. **Helfer skin tap technique:** Helfer Skin Tap technique refers to stretching the gluteus maximus muscle by making a wide V with thumb and the rest of the fingers of the non-dominant hand, over the buttocks and taping the skin with middle, ring and little finger of the dominant hand by counting 1, 2, 3 and inserting the needle just after that.

4. Children*:* In this study children refers to children who are in the age group of 1 – 3 yrs. and attending to Immunization clinic.

CONCEPTUAL FRAMEWORK:

Concepts are building blocks of a theory. Conceptual framework deals with abstractions (concepts) that are assembled by virtue of their relevance to common theme. Conceptualization is a process of forming ideas, which is utilized and form conceptual framework for the development of research design. It helps the researcher by giving direction to about the entire research process[11].

Conceptual frame work adopted to this study is Gate control theory of pain.

Gate control theory of pain: The gate control theory of pain was proposed in (1965) by Melzack and Wall. This theory states that pain impulses from the periphery travel to the gray matter in the dorsal horn of the spinal cord, where a "gating" mechanism exists, called the substantiagelatinosa, which can either open or close the transmission of pain impulses to the brain. The gating activity depends on the amount of stimulation received from facilitatory fibers and inhibitory fibers.

Inhibitory fibers: Are those which block the signal in the projection neuron which connects to the brain. The "gate is closed", and therefore no pain.

Facilitatory fibers: Are those which activate the signal in the projection neurons which connects to the brain. The "gate is open", and therefore pain is present.

Gate control: It is that which has got both inhibitory fibers and facilitatory fibers, in which it acts as an opening and closing of the gate depending on the pain signals which they receive.

If more inhibitory fibers are stimulated than the facilitatory fibers, then the gate is closed and pain transmission is inhibited.

If more facilitatory fibers are stimulated than the inhibitory fiber, then the gate is opened and pain transmission is facilitated.

The gate control theory emphasizes the probability that there is an inhibitory system within the brain stem that also acts as a "gate" inhibiting pain transmission. This brain stem inhibitory circuit involves structures in the midbrain, medulla and spinal cord. Activation of cells in the midbrain's periqueductal gray matter, in turn stimulates structures in the medulla. These medularry structures then project to and inhibit spinal pain transmission fibers[13].

Based on the principles of gate control theory the following conceptual framework was formed. Distraction technique used was Helfer skin tap technique during vaccination, brings about diversion of the child's mind from pain, in which Inhibitory fibers, closes the gate and blocks the pain sensations, thereby reducing the intensity and diminishing the pain perception as, only minimum amount of pain reaches the sensory cortex.

Pain transmission can also be altered by thoughts, feelings and memories. There is conscious control over how pain is perceived and this helps to explain the various ways that children react and adjust to the pain. When modalities of distraction and pain applied simultaneously, the child will get less cognitive perception towards the pain process during the painful procedure" closes the gate" in the brain, limiting the amount of pain perceived by the brain, thereby reducing the pain intensity experienced.

Hence Helfer Skin Tap technique is used as distraction to alter thought, feelings and memory of children, which inhibits pain transmission and reduces the pain intensity. This promotes child's coping during painful procedure, thereby reducing the deleterious effects of pain.

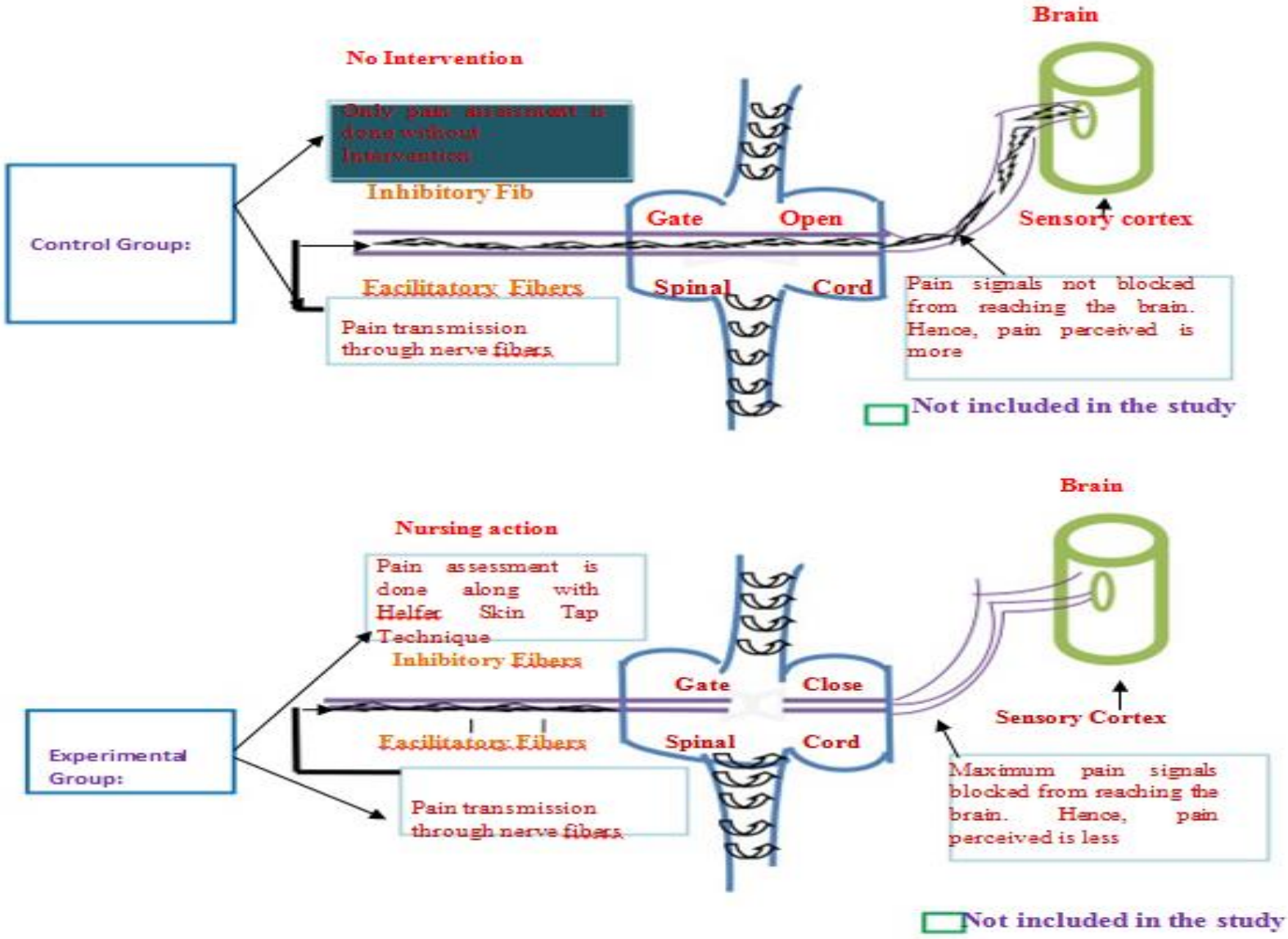

Figure 1: Conceptual frame work adopted from Gate control theory of pain by Melzack and Wall (1965)

CHAPTER-3

REVIEW OF LITERATURE

This chapter deals with selected studies which are related to the objectives of the proposed study. A review of research and non- research literature relevant to the study was undertaken which held the investigator to develop deeper insight into the problem and gain information on what have been done in the past.

