

# Study Protocol

## **Efficacy of new vibration device in reduction of injection pain among children-A Randomized Control Trail**

### **ABSTRACT**

Needle-related procedures considered as the very crucial sources of pain in children. Pain management during invasive procedure is a challenge to direct health care providers. Unnecessary pain can spoil the nurse-patient relationship. Injections usually reason for some level of pain at the injection site. To develop and validation of the new vibration device for reduction of injection pain and compare the injection pain score among children between experimental and the control group. We will base this study on Analytical intervention approach. A hospital-based Randomized Controlled Trial will consider the effect of a new vibration device in intervention and routine care in the control group for reduction of injection pain. The sample will be children of the age Group 4 years to 12 years. Researcher will take before data collection selection of children as per inclusion criteria, detail explanation about nature and purpose of the study the written consent from the child's parent. The computerized randomized sampling technique will use for the group formation. The setting of the study will be Acharya Vinoba Bhave Rural Hospital, Sawangi, Wardha. There will be an efficacy of interventions on children's outcomes reduce injection pain and stable emotional behaviour and stable physiological parameter. Researcher will draw conclusion after the analysis of data collected from the predetermined sample size. Researcher will publish the findings of the study in an open access peer-reviewed journal.

**Keywords:** Efficacy, Vibration Device, Injection Pain, Children

## INTRODUCTION

Children between the age groups of 4-10 years are pre-schoolers and schooler who are concrete, egocentric and have magical thinking that restrict ability to understand the incident because they sight all the experiences from their own self referred perspective and, in this context, pain is often a panic experience to them. Simple venous access procedures are a notable cause of pain and distress for children receiving care. As a grade of acute pain, children have recognized needle pain as the very common of procedural pain. When paediatric pain is insufficient managed, it can risk to physical and psychological effect on child. Researcher has documented both the short-term and long-term effects from inadequately treated paediatric pain. However, in practice, injection pain is unconsidered, ignorance and mismanaged in children because of various restrictions,

Injection procedure, like intramuscular injection, intravenous injection and cannula insertion and these route use for administration of medication and considered as the very prominent cause of pain and discomfort in children at varies settings (1). Pain management during injection procedure is of outmost importance as pain could cause several physiological, psychological, and emotional long-term effects on children (2). A bad outcome of unmanaged injection pain in children is needle phobia, defined as an almost fear and anxiety related to injections (3). The most children assume the prospective pain and manifest misbehaviors go along with anxiety, resulting in a lot of time required to carry out an injection procedure (4). Cross-sectional analysis showed that more than 60% of children had experiences of pain related to injection and fear needle-related procedures. (5). Children's responses to pain enhance a nursing problem; behavioral responses among children aged from 1 to 12 years reported as significant for venous catheterization and insertion of IV lines (6). Negligence in strategies of pain relief can mentally and physically harm to children. In continuing to inducing afraid and mistrust, exposures to pain can change the central nervous system and increase a child's reactivity to pain(7). The usually give the vaccines in injectable form, which is painful and almost always causes anxiety among infants and their parents. Non-pharmacological interventions in pain management are essential for infants or children because there is a high vulnerability to the effects of pain in infants or children because of repeated pain stimuli (8). The stimulation such as vibration device can relieve injection pain it is based on the gate control theory. The simultaneous trigger of nerve

fibers that conduct non-noxious stimuli can reduce mechanisms of pain relieve caused by vibration. (9). (M Shilpapriya Jul 9, 2015).[10]

Patients are often afraid of receiving injections because they perceive it will be painful. Unnecessary pain can harm the nurse- patient relationship, whereas knowledge of alternative techniques can improve patient cares, clinicians have tried to explore many strategies plan to reduce pain, including the pain of injections and satisfaction. Researcher will develop a new vibration device it will help in reduce injection pain and develop a changed protocol for injection procedure in children.

