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ANNEXURE 1

Ethical Committee permission letter to conduct the study

Swami Rama Himalayan University

(Est. vide Uttarakhand Act No. 12 of 2013)

Swami Ram Nagar, Jolly Grant, Dehradun-248016
Uttarakhand, India



स्वामी राम हिमालयन विश्वविद्यालय

(उत्तराखण्ड अधिनियम सं. 12 वर्ष 2013 द्वारा स्थापित)

स्वामी राम नगर, जोलीग्रान्ट, देहरादून-248016
उत्तराखण्ड, भारत

"Ethics Committee"

SRHU/HIMS/E-1/2020/ 47

Date: 09.03.2020

To,
Ms. Pooja Thakar, Nursing Tutor
Ph.D Scholar,
Himalayan College of Nursing
Swami Rama Himalayan University.

Ref: Ph.D Synopsis, entitled: "Effectiveness of an individualized communication protocol on clinical outcomes of comatose patients in selected intensive care unit of tertiary care Hospital"

Submitted by Principal Investigator, Pooja Thakar, Nursing Tutor, Ph.D Scholar, AIIMS- Patna

Dear, Ms. Pooja Thakar,

With reference to your submission letter, dated 16.10.2019, the Ethics Committee, Swami Rama Himalayan University reviewed and discussed your application for approval of the above referred research protocol on 21/11/2019.

The following members were present in the meeting held on 21/11/2019, at 11:00 AM in the dept of Pharmacology, H.I.M.S.:
Swami Rama Himalayan University.

Sr. No.	Name of the Member	Designation and Qualification	Representation as per Schedule V	Gender	Affiliation with the Institution
1.	Prof. K.C. Mishra	Chairman MBBS, MD, MAMS	Ex. Principal	M	No
2.	Mr. G.N.S. Gurudutt	Member M.A., M.phil.	Social Scientist	M	No
3.	Mr. Arun Kundra	Member M.A., L.L.B.	Practicing Advocate	M	No
4.	Mr. Sagar Manwal	Member Gram Pradhan, Athurwala	Community Representative	F	No
5.	Prof. Mushtaq Ahmed	Member MBBS, MD(Radiotherapy)	Professor, Dept. of Radiotherapy	M	Yes
6.	Dr. Jaynati Semwal	Member MBBS, MD, (Community Medicine)	Clinician Professor of Paediatrics	M	Yes
7.	Dr. Aksh Dubey	Member MBBS, MD, (Anatomy)	Assoc. Professor, Dept. of Anatomy	M	Yes
8.	Prof. D.C. Dhasmana	Member Secretary, MBBS, MD(Pharmacology)	Pharmacologist	M	Yes

This is to confirm that only members, who were independent of the Investigator of the study, have voted and provided opinion on the study.

The Ethics Committee, Swami Rama Himalayan University, has no objection to the conduct of the study in the present form, as per the submitted protocol, subject to the prior approval of local Ethics Committee empowered to supervise the project at the study site.

Further, the permission is subject to the statutory provisions and permissions, as deemed necessary, to be obtained from concerned authorities.

The Ethics committee, Swami Rama Himalayan University expects to be informed about the progress of the study, any changes in the protocol and asks to be provided a copy of the final report.

The Ethics committee, Swami Rama Himalayan University follows procedures that are in compliance with the requirements of ICH (International Conference on Harmonization) guidelines related to GCP (Good Clinical Practice) and applicable Indian regulations, revised and updated from time to time.


Dr. D.C. Dhasmana,
Member Secretary, Ethics Committee

ANNEXURE 2

Letter seeking permission from Medical superintendent to conduct the Study at Himalayan Hospital

To,
The Chief Medical Superintendent
SRHU, Jolly Grant, Dehradun

(Through Proper channel)

Subject: Permission letter for data collection and research work

Respected Sir ,

I, Pooja Thakur, Ph.D scholar of Swami Rama Himalayan University (Enrolment No:SRHU18000070, Registration No-DD20165010002, would like to state that I was registered in Ph.D Nursing Program of SRHU on 22/01/2016.

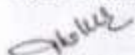
My Ph.D research topic is "Effectiveness of an Individualized Communication Protocol on clinical outcomes of comatose patients in selected Intensive Care Unit of Tertiary Care Hospital" under the supervision of Dr Sanchita Pugazhendī, Professor and Dean, Faculty of Nursing and Dr. Kamli Prakash, Associate Professor, Himalayan College of Nursing, SRHU.

I had received ethical clearance on 19/03/2020 from Ethical Committee, SRHU. I would like to obtain administrative permission to conduct study at Himalayan Hospital.