Review of literature is a key step in the research process. Review of literature is defined as a broad comprehensive, in depth, systematic and critical review of scholarly publications, unpublished scholarly publications audio-visual materials and personal communications. It refers to extensive, exhaustive and systematic examinations of publications relevant to the research project[12]

Review of literature on the research topic makes the researcher familiar with the existing studies and provides information which helps to focus on a particular problem and lays a foundation upon which to base a new knowledge [12]. The related literature review was done from journals, research articles, books, unpublished dissertations, PubMed and Medline.

REVIEW OF LITERATURE

Review of relevant and related literature will be done and organized under the following headings

- Literature related to level of pain during Intra-muscular injection among children.

- Literature related to Effectiveness of diversional therapy in reduction of pain during Intra-muscular injection among children.

Literature related to level of pain during Intra-muscular injection among children.

Comparative study was conducted at Victoria Hospital, Bangalore Medical College and Research Centre, Bangalore, Karnataka, India in 2012, to assess The perception of intramuscular injection pain in men vs women. 300 subjects 140 men and 160 women. Subjects included both men and women in the age group 15 to 45 years. Subjective pain was assessed using Visual Analog Scale(VAS) on 0 (no pain) – 10 (maximum pain) scale All subjects received multivitamin intramuscular injections (3 ml) in the gluteal region using 23G needle. Intra-muscular injections were administered by trained and experienced professional nurses. Subjective pain was assessed using VAS on 0 (no pain) – 10 (maximum pain) scale in the subjects and were compared.. Statistical Analysis of data were analysed by SPSS 15.0, stata 8.0, Med Calc 9.01 and Systat 11.0.Results on continuous measurements were presented as Mean ± SD (Min-Max) and results on categorical measurements are presented in Number (%). Significance is assessed at 5% level of significance. Mann Whitney U test (two tailed, independent) has been used to find the significance of study parameters on continuous scale between men and women (inter group analysis). Using Mann Whitney U test (two tailed, independent), a moderately significant higher pain scores were observed in women (1.94 ± 1.10) as compared to men (1.74 ± 1.24) (p = 0.060) . Also statistically significant higher pain scores were observed in women (2.24 ± 1.19) as compared to men (1.71 ± 1.06) in the age group of 21-30 (p = 0.036). Pain perception is characterized by tremendous individual differences and influenced by multiple bio psycho social variables, ethnicity and gender[13].

Quantitative approach and experimental design, cross over design. was conducted to assess the Effectiveness of Helfer Skin Tap Technique and Routine Technique on Pain Reduction among Patients Receiving Intramuscular Injection at Government General Hospital, Puducherry by Simple random sampling technique(lottery method), 25 subjects were first assigned for intramuscular injection using Helfer Skin Tap Technique followed by

Routine Technique for the next dose of injection and other 25 subjects were first assigned for intramuscular injection using Routine Technique followed by Helfer Skin Tap Technique for the next dose of injection. The subjects were examined with 4 variables viz pain, systolic and diastolic blood pressure and pulse rate. The intervention was implemented for four continuous days for both the groups. "t – Test" was used to compare the pain level and physiological parameters between Helfer Skin Tap Technique and Routine Technique, and it is significant if ($p<0.05$). The results show that on the day 1, the obtained t value was 2.01 at p level of 0.05. On the day 2, the obtained t value was 2.33 at p level of 0.02. On the day 3 & 4, the obtained t value was 2.76 at p level of 0.01. study concludes that Helfer skin tap technique is statistically significant than routine technique on all the 4 days[14].

An exploratory study was conducted in Ohio on58 Children's (3-6 years) who are undergoing painful procedure in nursing homes was investigated by using FLACC pain scale. Four nurses simultaneously, but independently, observed and scored pain behaviors twice in 58 children: before administration of an analgesic or during a painful procedure, and 15 to 30 minutes after the procedure. Two nurses used the FLACC scale; and the other two used the Checklist of Nonverbal Pain Indicators. For 60 observations, FLACC scores correlated highly when compared with the other 2 scores ($\rho = 0.945$ and 0.834, respectively), supporting criterion validity. Significant decreases in FLACC scores after analgesia supported validity of the tool (mean, 5.15; SD, 2.1vs mean, 0.49; SD, 1.4; $P< .005$)[15].

A comparative study was done in Chicago on child's self report, to test the validity of the Faces, Legs, Activity, Cry and Consolability (FLACC) Behavioral Pain Assessment Scale for use with children. 30 children aged 3-7 years who had undergone a variety of surgical procedures were observed and assessed for pain intensity at 20 + 2 hours after surgery. FLACC scores were assigned by one of the nurse investigators, and a self-report of

pain was obtained from the child. There were significant and positive correlations between the FLACC and self report scores for the entire sample. The interaction was significant (F = 5.04, p< 0.001)[16]

An evaluative study was conducted in Netherland on reliability and validity of FLACC pain scale in assessing acute pain in critically ill patients. Three nurses simultaneously, but independently, observed and scored pain behaviors twice in 29 critically ill adults and 8 children: before administration of an analgesic or during a painful procedure, and 15 to 30 minutes after the procedure. Two nurses used the FLACC scale; the third used the Checklist of Nonverbal Pain Indicators (for adults and children). For 73 observations, FLACC scores correlated highly compared to the other score (ρ = 0.963 and 0.849, respectively), supporting criterion validity. Significant decreases in FLACC scores after analgesia (or at rest) supported construct validity of the tool (mean, 5.27; SD, 2.3 vs mean, 0.52; SD, 1.1; P< .001)[17].

A descriptive study was conducted on 60 preschool children in Bangladesh who were reported to be easily completed and scored in analog situation, for measuring children's pain and coping style during actual painful medical procedures by using FLACC pain scale. 60 preschool children who were receiving immunizations at a health department were subjects. Objective measures (FLACC pain scale) and subjective measures (child, parent, and nurse-report) were used[18].

Literature related to Effectiveness of diversional therapy in reduction of pain during Intra-muscular injection among children:

A Randomized clinical trial study was conducted, a comparative study on vaccination pain in the methods of massage therapy and mothers' breast feeding during injection of infants referring to Navabsafavi Health Care Center in Isfahan, during April — July 2011. Ninety-six infants were allocated randomly and systematically to three groups (breast feeding, massage, and control groups). The study population comprised all infants, accompanied by their mothers, referring to one of the health centers in Isfahan for vaccination of hepatitis B and DPT at 6 months of age and for MMR at 12 months of age. Data gathering was done using questionnaire and checklist [neonatal infant pain scale (NIPS)]. Data analysis was done using descriptive and inferential statistical methods with SPSS software. Findings of the study showed that the three groups had no statistically significant difference in terms of demographic characteristics ($P>$ 0/05). The mean pain scores in the breast feeding group, massage therapy, and control group were 3.4, 3.9, and 4.8, respectively ($P<$ 0.05). Then the least significant difference (LSD) *post hoc* test was performed. Differences between the groups, i.e. massage therapy and breast feeding (P = 0.041), breast feeding group and control ($P<$ 0.001), and massage therapy and control groups (P = 0.002) were statistically significant.Considering the results of the study, it seems that breast feeding during vaccination has more analgesic effect than massage therapy. Therefore, it is suggested as a noninvasive, safe, and accessible method without any side effects for reducing vaccination-related pain[19].

