# CHAPTER-III

# MATERIALS AND METHODS

The study was done during one-year period (2020–2021) in the Intensive Care Unit (ICU) of Himalayan Hospital, Dehradun.

**Research Approach**

In this study the quantitative research approach was used. The investigator had done the study in two phases

**Phase I**- training of staff nurses on Individualized Communication Protocol (ICP) was done.

**Phase II-** effectiveness of Individualized Communication Protocol (ICP) on clinical outcome of comatose patients was done.

**Research Design-Phase I**

In this study, one-group pre-test-post-test design was used to assess effectiveness of the training program on Individualized Communication Protocol on the knowledge and practice of nurses working in ICU.

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( O1 )  ⇨  ( X )  ⇨  ( O2 )
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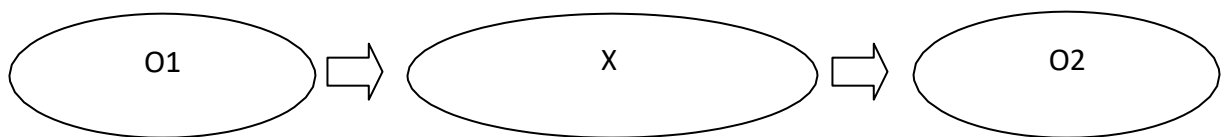
**Key:**

O1-Assessment of pre-test knowledge and practice of staff nurses

X: Intervention: Administration of Individualized Communication Protocol to staff nurses

O2-Assessment of post-test knowledge and practice of staff nurses after Intervention

**Research Design-Phase II**

A 'quasi-experimental design' was adopted to assess the effect of an Individualized Communication Protocol on clinical outcomes of comatose patients in ICU.

**Diagrammatic representation of Research Design Phase-II**

| Group | Pre-test on day first of ICU admission | Intervention | Post-test (14 days/ transfer outof patients from ICUs /Death /LAMA whichever was earlier |
|---|---|---|---|
| ControlGroup | OC1 | Received routine care | OC2 |
| Experimental Group | OE1 | XI | OE2 |

**Key:**

OC1: Assessment of pre-intervention clinical outcome parameters of the control group on 1$^{st}$ day.

OC2: Assessment of post-intervention clinical outcome parameters of the control group (till 14 days or till transfer out of patients from ICU as a patient recovers from or stabilizes after a critical illness/death/LAMA, whichever was earlier).

OE1: Assessment of pre-intervention clinical outcome parameters of the experimental group on 1st day.

OE2: Assessment of post intervention clinical outcome parameters of the experimental group (till 14 days or till transfer out of patients from ICU as a patient recovers from or stabilizes after a critical illness/death/LAMA, whichever was earlier).

X1: Intervention – Administration of Individualized Communication Protocol to comatose patients by staff nurses.

**Research Setting**

The setting for the present study was the intensive care unit of Himalayan Hospital, which is a 1200 bedded hospital covering all specialties and super-specialties located in the Dehradun district of Uttarakhand. Intensive care unit has 42 beds that are separated by curtains. Approximately 183 staff nurses work in ICU. Patients with head injuries, neurological, metabolic, renal, cardiovascular and respiratory disorders are admitted in the ICU. Approximately 130 patients are treated in a month with an altered level of consciousness, of which 70% to 80% patients are put on mechanical ventilator (MV). The setting was chosen based on the availability of sample and the feasibility of the study.

**Population**

The population for the present study comprised of all staff nurses working in the intensive care unit of Himalayan Hospital and comatose patients with GCS≤8/15 admitted in ICU.