I request you to kindly grant me permission for the same. I shall be highly obliged

Thanking You


Yours Sincerely,


Pooja Thakur
Ph.D Scholar
Enrollment No: SRHU18000070
Registration No-DD20165010002
Dated: 21/12/2020

*Forwarded to Respected
CMS Sir for receipt
PB
21-12-20*

Enclosure:

1. Ethical committee clearance .


Chief Medical Superintendent
Himalayan Hospital
(A constituent unit of SRHU)
Swami Ram Nagar, P. O. Jolly Grant
Dehradun-248140

ANNEXURE 3

Permission letter from Head of Department of Critical Care Medicine to conduct the study

To,
The Incharge
Critical Care Medicine
SRHU, Jolly Grant, Dehradun

(Through Proper channel)

Subject: Permission letter for data collection and research work

Respected Sir ,

I, Pooja Thakur Ph.D scholar of Swami Rama Himalayan University (Enrolment No:SRHU18000070, Registration No-DD20165010002, would like to state that I was registered in Ph.D Nursing Program of SRHU on 22/01/2016.


My Ph.D research topic is "Effectiveness of an Individualized Communication Protocol on clinical outcomes of comatose patients in selected Intensive Care Unit of Tertiary Care Hospital" under the supervision of Dr Sanchita Pugazhendi, Professor and Dean faculty of Nursing, and Dr. Kamli Prakash, Associate Professor ,Himalayan College of Nursing, SRHU. I had received ethical clearance on 19/03/2020 from Ethical Committee, SRHU . I would like to obtain permission to conduct study in Intensive Care Unit, Himalayan Hospital, SRHU.

I request you to kindly grant me permission for the same .

I shall be highly obliged

Thanking You

Yours Sincerely,


Pooja Thakur
Ph.D Scholar
Enrollment No: SRHU18000070
Registration No-DD20165010002
Dated: 21/12/2020


Anand
23/12/2020

Enclosure:

1. Ethical committee clearance .
2. Permission letter from Medical Superintendent

ANNEXURE- 4

LETTER SEEKING EXPERT'S OPINION FROM VALIDATORS FOR CONTENT VALIDITY OF THE TOOL

From,
Ms. Pooja Thakur
Ph.D. Scholar
SRHU, Swami Ram Nagar
Jolly grant, Doiwala, Dehradun

Subject: Requesting the opinion and suggestion by expert for establishing content validity of Research tool

To,
Respected Sir/Madam

I am Ph.D. Scholar of Swami Ram Himalayan University, Dehradun. In partial fulfilment of the course requirement, I have to undertake a research project and to be submitted to Swami Rama Himalayan University, Uttarakhand. The title of my project is **“Effectiveness of an Individualized Communication Protocol on Clinical Outcomes of Comatose patients in selected Intensive Care Unit of Tertiary Care Hospital.”**

I have prepared the following tools for the purpose of data collection and I request you to go through the content of the following tool for relevancy and appropriateness.

1. Tool I -Demographic variables
2. Tool II- Physiological variables of comatose patients
3. Tool III: Full Outline of Un-Responsiveness (FOUR) scale
4. Tool IV: Richmond Agitation Sedation Scale (RASS).
5. Tool V: Behavioural Pain Scale (BPS)
6. Tool VI:

Section A: Personal Profile of Nurses Working in ICU

Section B: Knowledge questionnaire

Section C: Practice Questionnaire

Section D: Opinionnaire

Intervention –Individualised Communication Protocol for Comatose patient

Here with, I am enclosing the copy of research tools, statement of the problem, objectives of the study and criteria for content validity. Kindly go through the tools and validate the content as well as give your valuable suggestions.

Kindly do the needful at earlier possible. Hope to receive an early reply.

Thanking you in anticipation with warm regards.

Yours sincerely,
Ms. Pooja Thakur

Encl: 1. Criterion checklist for validation
2. Blueprint of the tool

CRITERIA CHECKLIST FOR TOOL VALIDATION

S.No	Relevance		Adequacy		Accuracy		Organization		Remark
	Agree	Disagree	Agree	Disagree	Agree	Disagree	Agree	Disagree	
1.									
2.									
3.									
4.									
5.									
6.									
Clinical profile									
7.									
8.									
9.									
10.									
11.									
Cont									