Quasi-experimental design was conducted to assess The effect of using musical mobiles on reducing pain in infants during vaccination at a primary healthcare center in the east of Turkey..from January 1 to May 15, 2008sample size of 120, two-month-old, healthy infants, who were presented to the healthcare center for their first Diphtheria, acellular Pertussis, Tetanus, Inactivated Polio, Haemophilus Influenza type b (DPT-IPV-Hib) combined vaccination between 1 January and 15 May 2008. The infants were divided into the

control and test groups, and were to receive vaccination in a room furnished with or without a musical mobile. In the healthcare center, vaccination procedures are normally performed on two consecutive days every week. Infants who came in first place to the healthcare center for vaccination were assigned to the test group and infants who came in second place to the center were assigned to the control group. It was lasted in this way. For both groups, the injections were administered by the same staff nurse from the primary healthcare center. The data were collected between January 1 and May 15, 2008. The question form and FLACC Pain Scale were used in data collection and the infants' responses to the procedure were video recorded. Data analysis was done by usingSPSS 11.0 version computer program was used. Statistical significance was considered at a *P*-value less than 0.05. Study concluded that, a musical mobile with both visual and auditory elements is a validated and reliable observational measure and a practical way of distracting infants from vaccination pain[20].

quasi experimental post-test only control group design, was conducted, To assess the effectiveness of diversion therapy on pain among infants receiving injections in a selected Primary Health Centre at Mangalore, population comprised of children in the age group of 1 ½ -4 months who were undergoing parenteral immunisation. The sample size was 60 infants, 30 each in the control and experimental groups. Purposive sampling technique was used to select the sample.Samples in the experimental group were given diversion therapy before during and after the injection. Tools used were Neonatal Infant Pain Scale (used with permission) The independent variable (diversion therapy -bright colored sound producing rattle) was introduced into the experimental group prior to the injection. The parents were holding the infants, and the infants were encouraged to touch and hold the rattle. In the control group, the parents were holding the infants and giving standard care (cuddling, holding the baby close) .The pain was observed by the investigator during and after the procedure. The entire study sample experienced severe pain during injection but after the

injection, majority of the samples (86.66%) in the control group experienced moderate pain and 13.34% experienced severe pain. In the experimental group majority (83.34%) were found to have moderate pain and 16.66% experienced mild pain[21].

An Experimental study was conducted on 69 children aged 2-6 years undergoing venipuncture. The children were randomly divided into three groups: a control group (C) without any distraction procedure, a group (M) in which mothers performed active distraction, and a TV group (TV) in which passive distraction (a TV cartoon) was used. Both mothers and children scored pain after the procedure. Scores assigned by mothers and children indicated that procedures performed during TV watching were less painful ($p<0.05$) than control or procedures performed during active distraction. TV watching was more effective than active distraction[22].

An Experimental study was conducted among 62 children's to, Watch TV as audiovisual Distraction in Preschool Immunization, they were randomly assigned to watch television (TV) (N = 29) or a blank TV screen (control) (N = 33) during immunization, and were videotaped. Videotapes were coded for pain behaviors and for distraction. "T" tests determined between-group mean differences and chi-square tests compared proportions for clinically significant self-reported pain. 5 year-old children (N = 62), undergoing diphtheria, polio, tetanus, and pertussis immunization, and their parents. An age-appropriate musical cartoon or a blank TV screens. Pain measurements were the children's self-reports on Faces Pain Scale, facial actions on Child Facial. The relative risk estimate for clinically significant pain among the distraction group was 0.64 (range: 0.23–1.80). Higher levels of distraction (i.e., greater time looking at the TV screen) related to lower levels of pain on all three pain measures. Conclusion watching cartoons distract children during needle injection and reduce their pain[23]

CHAPTER -4

METHODOLOGY

This chapter deals with the methodology selected for the study. It includes research approach, research design, variables, setting of the study, population, sample and sampling technique, sampling criteria, selection of the tool, performing Helfer Skin tap technique, procedure of data collection and plan for data analysis.

Research Approach:

Quantitative approach is the basic procedure for the research inquiry. The research approach helps the researcher to determine what data to collect and how to analyze it[24].

The present study aimed at determining the the Effectiveness of Helfer Skin Tap technique on Pain during Intra muscular injection among children attending Immunization clinic at selected Hospital at Selected Hospital, Kolar, Karnataka.

Research Design:

Research design is the arrangement of conditions for collection and analysis of data in a manner that aims at the research purpose with economy in procedure.

In this study quantitative approach with True Experimental (posttest only with control group) design was adopted.

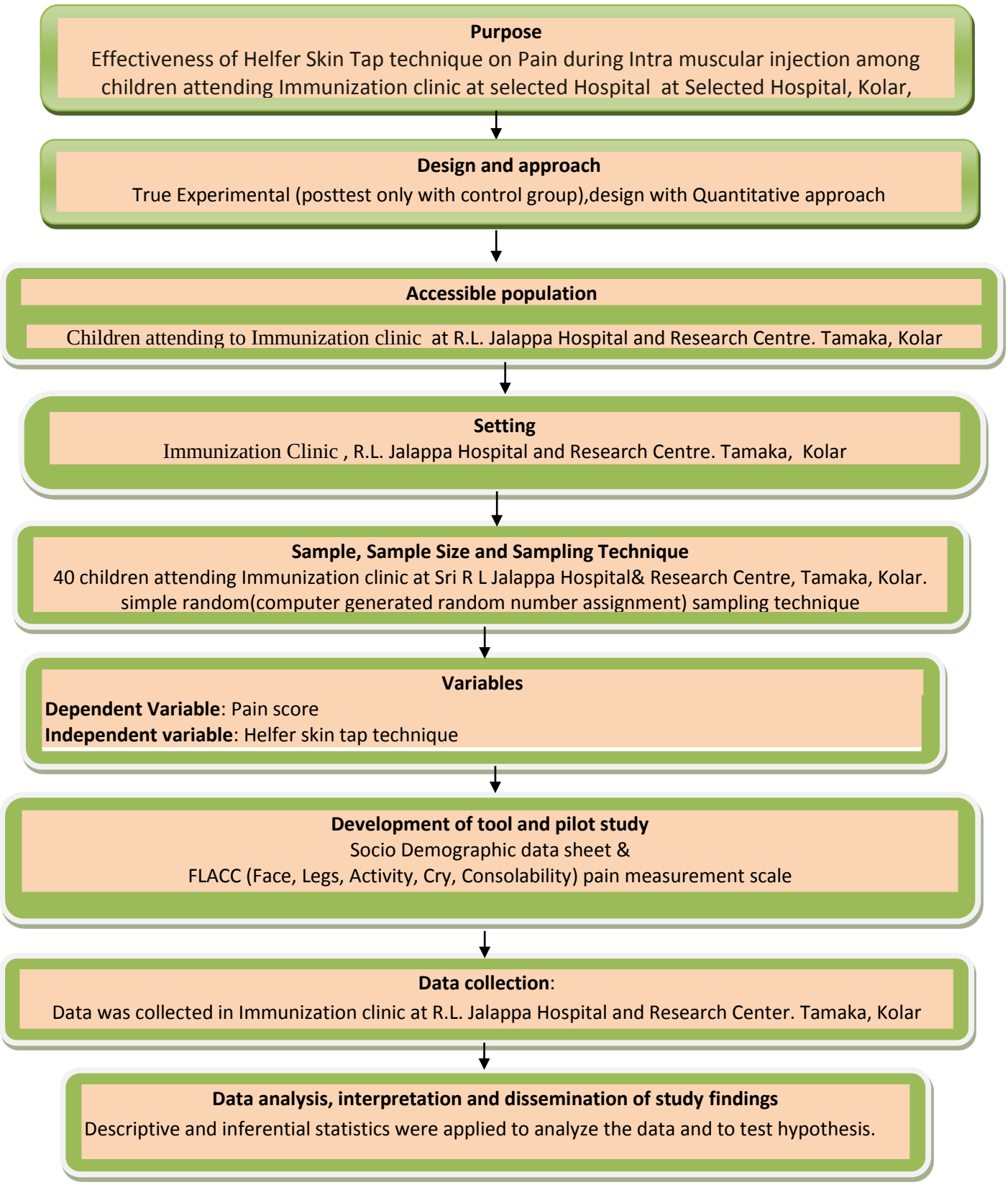

Fig.2: Schematic Representation of the Study Research Design

Variables

Variables are qualities, properties, characteristics of persons, things, situation that change or vary[12].