**Aims:** To develop and evaluate the efficacy of a new vibration device in reduction of injection pain among children. **Objectives** of the study develop, pilot and validation of the vibration device for reduction of injection pain. To assess the injection pain score, emotional behaviour scale and physiological parameters score among children of the experimental group and control group. To compare the injection pain score, emotional behaviour score and physiological parameters score among children between experimental and the control group

#### **MATERIAL AND METHOD**

The study design Randomized Control trial. Researcher will conduct a study in the Pediatric Unit in a hospital setting in Acharya Vinoba Bhave Rural Hospital, Sawangi, Wardha and the population referred to the 4 to 12yrs children. Researcher will use the computerized randomized sampling technique will be use for the group formation of intervention and control group All participating children who are registered indoor patient or outdoor patient (IPD or OPD) bases are allocated automatically in equal proportion to an Experimental group (New vibration device) or control group (conventional method) Randomization will be implemented using the computerized randomized numbers allotted to intervention and control group. The blinding will done to the outcome assessors to avoid detection bias as the intervention will be done by the researcher and injection will administered by staff nurse who are not being disclosed about the type of intervention/treatment given to the sample.

**Sample:** The sample will consist of 4-12yrs children's age group in Pediatric ward, Pediatric Intensive Care Unit (PICU) , Pediatric OPD & Immunization room.