**Sample –PHASE-I**

The sample for Phase I comprised of staff nurses working in the intensive care unit who were available during data collection period and met the inclusion criteria. The following inclusion and exclusion criteria were used to recruit 171 staff nurses of both genders working in the above mentioned ICU for this study.
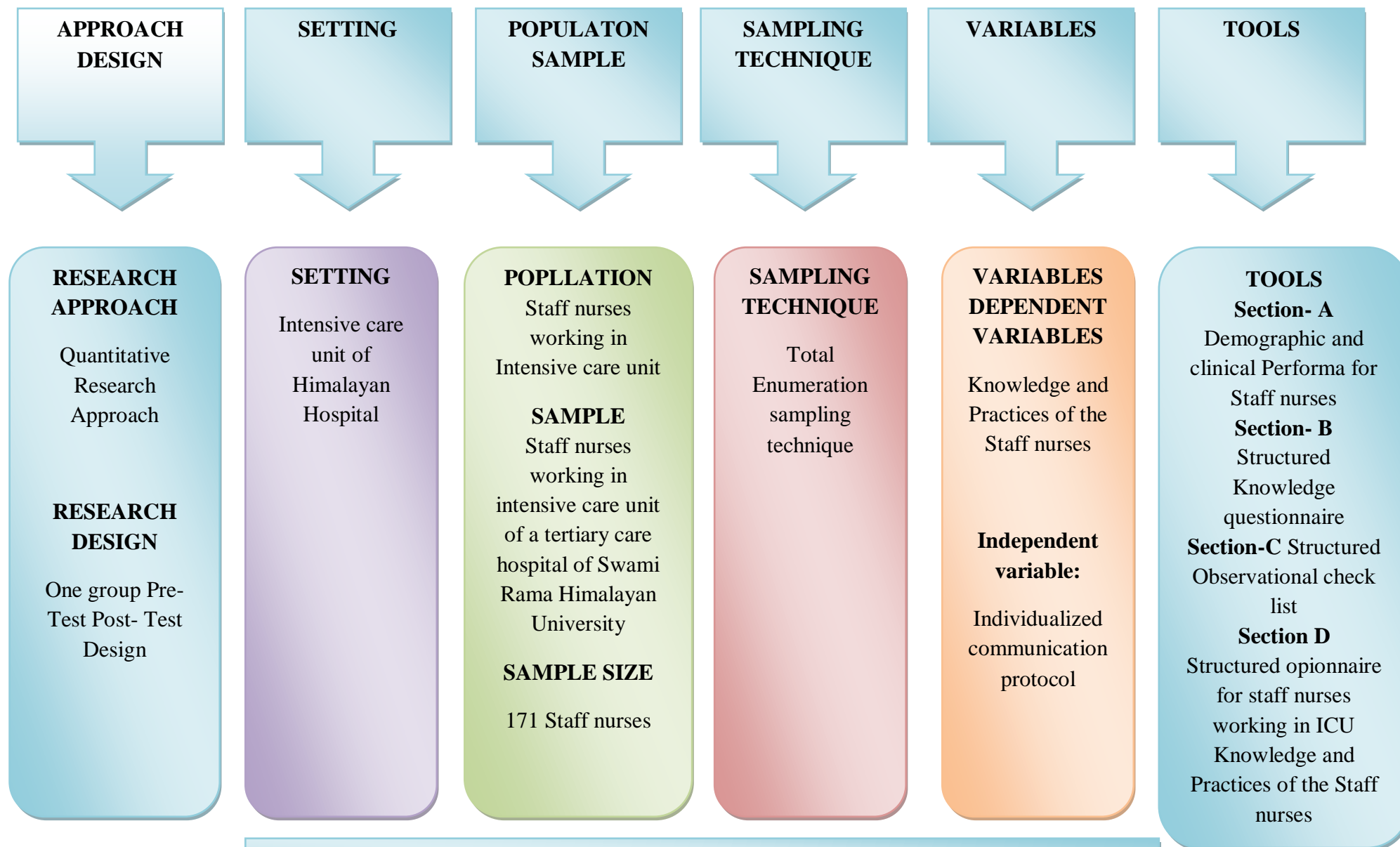
| APPROACH DESIGN | SETTING | POPULATON SAMPLE | SAMPLING TECHNIQUE | VARIABLES | TOOLS |
|---|---|---|---|---|---|
| **RESEARCH APPROACH**<br><br>Quantitative Research Approach<br><br><br>**RESEARCH DESIGN**<br><br>One group Pre-Test Post- Test Design | **SETTING**<br><br>Intensive care unit of Himalayan Hospital | **POPLLATION**<br>Staff nurses working in Intensive care unit<br><br>**SAMPLE**<br>Staff nurses working in intensive care unit of a tertiary care hospital of Swami Rama Himalayan University<br><br>**SAMPLE SIZE**<br><br>171 Staff nurses | **SAMPLING TECHNIQUE**<br><br>Total Enumeration sampling technique | **VARIABLES DEPENDENT VARIABLES**<br><br>Knowledge and Practices of the Staff nurses<br><br><br>**Independent variable:**<br><br>Individualized communication protocol | **TOOLS**<br>**Section- A** Demographic and clinical Performa for Staff nurses<br>**Section- B** Structured Knowledge questionnaire<br>**Section-C** Structured Observational check list<br>**Section D** Structured opionnaire for staff nurses working in ICU Knowledge and Practices of the Staff nurses |

**FIGURE 2 SCHEMATIC PRESENTATION OF RESEARCH DESIGH FOR PHASE-1**

**Inclusion Criteria for Nurses:**

1. All registered staff nurses who had completed a diploma or graduation programme in nursing.

2. Staff nurses who were taking care of patients with GCS score $\leq 8/15$

**Exclusion Criteria for Nurses:**

1. Nurses who were not willing and not available during data collection.

2. Nurses who were on rotation to other wards at the time of data collection or who were assigned to the COVID unit in the ICU.

**Sample for Phase II:**

The sample for Phase II comprised of comatose patients (neurological, respiratory, metabolic, cardiovascular and renal disorders) were admitted in the intensive care unit and met the inclusion criteria. The following inclusion and exclusion criteria were used to recruit 113 comatose patients of both genders admitted in the above mentioned ICU for this study

**Inclusion Criteria for comatose patients:**

The study included comatose patients who met the following criteria:

1. Age group between 18 to 65 years
2. On mechanical ventilation
3. Had GCS score $8\leq/15$

**Exclusion Criteria for comatose patients:**

If a patient met one of the following criteria while in a comatose state, they were excluded from the study:

1. Hearing loss in the past
2. Diagnosed with injury to the auditory pathways
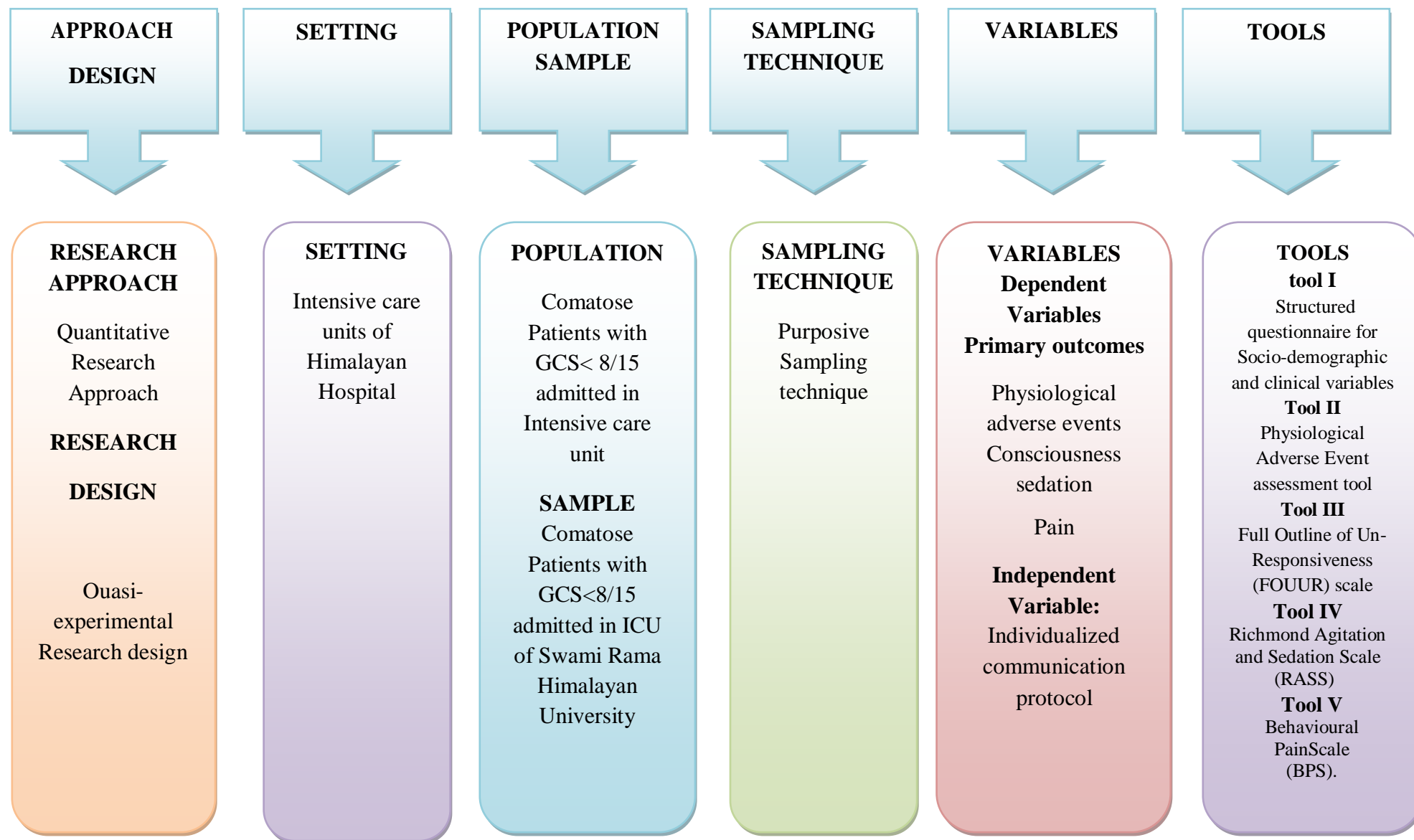3. Were induced into coma by the infusion of neuromuscular blockade

| APPROACH DESIGN | SETTING | POPULATION SAMPLE | SAMPLING TECHNIQUE | VARIABLES | TOOLS |
|---|---|---|---|---|---|
| **RESEARCH APPROACH**<br><br>Quantitative Research Approach<br><br>**RESEARCH**<br><br>**DESIGN**<br><br>Ouasi-experimental Research design | **SETTING**<br><br>Intensive care units of Himalayan Hospital | **POPULATION**<br><br>Comatose Patients with GCS< 8/15 admitted in Intensive care unit<br><br>**SAMPLE**<br>Comatose Patients with GCS<8/15 admitted in ICU of Swami Rama Himalayan University | **SAMPLING TECHNIQUE**<br><br>Purposive Sampling technique | **VARIABLES**<br>**Dependent Variables**<br>**Primary outcomes**<br><br>Physiological adverse events Consciousness sedation<br><br>Pain<br><br>**Independent Variable:**<br>Individualized communication protocol | **TOOLS**<br>**tool I**<br>Structured questionnaire for Socio-demographic and clinical variables<br>**Tool II**<br>Physiological Adverse Event assessment tool<br>**Tool III**<br>Full Outline of Un-Responsiveness (FOUUR) scale<br>**Tool IV**<br>Richmond Agitation and Sedation Scale (RASS)<br>**Tool V**<br>Behavioural PainScale (BPS). |

**FIGURE 3: SCHEMATIC PRESENTATION  OF RESEARCH DESIGN FOR PHASE -II**

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**3. Calculation of Sample Size and Sampling Technique:Sample Size and sampling technique for staff nurses**

The current study included a total of 171 staff nurses by total enumeration method.