Independent Variable:

Independent variable is the variable that stands alone and does not depend on any other. In this study, Helfer Skin Tapping technique was the independent variable[12].

Dependent Variable:

The dependent variable is the variable the researcher is interested in understanding, explaining or predicting[12].

In this study, it refers to the pain in children due to Intramuscular Injection.

Extraneous Variable:

All those variables which are present in the research environment that may interfere with research findings[12].

In this study it refers to the selected variables like Age of child in months, No.of vaccines (in No), Type of Vaccines, Route of Vaccines.

Setting of the study:

Setting is the physical location and condition in which data collection takes place.

The study was conducted at Immunization Clinic of R.L Jalappa Hospital and Research centre, Tamaka, Kolar. RLJH&RC is an multi-Specialty Hospital with 1200 bed strength. Immunization clinic runs on every day, with minimum of 50 children attends per week.

Population

The term population refers to the aggregation of all the units in which a researcher is interested[25].

In this study the population refers to children undergoing Immunization.

The sample of the study comprises of children between 1-3 years age.

Sample:

The sample may be defined as representative unit of a target population, which is to be worked upon by researcher during their study[25].

Sampling Technique:

Sampling technique is the process of selecting a portion of the population to represent the entire population[25].

Simple random (computer generated random number assignment) sampling technique and following inclusion criteria

Criteria for Selection of Samples:

Inclusion criteria

1. Children attending Immunization clinic.

2. Parents willing to participate in the study.
3. Parents who are able to understand and respond in English, Telugu and Kannada Language.

Exclusion criteria: Children who

1. Have received any analgesics less than six hours before the procedure
2. Mothers who are not willing to participate.

Selection and development of the tool:

Data collection tool is the procedure or instrument used by the researcher to observe or measure the key variables in the research problem[25].

Data collection tool used in this study consists of two sections.

Section. A: Socio demographic data.

Section.B: FLACC –Pain Measuring Scale, Comprises of Face, Legs, Activity, Cry, Consolability.

Tool developer: Merkel, S.I., Voepel-Lewis, T., Shayevitz, J.R., Malviya S., 1997, USA

It is a behavioral scale for measuring the intensity of post procedural pain in young children. It includes five indicators (face, legs, activity, cry, and Consolability) with each item ranking on a three point scale (0–2) for severity by behavioral descriptions resulting in a total score between 0–10. FLACC is an easy and practical scale to use in evaluating and measuring pain especially in pre-verbal children from 2 months to 7 years. Numerous studies have proven its validity and reliability34.

Interpreting the Score:

0 = Relaxed and Comfortable

1-3 = Mild discomfort

4-6 = Moderate pain

7-10= Severe pain or discomfort or both

Reliability of FLACC pain scale

Reliability test for stability was analyzed by inter-rater reliability by using the correlation co-efficient formula with 10 samples obtained 'r' value was 0.99.Thus the tool was found to be reliable in terms of stability.

Pilot Study:

Pilot study is the small scale version/trial run, done in preparation of the main study

The main objective of the pilot study is to help the researcher to become familiar with the use of tool and find out the difficulty to conduct the main study. The pilot study was conducted at Sri R.L. Jalappa Hospital and Research Centre, Kolar from **03-06-18 to 10.06-18.**

The researcher did not encounter any problems during the time of data collection and the study was found feasible and practicable.

Method of data collection

Data collection is the process of selecting subjects and gathering data from these subjects.

The data was collected from **20-06-2018 to 20-07-2018** over a period of 30 days. The time schedule for data collection was every day from 10 am to 4 pm. The data was collected under the following phases:

1. **Preparatory Phase**

- Ethical clearance was obtained from the institutional ethics committee of Sri Devaraj Urs College of Nursing
- A formal written permission was obtained from Medical Superintendent of Sri R.L. Jalappa Hospital and Research Centre.
- The sample was selected and allotted to experimental group and control group by using Simple Random(computer generated random number assignment) sampling technique and following inclusion criteria

Data Collection Phase.

Children attending to Immunization clinic were selected and placed into Experimental and Control group based on Inclusion criteria.

Concent was taken from mothers of Children in Experimental group and prepared for vaccination, positioned the child, identified the site and started tapping at Injection site for 3mts before, during and after vaccination. Pain scores were assessed by video recording from the time of initiating the intervention, till completion.Then the video was analyzed by using FLACC Pain Measuring Scale.

For the babies of control group ,routine steps of vaccination were followed and pain scores were assessed, by using FLACC Pain Measuring Scale.

Plan for data analysis:

The analysis of data requires a number of close operations such as establishment of categories, the application of these categories to raw data through coding, tabulation and then drawing statistical inference.

The data obtained was analyzed by descriptive and inferential statistics in achieving the objectives of the study.

- Organization of data in master sheet.
- To analyze demographic characteristics. Frequencies, percentages, Mean, were used
- To analyze effectiveness of Helfer skin Tap technique on pain reduction independent t-test will be used.
- Chi-square analysis will be done to determine association between socio demographic variables and pain reduction in children attending to Immunization clinic.

Summary:

This chapter deals with the methodology, research approach, research design, setting, population, sample, sampling technique, description of the tool, reliability of the tool, pilot study, method of collection, data collection procedure and plan for data analysis. The analysis and interruption of the results have been presented in the following chapter.

CHAPTER-5

RESULTS

This chapter deals with analysis and interpretation of data gathered to determine the Effectiveness of Helfer Skin Tap technique on Pain during Intra muscular injection among children attending Immunization clinic.

Analysis of data can be defined as the systematic organization and synthesis of research data and the testing of research hypothesis using the data. Analysis is described as categorization, ordering, manipulating, and summarizing the data to obtain the answer to the research question. The purpose of analysis is to reduce the data to an intelligible and interpretable form so that the relation of research problem can be studied[32].

The data has been analyzed and interpreted in the light of the objectives and Hypothesis of the study.

Objectives of the Study:

1. To Evaluate the Effectiveness of Helfer Skin Tap technique on Pain by using pain scale.

2. To determine the association with level of pain during Immunization with number if vaccinations, age of child and type of vaccine.

Null Hypotheses:

Ho_1 : There will be no significant difference in level of pain among children between experimental and control group.

Ho_2 : There will be no significant association between level of pain with selected socio demographic variables.

Organization of findings:

The data was analyzed and presented under the following headings.

Section I: Socio demographic characteristics of children attending to Immunization Clinic

Section II: Pain scores of children in Experimental and Control group before and after intervention

Section III: Comparison of Mean scores of Pain between Experimental and Control group

Section IV: Association between pain scores and socio demographic variables of children attending to Immunization clinic.

Section I: Socio Demographic Characteristics of Children attending to Immunization Clinic.