**Sample size:** Total 100 sample, 50 samples will needed for experimental groups and 50 samples for control group.

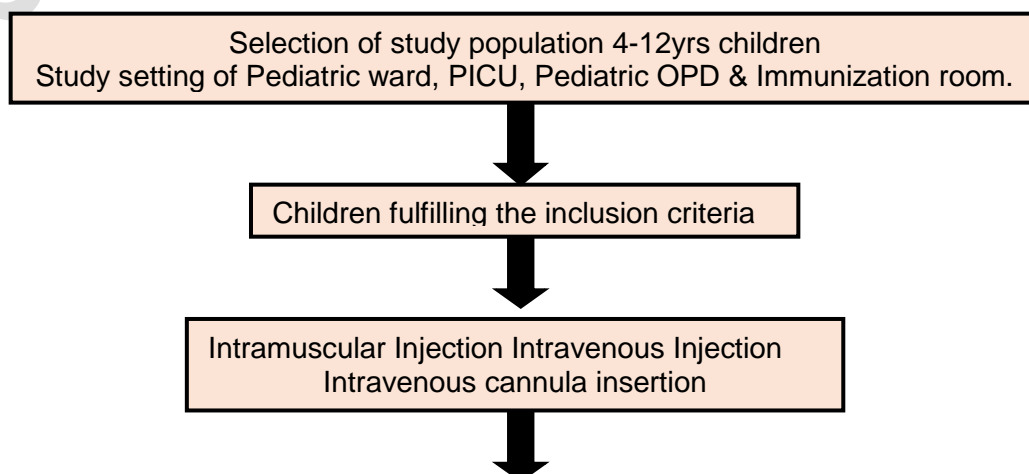
**Inclusion criteria:**

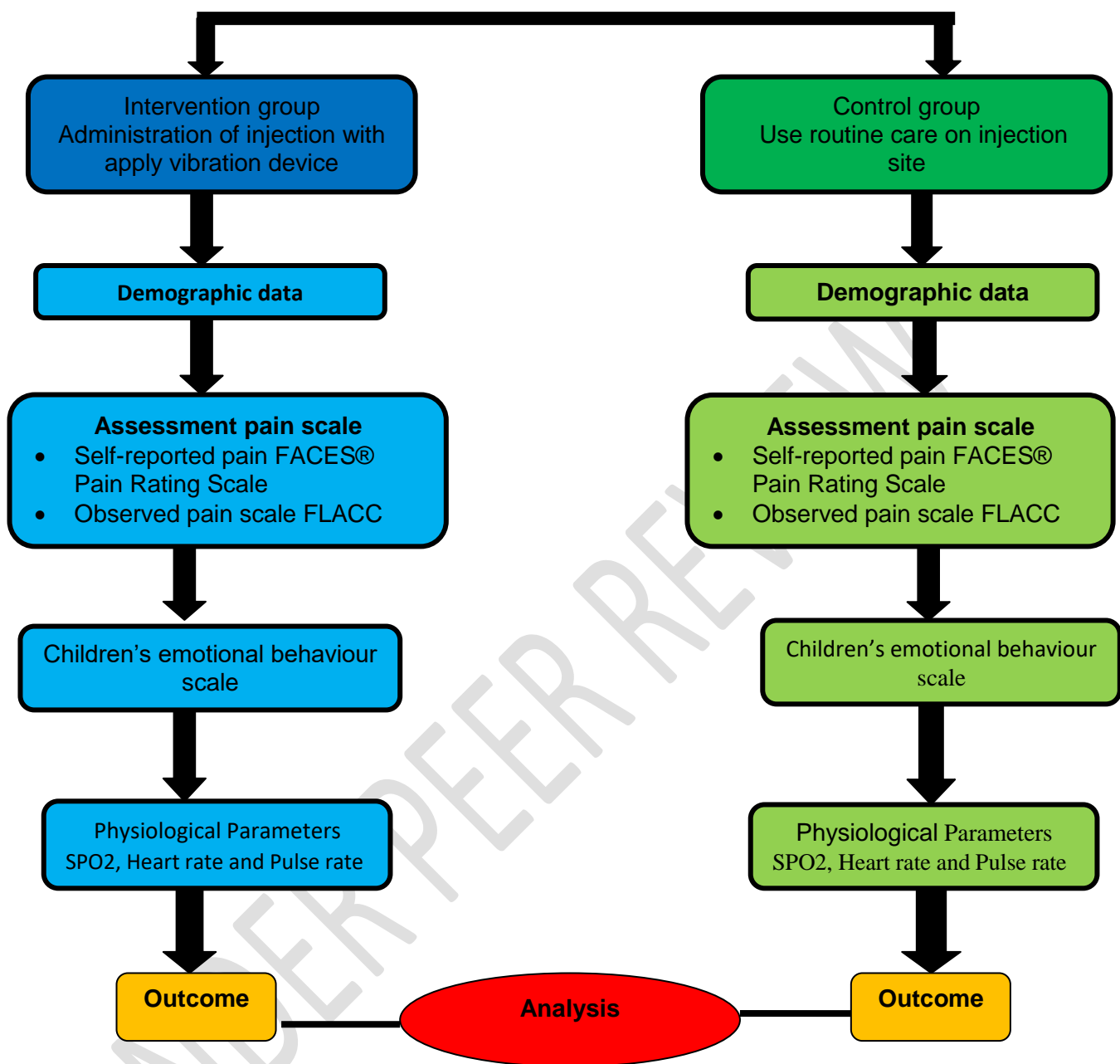
- Child who are in pediatric unit.
- Pediatrician prescribed injection or Intravenous cannula to children as treatment part
- Those children are fully conscious.
- Age of children 4 to 12years.
- Parents who have willing to participate their child in study.

**Exclusion criteria:**

- Those children having critical condition.
- Those children admitted in PICU with ventilator support.
- Those children are mentally handicaps.
- Extensive hospitalization for chronic illness
- Those children having neuro-behaviour disorders (Paralysis, Cerebral palsy)
- Those children having behaviour problem (Autism, temper tantrum, Attention-deficit hyperactivity disorder.
- Those children having injection side abscess or any complication.
- Chronic pain due to an injury or disease,
- Past history of surgery within six months
- History of intake of any analgesic within the last 6 hours,

**Researcher will plan for data collection: [Figure no. 1]**





**Figure: 1. Schematic Presentation of Methodology**

The investigator will visit to Hospital after obtain the necessary permission from the Chief Medical Office or concerned authorities. The written permission letter will be given to the HOD of pediatric department with necessary information about the plan of action to get their cooperation.