**Sample Size calculation for comatose patients**

On the basis of previously published literature (Othman, 2015), sample size calculation was done. The mean ± SD was taken from the above stated article to achieve 80% power (B) at a 5% level of significance (α). Calculated sample size was 90. Considering 10% dropout, the researcher enrolled 113 patients in both experimental and control groups.

The formula for sample size calculation was as follows:

$$N=[ (Z\alpha+Z\beta /\delta)\sigma]^2$$

**Sampling technique for comatose patients**

The samples were chosen using purposive sampling technique. The present study enrolled 113 comatose patients admitted in ICU.

**Variables under study:**

**Independent variables**: Individualized Communication Protocol

**Dependent variables**:

1. Knowledge and practice of staff nurses.

2. The clinical outcomes of the comatose patients in terms of physiologicalclinical variables, consciousness, sedation, and pain.

## DESCRIPTION OF TOOLS

### Tool No. 1: Demographic and Clinical Proforma.

It is a structured tool comprised of two sections containing 24 items.

### Section-A: Demographic profile of staff nurses

Following variables were included in the demographic variables: age, gender, marital status, professional qualification, area of experience, years of clinical experience, additional-qualification (s), and nurse patient ratio.

### Section-B: Structured knowledge questionnaire

It consisted of 24 multiple choice items. The minimum and maximum score were 1 and 24, respectively. The correct responses were awarded 1 mark and wrong responses were scored as 0.

### INTERPRETATION:

The interpretation of scoring was done as follows:

| S.No. | Level of knowledge score | Score range | Percentage |
|-------|--------------------------|-------------|------------|
| 1 | Poor Knowledge | 0 –11 | below 50% |
| 2 | Good Knowledge | 12- 18 | ≥50%-75% |
| 3 | Very Good Knowledge | 19–24 | (>75-100% |

The Knowledge tool consisted of the following domains:

   (a) Coma and its complications

   (b) Verbal aspects of communication with comatose patients

   (c) Nonverbal aspects of communication with comatose patients

**Section-C: Structured observational checklist**

The observational checklist consisted of the following domains:

    (a) Verbal communication with comatose patients

    (b) Nonverbal communication with comatose patients

The minimum and maximum score were 1 and 43, respectively.

**SCORE INTERPRETATION**

The interpretation of scoring was done as follows

| S.No. | Level of Practice Score | Score Range | Percentage |
|-------|-------------------------|-------------|------------|
| 1 | Below Average | 0-21 | below 50% |
| 2 | Average | 22-32 | ≥50%-75% |
| 3 | Above Average | 33-43 | >75-100% |

**Section-D: Structured opinionnaire for nurses working in ICU**

The opinionnaire consisted of eight items on acceptability of Individualized Communication Protocol by nurses working in ICU. All items had options to mark a tick to indicate following opinions - accept fully; accept; do not accept.

**Tools used for comatose patients**

- **Tool I: Socio-demographic and clinical proforma**

This tool had two parts:

**Part one:** Consisting of socio-demographic variables of comatose patients like age, gender, marital status, level of education, place of living, and occupation.

**Part two:** Consisting of clinical variables like medical diagnosis, admission to ICU, Glasgow coma scale, length of stay in ICU, length of the mechanical ventilation, and APACHE II score.

- **Tool II: Assessment of physiological adverse events**

This included "temperature (T), systolic blood pressure (SBP), diastolic blood pressure (DBP), heart rate (HR), oxygen saturation (SpO2), respiratory rate (RR), and blood glucose level (BGL)". The physiologic adverse events were recorded during the entire course of the investigation. These variables were described as the occurrence of clinically significant differences after communication, which included the following:

**Table No: 1 Assessment of clinical parameters**

| S.No. | Clinical Parameters | Physiological Adverse Events | | |
|---|---|---|---|---|
| 1 | **Heart rate** | Bradycardia heart rate ≤ 60 beats/min | Normal heart rate 60-100 beats/minute | Tachycardia heart rate ≥ 100 beats/minute |
| 2 | **Blood Pressure** | Hypotension SBP≤95 mmHg, DBP≤60 mmHg | Normal SBP 90−140 mmHg, DBP 60−90 mmHg | Hypertension SBP≥140 mmHg, DBP≥90 mmHg |
| 3 | **Temperature** | HypothermiaT≥97 DegreeFahrenheit | Normal 97−99 Degree Fahrenheit | HyperthermiaT≥99 DegreeFahrenheit |
| 4 | **Oxygen saturation** | Desaturation ≤90% | ub-normal 90−94% | Normal95≤% |
| 5 | **Respiratory rate** | Bradypnea respiratory rate ≤12 cycle/min | Normal Range respiratory rate 12-35 cycle/min | Tachypnoea respiratory rate ≥35 cycle/min |
| 6 | **Blood glucose level (BGL)** | Hypoglycaemia BGL <70 mg/dl | Normal rangeBGL 70-180 mg/dl | Hyperglycaemia BGL ≥180 mg/d |