Table-1: Frequency and percentage distribution of socio demographic variables

N=40

Sl.No	**Socio demographic variables**	**Experimental group($n_{1=20}$)**		**Control group($n_{2=20}$)**	
		Frequency	**Percentage (%)**	**Frequency**	**Percentage (%)**
1	Age of child (in months)				
	a.01-09	16	80	14	70
	b.10-18	04	20	06	30
	c.19-27	-	-	-	-
	d.28-36	-	-	-	-
2	No.of vaccines (in. No)				
	a.01-03	14	70	13	65
	b.04-06	03	15	03	15
	c.07-09	03	15	04	20
	d.10-36	-	-	-	-
3	Type of Vaccines				
	a. live attenuated	20	100	16	80
	b. killed vaccines	-	-	04	20
4	Route of vaccination				
	a. Intra-muscular	20	100	20	100
	b.Subcutaneous	-	-	-	-
	c. Intra-venous	-	-	-	-
	d. others	-	-	-	-

Table 1: shows that majority i.e. 80% (16) children were in the age group of 1-9 months and 20% (04) were in the age group of 10-18 months in Experimental group where as in Control group majority i.e. 70% (14) children were in the age group of 1-9 months and 30% (06) were in the age group of 10-18 months respectively.

With regard to No of Vaccinations i.e. 70% (14) children were Immunized for 01-03 times,15 %(03) were Immunized for 04-06 times, 15 %(03) were Immunized for 07-09 times in Experimental group where as in control group**,** 65% (13**)** were Immunized for 01-03 times,15 %(03) were Immunized for 04-06 times, 20 %(04) were Immunized for 07-09 times respectively.

With regard to type of vaccination 100% (20) of children were vaccinated against Live attenuated Vaccines both in Experimental and Control groups respectively.

With regard to Route of vaccination 100% (20) of children were vaccinated Intra-muscularly both in Experimental and Control groups respectively.

Section II: Pain scores of children in Experimental and Control group before and after intervention+

Table 2: Frequency and Percentage distribution of Pain Scores of Children in Experimental and Control group

N=40

Pain Score Ratings	Experimental group N(20)		Control group N(20)	
	Frequency	**Percentage (%)**	**Frequency**	**Percentage (%)**
0-No pain	-	-	01	05
1-3 Mild Discomfort	-	-	-	-
4-6 Moderate Pain	13	65	-	-
7-10 Severe pain/no pain/both	07	35	19	95

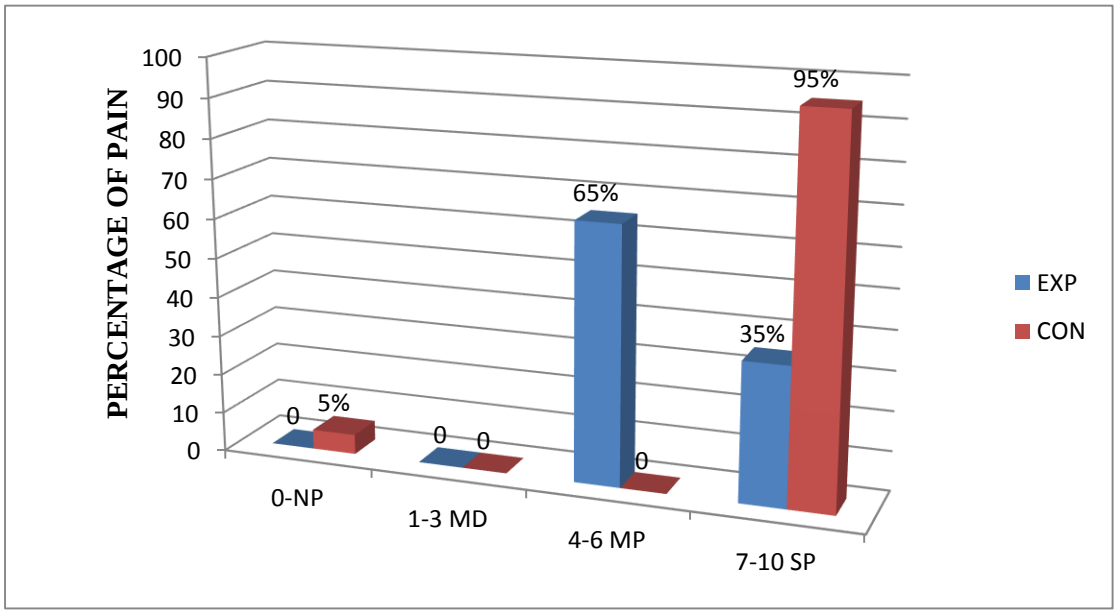

Figure: 3 Column Diagram showing mean pain scores among children attending Immunization clinic in Experimental and Control groups.

Findings revealed that frequency and percentage distribution of pain scores of children in Experimental and Control groups. 65% (13) children were having moderate pain ,35% (07) of children were having Severe pain in Experimental group, whereas 95% (13) children were having severe pain , 5% (01) of child has no pain in Control group respectively.

Section III: Comparison of Mean scores of Pain between Experimental and Control group

Table 3: Comparison of Mean scores of Pain between Experimental and Control group

N=40

Group	Mean	S.D	t-value	df	p-value	Inference
Exp.Group N_1=20	6.30	0.571	22.75	38	.024	SS
Con.Group N_2=20	7.30	1.809				

Table 3: Presents the mean Pain score of Experimental group was 6.30 with SD of 0.571, where as in Control group 7.30 with SD of 1.809 respectively at 38 df and calculated't'-value was 22.75 which is less than table value at 0.05 level of significance indicating statistically significant. Hence the stated null hypothesis is rejected.

Section IV: **Association between pain scores and socio demographic variables of children attending to Immunization clinic**.

Table 4: Association between pain scores and socio demographic variables of children attending to Immunization clinic in Experimental group

N=40

Sl.no	Socio demographic variables	Pain scores		χ^2 Calculated value(at 0.05 levels)	p-value	df	Inference
		Below & equal to median **06**	Above median				
1	Age of Child in months 1-9	9	7	1.11	3.84	01	NS
	9 and above	4	-				
2	No of vaccines in No's 1-3	8	6	3.58			NS
	3 and above	5	1				
3	Type of vaccine Live attenuated	13	7	0.17			NS
	Killed	-	-				
4	Route of vaccination I.M	13	7	0.17			NS
	Others	-	-				

Table 4 indicates that, chi- square calculated value is less than table value at 0.05 level of significance for Age of Child, No. of vaccinations in No's, Type of Vaccination and Route of vaccination. Hence the stated H_{02} is accepted.

Table 5: Association between pain scores and socio demographic variables of children attending to Immunization clinic in Control group

N=40

Sl.no	Socio demographic variables	Pain scores		χ^2 Calculated value(at 0.05 levels)	p-value	df	Inference
		Below & equal to median **06**	Above median				
1	Age of Child in months 1-9	13	1	0.12	3.84	01	NS
	9 and above	6	-				
2	No of vaccines in No's 1-3	12	1	0.25			NS
	3 and above	7	-				
3	Type of vaccine Live attenuated	15	1	0.01			NS
	Killed	4	-				
4	Route of vaccination I.M	19	1	3.36			NS
	Others	-	-				

Table 5 indicates that, chi- square calculated value is less than table value at 0.05 level of significance for Age of Child, No. of vaccinations in No's, Type of vaccination and Route of vaccination. Hence the stated H_{02} is accepted.

Summary:

This chapter dealt with the analysis and interpretation of findings of the study. The data was analyzed by using inferential and descriptive statistics. The analysis has been organized and

presented under various sections like description of demographic variables, description of pain score before and after intervention, with their selected socio demographic variables

DISCUSSION

This chapter presents the major findings of the study and discusses them in relation to similar studies conducted by other researchers.

The aim of this study was to evaluate the Effectiveness of Helfer skin tap technique to assess the pain of children undergoing vaccination intramuscularly. Data collection and analysis were carried out based on the objectives of the study.