After completing the official formalities, the investigator will stay in the study area as per the scheduled plan for conducting the study. In the hospital, randomly select the children based on inclusion criteria and will seek written consent from the parent for the participation of

their child in the study. The purpose of the study, potential benefits, right to confidentiality, and right to withdrawal will explain to each subject, and it will clear additional doubts with explanation. I will request those parents who will let their children be a part of the study to sign a written consent form about their willingness to participate their children in the study. Two groups will be in the study: one experiment and another control group the will selected on the random method in the experimental group will be the intervention of vibration device during administration of injection in children in control group without intervention administration of the injection. Written consent from the parents (Mother or Father) whose children are in this study, the sample consists of children in AVBR Hospital. The children will screen form pediatric unit Pediatric Intensive Care Unit, Pediatric ward Outdoor & Immunization room.

The injection will be administered by a pediatric nurse for both the groups experimental and control group, to minimize the bias for injection technique. Researcher will apply the new vibration device in intervention group device hold with the help of strip attached in a device the place about 5 cms above the injection site close as possible above the needle insertion site and the vibration is activated 30s-60s prior the administration of injection it will continue after the injection procedure up to 30s than off the device by researcher. The device has to be kept in place throughout the procedure. Total time will consume for one sample near about 5mins

The outcome will measure pain in children during injection and will record and assessed by researcher. Researcher will assess pain score with the help of standardized Wong-Baker FACES pain rating scale and Observed pain scale FLACC scale (Face, Legs, Activity, Cry, Consolability) and will assess emotional behaviour with the help of Children's Emotional Behaviour Scale the researcher will check then Physiological changes before and after injection (SpO2 Heart rate or pulse rate with pulse-oximetry and Respiration rate with inspection). 5minutes before and after injection procedure with the help of pulse oximetry.

### **Statistical Analysis:**

Statistical analysis will be done by using descriptive and inferential statistics using Chi-square test, Student's paired and unpaired t test, and software used in the analysis will be Statistical Package for the Social Sciences (SPSS) 22.0 version and Graph Pad Prism 6.0

version and  $p < 0.05$  is level of significance. Comparison of respiratory rate, heart rate, and SpO<sub>2</sub> would be performed using repeated measures ANOVA.

**Expected results:** There will be a reduction of injection pain, stable Emotional Behaviour & physiological parameters in children after intervention.

## DISCUSSION

Canbulat N (2015) conducted a study of children, 7 to 12 years, randomized to either a control no any intervention and experimental group that received external cold and vibration device. Comparison of the two groups showed 52-60% pain reduce ( $p < .001$ ) and significantly lower anxiety levels in the experimental group (10). Tung (2018) RCT conducted on 150 children aged 7-14 years divided into three groups G1: No vibration- 50 children G2: Manual stimulation- 50 children G3: Dental Vibe- 50 children. 20% benzocaine gel. 50 - G1: No vibration 50 - G3: Dental Vibe Dental Vibe WB- FPR Scale Pulse rate. The researcher found a pain score statistically significant decrease in the Dental Vibe® group compared to the control group and the manual stimulation group ( $P < 0.001$ ). Dental Vide device was effective in reducing pain than other groups (11).

## CONCLUSION

At the completion of the study, the researcher will come to know the effect of vibration device on reduction on injection pain in the children. The researcher will add the new vibration device in the injection protocol at the hospital setting.

## SCOPE OF THE STUDY

They broadly used new vibration device for the injection procedure and vaccination in children. It is noninvasive, safe and easily applicable during injection procedure in all the setting. Hence, this study will evaluate the efficacy of a new vibration device reducing pain during injection procedure in children.

## LIMITATIONS

This study is limited to Intramuscular, Intravenous injection and Cannulation only.

## CONSENT AND ETHICAL APPROVEL

The research is endorsed by Committee on Institutional Ethics of Datta Meghe Institute of Medical Sciences (DMIMS (DU)/IEC/2018-19/7456). All participants must be request to read and sign informed consent.

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