- **Tool III: 'Full Outline of Un-Responsiveness Scale' (FOUR)**

  The Wijdicks scale is used to evaluate the patient's consciousness level following communication activities. It is made up of four parts: the eye response, the motor response, the brain stem reflex, and the respiratory pattern (including mechanical ventilation). The overall score varies between 0 and 16, maximum score being 4. A score of 0 indicates that brain stem and breathing reflexes are absent, while a score of 16 indicates complete consciousness.[107]

- **Tool IV 'The Richmond Agitation–Sedation Scale' (RASS)**

  The patient's level of agitation and sedation were determined by using this scale. The RASS is a 10-point scale ranging from levels (-5 to +4). Levels (-1 to -5) denotes five levels of sedation. Levels (+1 to +4) denoted level of agitation.[108]

- **Tool V: 'Behavioral Pain Scale' (BPS)**

  The patient's degree of comfort and pain was measured using this scale. It measures three behavioral gestures viz. facial expressions, upper limb movements and compliance with mechanical ventilation. Each of the three behavioral expressions is scored on a scale of 1 to 4, with higher numbers indicating greater discomfort. The total score ranged from 3 (no pain) to 12 (extreme pain).[109]

**VALIDITY OF TOOLS**

To ensure the validity of the content of observational checklist, a knowledge questionnaire and an opinionnaire were given to nine nursing and critical care medicine professionals, and they were requested to validate the content of tools. The checklist and questionnaire were modified according to experts' opinions and suggestions. Based on the guidelines content validity index were collected. Item Conduct Validity Index & Scale Conduct Validity Index values of knowledge tool were 0.8-1 and 0.95 respectively and for practice checklist were 1 and 1 respectively.

**RELIABILITY OF TOOLS**

The reliability of a knowledge questionnaire, observational checklist and opinionnaire were checked. The tools were found to be reliable. The reliability of the tools are depicted in Table. 2

**Table No: 2 Reliability for the tools**

| S.No. | Tools | Methods | Statistical test applied | Value |
|---|---|---|---|---|
| 1 | Four Outline of Unresponsiveness Scale | Inter-rater | Kappa coefficient 0.99 | Cronbach α 0.87 |
| 2 | Richmond Agitation Sedation Score | Inter-rater | Kappa coefficient 0.71 | (r=0.95) |
| 3 | Behavioural Pain Scale | Inter-rater | | Cronbach α 0.885 |
| 4 | Knowledge Questionnaire | Split-half | Spearman Brown's Prophecy | (r= 0.82). |
| 5 | Observational checklist | Inter-rater | Karl Pearson's correlation | (r = 0.92) |
| 6. | Opinionnaire for nurses | Test-retest | Karl Pearson's correlation | (r=0.87) |

**PRE-TESTING**

Pre testing was done on 20 staff nurses. The tools were found to be simple and easy to use. The knowledge questionnaire took on an average of 15 minutes to completewhereas it took 20 minutes to complete the observational checklist.

**DESCRIPTION OF INDIVIDUALIZED COMMUNICATION PROTOCOL**

The Individualized Communication Protocol was developed based on literature and personal experience of researcher and informal surveys. It included four components:

**Environmental preparation** included imparting privacy, maintaining personal space during care, maintaining environment feasibility for effective communication and developing a secured atmosphere etc.

**Framing of verbal messages by nurses** viz. use of moderate voice, preventing parallel communication during care procedures, speaking to the client directly, simplifying language by utilizing brief and understandable phrases, repetition of content or common phrases to clear the meaning as required, inculcating normal talking pattern as used by an adult, reducing distractions. Formation of message must have both good content of conversation (e.g., I am your nurse, I will give care to you) and verbal orders (e.g., Mr./Mrs. A! Come on, open your eyes), introducing self to the patients, orienting the patients, calling the patients by their preferred name, greeting the patients, locating the health care provider or a close relative, giving explanation of the nursing interventions before carrying it out and comforting the client at the completion of every procedure.

**Framing of non-verbal messages by nurses** included therapeutic touch, eye contact, posturing, and facial expressions. The three therapeutic touch techniques were caring touch (which provided reassurance and emotional support to the patient), task touch (which was often used while carrying out nursing processes), and protective touch, which was associated with keeping patients safe from harm.

Verbal and non-verbal communication by family: verbal communication by family members covered spiritual support, giving assurance about returning to family etc. Non-verbal communication by family members included tapping on the patient's face and- arms, keeping eye contact while communicating with the patient with a smile and bending forward.

## VALIDITY OF INDIVIDUALIZED COMMUNICATION PROTOCOL

Intervention was validated by nine experts from field of nursing, critical care, anaesthesiology and neurology. All suggestions given by experts were incorporated and intervention was modified accordingly (Annexure-4) Conduct Validity Index of Individualized Communication Protocol tool was 0.95.

 **Imlementation of Intervention:-**

**Phase I-** After assessing the baseline knowledge and practices of staff nurses regarding communication with the comatose patients, a structured teaching program regarding implementation of Individualized Communication Protocol (ICP) was provided to staff nurses working in selected ICU by the investigator. It was imparted with help of power point presentations, charts, hand-outs, and demonstration

method during morning, evening, and night-shifts as per availability of the staff nurses per session /day. After teaching sessions, time was given to staff nurses to practice Individualized communication protocol while rendering nursing care to comatose patients.