Objectives of the study:

1 To Evaluate the Effectiveness of Helfer Skin Tap technique on Pain by using pain scale.

2. To determine the association with level of pain during Immunization with number if vaccinations, age of child and type of vaccine.

Major findings of the study:

1. Socio demographic characteristics:

1. Majority i.e. 80% (16) children were in the age group of 1-9 months in Experimental group where as in control group 70 %(14) children were in the age group of 1-9 months.
2. Majority i.e. 70% (14) children were Immunized for 01-03 times in Experimental group where as in control group. 65% (13**)** were immunized for 01-03 times.
3. With regard to type of vaccination 100% (20) of children were vaccinated against Live attenuated Vaccines both in Experimental and Control groups respectively.
4. With regard to Route of vaccination 100% (20) of children were vaccinated Intra-muscularly both in Experimental and Control groups respectively.

The first objective of the study was**, To Evaluate the Effectiveness of Helfer Skin Tap technique on Pain by using pain scale.**

The findings (Table 3) revealed that the mean Pain score of Experimental group was 6.30 with SD of 0.571, where as in Control group 7.30 with SD of 1.809 respectively at 38 df and calculated 't'-value was 22.75 which is less than table value at 0.05 level of significance indicating statistically significant in pain scores between Experimental and Control groups. Hence the stated null hypothesis $H_{01}$is rejected.

Quantitative approach and experimental design, cross over design. was conducted to assess the Effectiveness of Helfer Skin Tap Technique and Routine Technique on Pain Reduction among Patients Receiving Intramuscular Injection at Government General Hospital, Puducherry by Simple random sampling technique(lottery method), 25 subjects were first assigned for intramuscular injection using Helfer Skin Tap Technique followed by Routine Technique for the next dose of injection and other 25 subjects were first assigned for intramuscular injection using Routine Technique followed by Helfer Skin Tap Technique for the next dose of injection. The subjects were examined with 4 variables viz pain, systolic and diastolic blood pressure and pulse rate. The intervention was implemented for four continuous days for both the groups. "t – Test" was used to compare the pain level and physiological parameters between Helfer Skin Tap Technique and Routine Technique, and it is significant if ($p<0.05$). The results show that on the day 1, the obtained t value was 2.01 at p level of 0.05. On the day 2, the obtained t value was 2.33 at p level of 0.02. On the day 3 & 4, the obtained t value was 2.76 at p level of 0.01. study concludes that Helfer skin tap technique is statistically significant than routine technique on all the 4 days[14].

An exploratory study was conducted in Ohio on58 Children's (3-6 years) who are undergoing painful procedure in nursing homes was investigated by using FLACC pain scale. Four nurses simultaneously, but independently, observed and scored pain behaviors twice in 58 children: before administration of an analgesic or during a painful procedure, and 15 to 30 minutes after the procedure. Two nurses used the FLACC scale; and the other two used the Checklist of Nonverbal Pain Indicators. For 60 observations, FLACC scores correlated highly when compared with the other 2 scores ($\rho = 0.945$ and 0.834, respectively), supporting criterion validity. Significant decreases in FLACC scores after analgesia supported validity of the tool (mean, 5.15; SD, 2.1vs mean, 0.49; SD, 1.4; $P< .005$)[15].

The second objective of the study was **to determine the association with level of pain during Immunization with number if vaccinations, age of child and type of vaccine.**

The findings (Table 4&5) revealed that, chi- square calculated value is less than table value at 0.05 level of significance for association between Age of Child, No. of vaccinations in No's, Type of vaccination and Route of vaccination, of children attending to Immunization clinic, indicating statistically not significant. Hence the stated null hypothesis H_{02} is accepted.

A Randomized clinical trial study was conducted, a comparative study on vaccination pain in the methods of massage therapy and mothers' breast feeding during injection of infants referring to Navabsafavi Health Care Center in Isfahan, during April — July 2011. Ninety-six infants were allocated randomly and systematically to three groups (breast feeding, massage, and control groups). The study population comprised all infants, accompanied by their mothers, referring to one of the health centers in Isfahan for vaccination of hepatitis B and DPT at 6 months of age and for MMR at 12 months of age. Data gathering was done using questionnaire and checklist [neonatal infant pain scale (NIPS)]. Data analysis was done using descriptive and inferential statistical methods with SPSS software. Findings of the study showed that the three groups had no statistically significant difference in terms of demographic characteristics (P> 0/05). The mean pain scores in the breast feeding group, massage therapy, and control group were 3.4, 3.9, and 4.8, respectively (P< 0.05). Then the least significant difference (LSD) *post hoc* test was performed. Differences between the groups, i.e. massage therapy and breast feeding (P = 0.041), breast feeding group and control (P< 0.001), and massage therapy and control groups (P = 0.002) were statistically significant.Considering the results of the study, it seems that breast feeding during vaccination has more analgesic effect than massage therapy. Therefore,

it is suggested as a noninvasive, safe, and accessible method without any side effects for reducing vaccination-related pain[19].

Quasi-experimental design was conducted to assess The effect of using musical mobiles on reducing pain in infants during vaccination at a primary healthcare center in the east of Turkey..from January 1 to May 15, 2008sample size of 120, two-month-old, healthy infants, who were presented to the healthcare center for their first Diphtheria, acellular Pertussis, Tetanus, Inactivated Polio, Haemophilus Influenza type b (DPT-IPV-Hib) combined vaccination between 1 January and 15 May 2008. The infants were divided into the control and test groups, and were to receive vaccination in a room furnished with or without a musical mobile. In the healthcare center, vaccination procedures are normally performed on two consecutive days every week. Infants who came in first place to the healthcare center for vaccination were assigned to the test group and infants who came in second place to the center were assigned to the control group. It was lasted in this way. For both groups, the injections were administered by the same staff nurse from the primary healthcare center. The data were collected between January 1 and May 15, 2008. The question form and FLACC Pain Scale were used in data collection and the infants' responses to the procedure were video recorded. Data analysis was done by usingSPSS 11.0 version computer program was used. Statistical significance was considered at a *P*-value less than 0.05. Study concluded that, a musical mobile with both visual and auditory elements is a validated and reliable observational measure and a practical way of distracting infants from vaccination pain[20].

Quasi experimental post-test only control group design, was conducted, To assess the effectiveness of diversion therapy on pain among infants receiving injections in a selected Primary Health Centre at Mangalore, population comprised of children in the age group of 1 ½ -4 months who were undergoing parenteral immunisation. The sample size was 60 infants,

30 each in the control and experimental groups. Purposive sampling technique was used to select the sample.Samples in the experimental group were given diversion therapy before during and after the injection. Tools used were Neonatal Infant Pain Scale (used with permission) The independent variable (diversion therapy -bright colored sound producing rattle) was introduced into the experimental group prior to the injection. The parents were holding the infants, and the infants were encouraged to touch and hold the rattle. In the control group, the parents were holding the infants and giving standard care (cuddling, holding the baby close) .The pain was observed by the investigator during and after the procedure. The entire study sample experienced severe pain during injection but after the injection, majority of the samples (86.66%) in the control group experienced moderate pain and 13.34% experienced severe pain. In the experimental group majority (83.34%) were found to have moderate pain and 16.66% experienced mild pain[21].

Summary:

This chapter has dealt with the discussion of major findings of the study along with the supporting studies for assessment of Pain among children attending to Immunization Clinic with its selected socio demographic variables.

CHAPTER-8

CONCLUSION

This chapter presents the major findings of the study, the conclusions drawn, implications, limitations, suggestions and recommendations.