**Phase II-** In this phase Individualized Communication Protocol was administered to the patients in experimental group by staff nurses working in ICU during their routine nursing care, such as bed bath, feeding, suctioning, and chest physiotherapy. These nursing care activities were routinely carried out between 9-11am in morning shift and between 3-5 pm in evening shift. Communication by Staff nurses consisted of the following components:

- o   Imparting privacy
- o   Maintaining  personal space during care etc.
- o   Use of moderate voice
- o   Introducing self to the patients
- o   Orienting the patients
- o   Calling the patients by their preferred name
- o   Therapeutic  touch
- o   Eye  contact
- o   Facial  expressions
- o   Tapping on the patient's face and arms
- o   Keeping eye contact while communicating with the patient

**PILOT TESTING**

A pilot study was conducted in December 2020 on eight comatose patients with severe head injuries who were admitted in neurosurgery ICU and met the predetermined selection criteria. The investigator first collected data of comatose patients in control group followed by training of the staff nurses on Individualized Communication Protocol (ICP) was done. The effectiveness of Individualized Communication Protocol (ICP) was evaluated in terms of knowledge and practice of staff nurses. After training, data of comatose patients in experimental group was collected and study was found to be feasible.

**DATA COLLECTION PROCEDURE:**

In order to avoid contamination between experimental and control group, the investigator first collected data of comatose patients in control group followed by which Individualized Communication Protocol (ICP) was administered to staff nurses. The effectiveness of Individualized Communication Protocol (ICP) was evaluated in terms of knowledge and practice of staff nurses. After one month, data of comatose patients in experimental group was collected.

**The investigator conducted the main study in two phases:**

**PHASE I: Administration of Individualized Communication Protocol to staff nurses and evaluation of its effectiveness in terms of knowledge and practice.**

The researcher obtained administrative permission from the concerned authority of Himalayan hospital. Out of 183 staff nurses working in ICU, researcher prepared list of 171 staff nurses, excluding nurses who were posted in COVID unit of ICU during data collection period.

Researcher divided 171 staff nurses into groups as per their availability and duty schedule, explained the purpose of the study and took written informed consent from them. Researcher collected information of staff nurses on socio-demographic variables and pre-test knowledge regarding communication with comatose patients by giving them tools and asking them to respond to the questionnaire. Each participant took about 30 minutes to fill the questionnaire. The pre-test on practice regarding communication with comatose patients was done with the help of an observational check list wherein one communicative event was observed while doing a nursing procedure by each staff nurses. The pre-test was done over a period of approximately two weeks.

After pre-test Individualized Communication Protocol (ICP)) was administered to all the staff nurses working in selected ICU. The Individualized Communication Protocol (ICP) consisted of four components.

1. **Environmental preparation:** This component focused on providing privacy, maintaining personal space during care, maintaining an environment feasible for effective communication and creating a safe, comfortable environment, etc.

2. **Verbal communication with comatose patients:** This component focused on nurses introducing self to patients, orientating the patient about the place, time and person, addressing the patient by his or her preferred name, wishing the patient etc.

3. **Non-verbal communication with comatose patients:** This component focused on therapeutic touch, facial expressions, posturing, eye contact, etc.

4. **Family verbal and nonverbal communication:** This component focused on spiritual support, concerns about the patient's recovery, external events, memories of daily life, home news.

The Individualized Communication Protocol (ICP) was administered to staff nurses in groups. Each group consisted of nine to twenty staff nurses. Teaching was imparted with help of power point presentations, charts, hand-outs, and demonstration method in many sessions during morning, evening, and nightshifts. Researcher taught all 171 staff nurses of ICU over a period of one week.

After administering the Individualized Communication Protocol (ICP) to staff nurses, time was given to them to practice Individualized Communication Protocol (ICP) on comatose patients while giving nursing care to them. Researcher with the help of senior nurses of ICU reinforced the staff nurses regarding regular practice of Individualized Communication Protocol (ICP) with comatose patients.

Post-test knowledge was assessed with help of validated knowledge questionnaire and post-test practice was done by observing one communicative event with the help of an observational checklist on the seventh day after administration of Individualized Communication Protocol (ICP) intervention.

Staff nurses were instructed to use individual communication protocol (ICP) daily while giving nursing care to their comatose patients for a period of one month.

**PHASE II (Part-1): Assessment of the clinical outcome of comatose patients in control group.**

Following admission of comatose patients in ICU, eligibility of patients to be enrolled in the study was evaluated. Patients meeting the sampling criteria were included in the study after obtaining written informed consent from their immediate relatives.

On the same day, the researcher collected data and documented information regarding the patient's socio-demographic and clinical variables. Baseline data on

temperature, blood glucose level were collected from patient's bedside chart and baseline data on clinical parameters, such as heart rate, systolic blood pressure, diastolic blood pressure, oxygen saturation, respiratory rate were collected from patient's bed side cardiac monitor. Researcher assessed patient's baseline level of consciousness by using 'Full Outline of Unresponsiveness scale' (FOUR), level of agitation and sedation by 'Richmond agitation and sedation scale' (RASS), and level of pain by 'Behavioural Pain Scale' (BPS).

Patients in the control group received routine communication from staff nurses working in ICU during nursing care, such as bed bath, feeding, suctioning, and chest physiotherapy. These nursing care activities were carried out daily between 9-11 am in morning shift and between 3-5 pm in evening shift.