This study was aimed at assessing the Effectiveness of Helfer Skin Tap technique on Pain during Intra muscular injection among children attending Immunization clinic at selected Hospital, Kolar, Karnataka, Quantitative approach with true experimental (posttest only with control group) design was adopted for this study. The data was collected from 40 children attended to Immunization Clinic.

The study based on Melzack and Wall(1965) Gate control theory of pain, the model the conclusions drawn from the study were as follows.

The Mean Pain score of Experimental group was 6.30 with SD of 0.571, where as in Control group 7.30 with SD of 1.809 respectively at 38 df and calculated 't'-value was 22.75 which is less than table value at 0.05 level of significance indicating statistically significant in pain scores between Experimental and Control groups. Hence the stated null hypothesis $H_{01}$is rejected.

The findings (Table 4&5) revealed that, chi- square calculated value is less than table value at 0.05 level of significance for association between Age of Child, No. of vaccinations in No's, Type of vaccination and Route of vaccination, of children attending to Immunization clinic, indicating statistically not significant. Hence the stated null hypothesis H_{02} is accepted.

Nursing Implications

The present study was conducted to determine the Effectiveness of Helfer Skin Tap technique on Pain during Intra muscular injection among children attending Immunization clinic at selected Hospital, Kolar, Karnataka, The findings of the study have following implications for Nursing Practice, Nursing Education, Nursing Administration, and Nursing Research. Results of the study would help

a) Nursing Practice

Helfer skin tap helps as a guideline for reducing the Pain among children undergoing painful procedures as a part of supportive care for children undergoing Vaccinations.

b) Nursing Education

Findings of the study would highlight the importance of Helfer skin tap technique to reduce the pain among children undergoing vaccinations Intra-muscularly.

c) Nursing Administration

d) In service education can be planned for staff works in Pediatrics to reduce the pain during Intramuscular injections.

e) Nursing research

- Contributes relevant additional information to the body of knowledge
- The suggestions and recommendations can be utilized by other researchers for further studies in the same filed.
- The outcome may serve as a guideline in preparing the protocols on Helfer skin tap.

Limitations of the Study

1. The effectiveness of Helfer skin tap were assessed by using FLACC pain Measurement scale.
2. Small number of subjects limited the generalization of the study.
3. The study was limited only to children attending Immunization clinic of R.L Jalappa Hospital &Research Center, kolar.

Recommendations

Based on the findings of the present study recommendations offered for the further study are:

1. Similar study can be replicated on a larger population.
2. Similar study can be conducted in all children undergoing Intramuscular injections.
3. Similar study can be conducted along with other developmental supportive interventions
4. Follow up studies can be conducted to assess the pain among children.

SUMMARY

This chapter has brought out various implications of the study and provided recommendations. Studies of this kind should be conducted to yield more reliable results.

CHAPTER-9

SUMMARY

The improvement of pain assessment in the clinical assessment in the clinical setting can be viewed as a patient care quality issue, and continuous quality improvement methods can be effectively to incorporate pain assessment as an integral component of every child's health care[11].

Helfer Skin Tap technique found in reducing the pain among children undergoing Intramuscular injections at Immunization clinic. Injections are the universal experience for children. Hence diversion therapy was found to be effective for reduction of pain of infants receiving injections. Therefore it can be used as a routine with Immunization so that infants' pain can be managed in an effective way. It is important for the health professionals, who administer immunization, to take the challenge for relieving the pain by distracting the infants[6].

With this view, a Quantitative approach was adopted to determine the Effectiveness of Helfer Skin Tap technique on Pain during Intra muscular injection among children attending Immunization clinic.

OBJECTIVES OF THE STUDY

1. To Evaluate the Effectiveness of Helfer Skin Tap technique on Pain by using pain scale.

2. To determine the association with level of pain during Immunization with number if vaccinations, age of child and type of vaccine.

HYPOTHESES

Ho_1 : There will be no significant difference in level of pain among children between experimental and control group.

Ho_2 : There will be no significant association between level of pain with selected socio demographic variables.

Major findings of the study:

1. Majority i.e. 80% (16) children were in the age group of 1-9 months in Experimental group where as in control group 70 %(14) children were in the age group of 1-9 months.
2. Majority i.e. 70% (14) children were Immunized for 01-03 times in Experimental group where as in control group. 65% (13**)** were immunized for 01-03 times.
3. With regard to type of vaccination 100% (20) of children were vaccinated against Live attenuated Vaccines both in Experimental and Control groups respectively.
4. With regard to Route of vaccination 100% (20) of children were vaccinated Intra-muscularly both in Experimental and Control groups respectively.

The findings revealed that the mean Pain score of Experimental group was 6.30 with SD of 0.571, where as in Control group 7.30 with SD of 1.809 respectively at 38 df and calculated 't'-value was 22.75 which is less than table value at 0.05 level of significance indicating statistically significant in pain scores between Experimental and Control groups. Hence the stated null hypothesis $H_{01}$is rejected.

The findings (table 4&5) revealed that, chi- square calculated value is less than table value at 0.05 level of significance for association between Age of Child, No. of vaccinations in No's, Type of vaccination and Route of vaccination, of children attending to

Immunization clinic, indicating statistically not significant. Hence the stated null hypothesis H_{02} is accepted.

Summary:

On the whole, carrying out the present study was an enriching experience to the investigator. It also helped a great deal to explore the effect of Helfer Skin Tap Technique helps in reducing pain among children undergoing Intramuscular Injection at immunization Clinic. The study also helps in practicing Helfer Skin Tap Technique at Pediatric wards in the hospitals. The experience gained through this study would motivate the investigator to conduct more studies of this nature and to provide good cultural attitude. The constant encouragement and guidance by the guide, co-operation and interest of mothers in the study contributed to the fruitful completion of the study.

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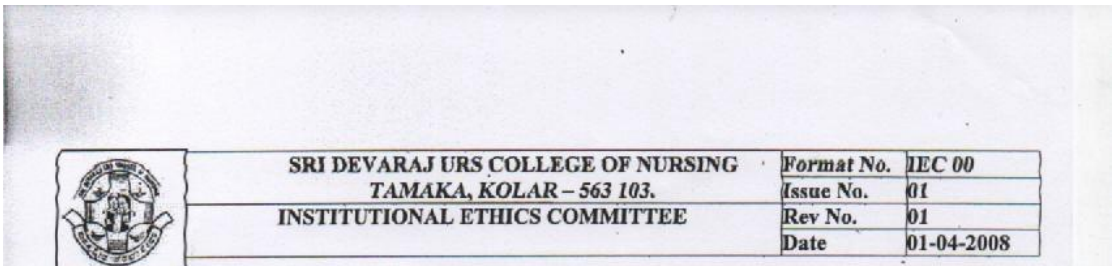
ANNEXURE-I

ETHICAL CLEARANCE



SRI DEVARAJ URS COLLEGE OF NURSING TAMAKA, KOLAR – 563 103. INSTITUTIONAL ETHICS COMMITTEE	Format No.	IEC 00
	Issue No.	01
	Rev No.	01
	Date	01-04-2008

ANNEXURE-II

PERMISSION LETTERS

From.
Saritha.V
I year MSc Nursing

Date- 29/10/18
Place-Tamaka. Kolar.

ANNEXURE-III

Patient Information Sheet

Study Title: "A study to Evaluate the Effectiveness of Helfer Skin Tap technique on Pain during Intra muscular injection among children attending Immunization clinic at selected Hospital, Kolar, Karnataka"

Principal Investigator : V.Saritha

Study site : Immunization clinic,Sri R.L.Jalappa Hospital & Research Center, Kolar Karnataka

Purpose of The study: The aim of the study

1. To evaluate the effectiveness of Helfer Skin Tap technique on Pain by using pain scale.

2. To determine the association with level of pain during Immunization with number of vaccinations, age of child, and type of vaccine.

Voluntary Participation: Your participation in this study is entirely voluntary. There is no compulsion to participate in this study. You will be no way affected if you do not wish to participate in the study. You are required to sign only if you voluntarily agree to participate in this study .Further you are at a liberty to withdraw from the study at any time.
Procedure:

Confidentiality: All information collected from you will be strictly confidential and will not be disclosed to anyone except if it is required by the law. This information collected will be used only for research, presentation and publication. This information will not reveal your identity.

We would not compel you any time during this process; also we would greatly appreciate your cooperation to the study. We would like to get your consent to participate in the study

For any information you are free to contact investigator. This study has been approved by the institutional ethical committee.

INFORMED CONSENT FORM

Name of the investigator: V.Saritha

Name of the Organization: Sri DevarajUrs College of Nursing

Title of the study: "A study to Evaluate the Effectiveness of Helfer Skin Tap technique on Pain during Intra muscular injection among children attending Immunization clinic at selected Hospital, Kolar, Karnataka"

If your agree to participate in the study I will collect information (as per proforma) from you or a person responsible for you or both. We will collect relevant details.

You are invited to part in this research study. You are being asked to participate in this study because you satisfy our eligibility our criteria. The information in the given document is meant to help you decide whether or not to take part. Please feel free to ask any queries. I give my consent to collect the information & also can be used for medical research, test validation, or education as long as my privacy is maintained.

I have read or it has been read and explained to me in my own language. I have understood the purpose of this study, the nature of information that will be collected and disclosed during the study. I had the opportunity to ask questions and the same has been answered to my satisfaction. I understand that I remain free to withdraw from this study at any time and this will not change my future care. I the undersigned agree to participate in this study and authorize the collection and is closure of m6y personal information for presentation and publication.

Patient's signature/ Thumb impression

Person obtaining consent and his/her signature:

Principal investigator signature:

Principal Investigator.

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CzsÀåAiÀÄ£ÀzÀ ²Ã¶ðPÉ: "PÀ£ÁðlPÀ PÉÆÃ¯ÁgÀzÀ°è, DAiÉÄÌ ªÀiÁrzÀ D¸ÀàvÉæAiÀÄ°è ®¹PÉ Qè¤QUÉ §gÀÄªÀ ªÀÄPÀÌ¼À°è ZÀÄZÀÄÑªÀÄ¢Ý¤AzÀ DUÀÄªÀ £ÉÆÃ«£À ºÉ®àgï ¹Ì£ï mÁå¥ï ¥ÀzÀÝwAiÀÄ ¥ÀjuÁªÀÄUÀ¼À£ÀÄß ªÀiï°åÃPÀj¸À®Ä MAzÀÄ CzsÀåAiÀÄ£À."

¥ÀæªÀÄÄR ¸ÀA±ÉÆÃzsÀPÀgÀÄ: ¸ÀjvÀ .«

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ANEXXURE-VII

Section-A: Socio Demographic Data of Experimental and Control Group

SAMPLES		EXPERIMENTAL GROUP				CONTROL GROUP		
	AOC	NOV	TOV	ROV	AOC	NOV	TOV	ROV
1	01	01	01	01	02	02	01	01
2	01	02	01	01	01	01	01	01
3	01	01	01	01	01	01	01	01
4	01	02	01	01	01	01	01	01
5	01	01	01	01	01	01	01	01
6	02	02	01	01	01	01	01	01
7	01	01	01	01	02	02	02	01
8	01	01	01	01	02	02	02	01
9	01	01	01	01	02	02	02	01
10	01	01	01	01	02	02	02	01
11	02	02	01	01	01	01	01	01
12	02	02	01	01	01	01	01	01
13	01	01	01	01	01	02	01	01
14	01	01	01	01	01	01	01	01
15	02	02	01	01	01	01	01	01
16	01	01	01	01	01	01	01	01

17	01	01	01	01	01	01	01	01
18	01	01	01	01	02	02	01	01
19	01	01	01	01	01	01	01	01
20	01	01	01	01	01	01	01	01

Section- A: Socio Demographic Data.

1)Age of child (in months)

a.1-9

b.10-18

c.19-27

d.28-36

2) No. of vaccines (in. No)

a.1-3

b.4-6

c.7-9

d.10-36

3) Type of vaccines.

a. Live attenuated vaccines

b. Killed vaccines

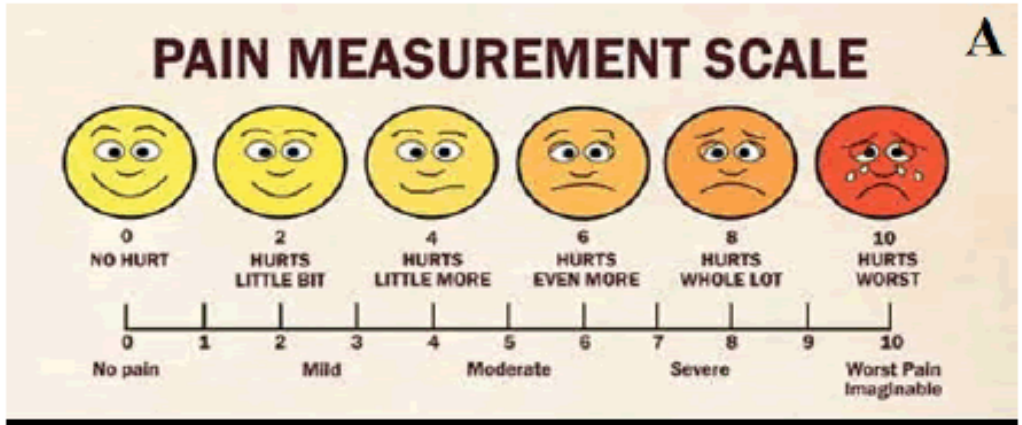
4) Route of vaccinations

a. Intra-muscular

b. subcutaneous

c.Intra-venous

d. others



B

Category	0	Scoring 1	2
Face	No particular expression or smile	Occasional grimace or frown withdrawn, disinterested	Frequent-constant quiver chin, clenched jaw
Legs	Normal position, relaxed	Uneasy, restless, tense	Kicking or legs drawn up
Activity	Lying quietly, normal position, moves easily	Squirming, shifting back & forth, tense	Arched, rigid or jerking
Cry	No cry (awake or asleep) occasional complaint	Moans or whimpers; sobs; frequent complaint	Crying steadily, screams,
Consolabilty	Content, relaxed	Reassured by occasional touching, hugging, or being talked to, distractible	Difficult to console or comfort

Figure 1: Pain scales for children less than and greater than three years of age; A. pain scale by Wong-Baker; B. the FLACC pain scale.

Interpreting the Score:

0 = Relaxed and Comfortable

1-3 = Mild discomfort

4-6 = Moderate pain

7-10= Severe pain or discomfort or both

Master sheet of Pain scores of children in Experimental and Control groups

Sl.No	Pain Score of Experimental Group	Pain Score of Control Group
1	7	8
2	7	7
3	7	8
4	6	8
5	6	8
6	6	7
7	7	8
8	6	8
9	6	7
10	6	8
11	5	8
12	6	9
13	7	8
14	6	7
15	6	7
16	6	8

17	**6**	**8**
18	**7**	**7**
19	**7**	**7**
20	**6**	**7**