From second day onwards in the ICU, researcher collected data on clinical parameters (as mentioned above) of comatose patients and assessed their level of consciousness, level of sedation and agitation and pain level twice daily between 9-11 am and 3-5 pm.

As per the sedation protocol of selected setting patients in control group received sedation i.e., injection Midazolam ranged from l ml to 3 ml (1 ml=0.8 mg/kg) and injection Fentanyl at 50 mcg/kg/hour to 100 mcg/kg/hr.

Researcher followed these patients in control group till 14 days/transfer out of patients from ICU/Death/LAMA, whichever was earlier. Data was collected on patients' clinical parameters, level of consciousness, level of agitation & sedation and pain level twice daily.

Researcher also collected data on duration of mechanical ventilation in terms of when the ventilator was first used until it was turned off and length of ICU stay. Total 58 comatose patients were included in control group

**PHASE II (Part-2): Assessment of the clinical outcome of comatose patients in experimental group.**

After introducing the Individualized Communication Protocol (ICP) to the staff nurses and having them practice it for a month, an opinionnaire was administered to staff nurses regarding the acceptability of the Individualized Communication Protocol, followed by data collection from patients of the experimental group.

Following admission of comatose patients in ICU, eligibility of patients to be enrolled in the study was evaluated. Patients meeting sampling criteria were included in the study after obtaining written informed consent from their relatives.

On day of admission, the researcher collected data and documented information regarding patient's socio-demographic and clinical variables. Baseline data on temperature, blood glucose level were collected from patient's bedside chart and baseline data on clinical parameters, such as heart rate, systolic blood pressure, diastolic blood pressure, oxygen saturation, respiratory rate were collected from patient's bed side cardiac monitor. Researcher assessed patient's baseline level of consciousness by using 'Full Outline of Unresponsiveness scale' (FOUR), level of agitation & sedation by 'Richmond agitation and sedation scale' (RASS) and level of pain by 'Behavioural Pain Scale' (BPS).

Patients in experimental group received Individualized Communication Protocol from staff nurses working in ICU during routine nursing care, such as bed bath, feeding, suctioning, and chest physiotherapy. These nursing care activities were

routinely carried out between 9-11am in morning shift am and between 3-5 pm in evening shift.

From first day in ICU staff nurses implemented Individualized Communication Protocol (ICP) on comatose patients. Staff nurses organized the cubicle before each verbal communication with the patient by drawing curtains to ensure privacy, maintained a quiet environment and the patient was put in a semi-Fowler's position. In each shift, staff nurses greeted the comatose patients, introduced themselves to patients, oriented patients about time, place and person and explained to them about each nursing procedure before and after completing it.
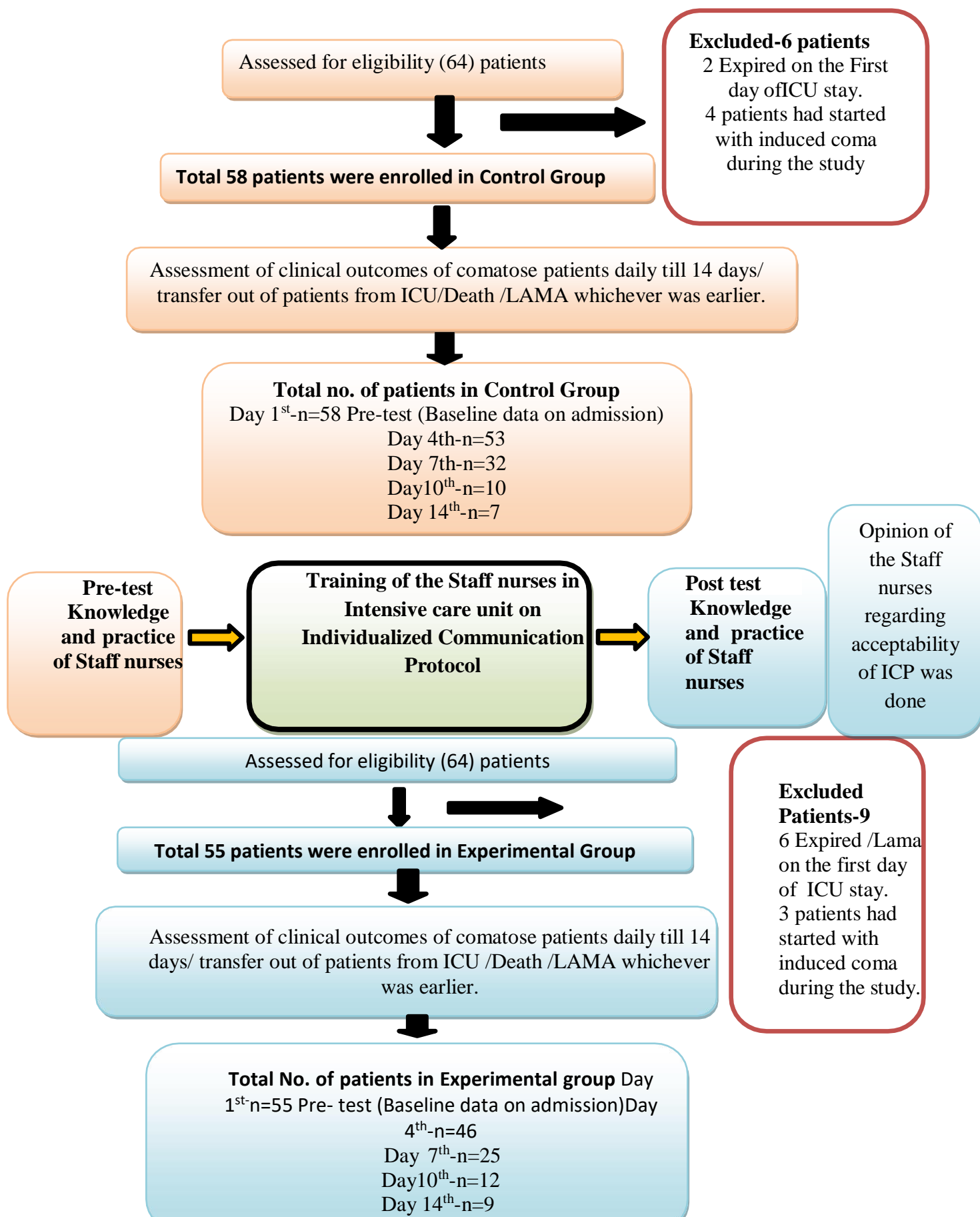
Figure: 4 Diagrammatic presentation of the flow of the study

The flowchart contains the following text:

Assessed for eligibility (64) patients

Excluded-6 patients
2 Expired on the First day ofICU stay.
4 patients had started with induced coma during the study

Total 58 patients were enrolled in Control Group

Assessment of clinical outcomes of comatose patients daily till 14 days/ transfer out of patients from ICU/Death /LAMA whichever was earlier.

Total no. of patients in Control Group
Day 1st-n=58 Pre-test (Baseline data on admission)
Day 4th-n=53
Day 7th-n=32
Day10th-n=10
Day 14th-n=7

Pre-test Knowledge and practice of Staff nurses

Training of the Staff nurses in Intensive care unit on Individualized Communication Protocol

Post test Knowledge and practice of Staff nurses

Opinion of the Staff nurses regarding acceptability of ICP was done

Assessed for eligibility (64) patients

Excluded Patients-9
6 Expired /Lama on the first day of ICU stay.
3 patients had started with induced coma during the study.

Total 55 patients were enrolled in Experimental Group

Assessment of clinical outcomes of comatose patients daily till 14 days/ transfer out of patients from ICU /Death /LAMA whichever was earlier.

Total No. of patients in Experimental group Day 1st-n=55 Pre- test (Baseline data on admission)Day 4th-n=46
Day 7th-n=25
Day10th-n=12
Day 14th-n=9

Staff nurses also communicated with comatose patients using nonverbal communication techniques such as tapping on their shoulders, cheeks, touching their forehead and holding their hands in conjunction with verbal techniques. The family members and close relatives were encouraged to communicate with comatose patients verbally and non-verbally while they visited their patients. The verbal exchange through close relatives included spiritual support, hope for recovery from illness, hope for future, and home information. Family members /relatives also used nonverbal communication techniques like tapping/touching the arms and face of patient, looking at patients, giving a smile, and bending their head while communicating with comatose patients.

From second day onwards researcher collected data on clinical parameters (as mentioned above) of comatose patients and assessed the level of consciousness, level of agitation & sedation, and pain level twice daily between 9-11 am in morning shift and 3-5 pm in the evening shift.

As per the sedation protocol of selected setting patients in control group received sedation i.e., injection Midazolam ranged from l ml to 3 ml (1 ml=0.8 mg/kg) and injection Fentanyl at 50 mcg/kg/hour to 100 mcg/kg/hr.

Researcher followed patients in the experimental group till 14 days/transfer out of patients from ICU/Death/LAMA, whichever was earlier and collected data on patients' clinical parameters, level of consciousness, level of sedation and agitation, and pain level, twice daily between 9-11 am in morning shift and between 3-5 pm in the evening shift.

Researcher also collected data on duration of mechanical ventilation in terms of when the ventilator was first used until it was turned off, and length of ICU stay. Total 55 comatose patients were included in experimental group.

## ETHICAL CONSIDERATIONS

1. An approval was obtained from the Institutional Ethics Committee of SRHUvide letter No. SRHU/HIMS/E-1/20/20/47 (Annexure-1)

2. Written informed consent was taken from staff nurses working in ICU. (Annexure-6)

3. Written informed consent was obtained from relatives of comatose patients.(Annexure-7)

## ADMINISTRATIVE PERMISSIONS:

1. Administrative permission was taken from the Medical Superintendent, Nursing Superintendent, and Head of the Department of Intensive Care Unit of the Himalayan Hospital, Jolly Grant Dehradun. (Appendix-2, 3)

## PLAN FOR DATA ANALYSIS:

It was planned to use descriptive. Statistics viz. frequency, percentage, mean, standard deviation, mean difference and inferential statistics viz. Mann Whitney U test, Paired —t test, Chi-square test , Fischer exact test and Kruskal-Wallis test for data analysis

**Summary**

This chapter described methodological strategies used for the study.