ANNEXURE- 5

LIST OF VALIDATORS FOR TOOLS AND INTERVENTION

S.No	Validators
1.	Dr Sushant Khanduri, Associate Professor & Department Critical Care Medicine, Himalayan Institute of Medical sciences
2.	Dr. Yashwant.Payal Additional Professor (Department of Anaesthesiology) AIIMS, Rishikesh
3	Dr Umesh Badhani Professor and Dean (Academics)(Department of Anaesthesiology) AIIMS, Patna
4.	Dr.Sukhpal Kaur Lecturer cum Academics In charge College of Nursing, (PGIMER,Chandigarh)
5.	Dr.Manju Dhandapani Lecturer, College of Nursing (PGIMER, Chandigarh)
6.	Dr. Gopichandran Associate Professor, College of Nursing, AIIMS, Delhi
7.	Dr Deepika Khakha. Associate Professor, College of Nursing, AIIMS, Delhi
8.	Dr. Binoy Kumar Singh Assistant Professor, Department of Neurosurgery , NEIGRIHMS.
9.	Dr.Hiranya Kumar Saharia Assistant Professor Department of Anesthesiology and critical care, Guwahati Medical college and Hospital

ANNEXURE- 6

Letter seeking consent from staff nurses

Written Informed consent

I, Mrs /Mr.....aged.....years voluntarily participating in the research study conducted by Ms Pooja Thakur from Swami Rama Himalayan University, Uttarakhand. I understand that the research project is designed to gather information about knowledge, practices and opinion of Critical care Nurses regarding Individualised Communication Protocol.

My Participation in this project is voluntary. I understand that I will not be paid for my participation. I may withdraw and discontinue participation at any time of the study. It has been informed to me that participation involves responding to knowledge, practice questionnaire and opinionnaire.

My name and information provided by me will be kept confidential and subsequent uses of records and data will be subject to standard data and policies which protect the anonymity of individuals and institutions.

I understand that this research study has been approved by the institutional Ethical and legal committee.

I have read and understood the explanation provided to me by researcher. I agree to participate in this study voluntarily and giving my consent willingly and not under any kind of threat/Pressure.

Name

Signature

Dated.....

ANNEXURE- 7

WRITTEN INFORMED CONSENT FORM RELATIVES OF PATIENTS

Participants Code number: _____

Participant identification number _____

Project Title: Effectiveness of an Individualized Communication Protocol on clinical outcomes of comatose patients in selected Intensive care unit of Tertiary care hospital.

Name of Principal Investigator: Ms Pooja Thakur.

Name and age of the Research Subject (Patient attendant)

I have read the participant Information sheet and its contents were explained by the researcher in my own language and

I have understood the contents. I had the opportunity to ask question and receive satisfactory answers.

I understand that me and my patient participation in the study is voluntary and that I have the right to withdraw at any time without giving any reason, without my patient medical care or legal rights being affected.

I understand that the information collected from me may be presented at meetings or published in journals without my name and personal identifications.

I agree and give consent to take part in the above mentioned study for me and my child. I also confirm that I have received a copy of the Participant Information Sheet

I agree to take part in the above study.

Date: (Signatures / Left Thumb Impression)

Place:

Name of the Participant: _____

Son / Daughter / Spouse of: _____

Complete postal address: _____

प्रतिभागी सूचित सहमति पत्र

इस अध्ययन के लिए रोगी की पहचान संख्या:

परियोजना का शीर्षक: तृतीयक देखभाल अस्पताल की चयनित गहन देखभाल इकाई में कॉमाटोज़ रोगियों के नैदानिक परिणामों पर एक व्यक्तिगत संचार प्रोटोकॉल की प्रभावशीलता।

प्रधान अन्वेषक का नाम: पूजा ठाकुर

दूरभाष।सं: (9719776044)पूजा ठाकुर

दी गई सूचना पत्र की सामग्री दिनांकित, उसे मेरे द्वारा ध्यान से पढ़ा गया है / मुझे विस्तार से समझाया गया है, उस भाषा में जिसे मैं समझता हूँ, मैं पुष्टि करता हूँ/ करती हूँ कि मुझे सवाल पूछने का अवसर मिला है। अध्ययन की प्रकृति और उद्देश्य और इसके संभावित जोखिम / लाभ और अध्ययन की अपेक्षित अवधि, और अध्ययन के अन्य प्रासंगिक विवरण मुझे विस्तार से बताए गए हैं। मैं समझता हूँ /समझती हूँकि मेरी भागीदारी स्वैच्छिक है और मैं बिना किसी कारण के किसी भी समय अध्ययन से पीछे हटने के लिए स्वतंत्र हूँ, मेरी चिकित्सा देखभाल या कानूनी अधिकार प्रभावित हुए बिना। मैं समझता हूँ कि इस अनुसंधान में मेरी भागीदारी से मेरे बारे में एकत्र की गई जानकारी और मेरे किसी भी चिकित्सा नोट को एम्स के जिम्मेदार व्यक्तियों द्वारा देखा जा सकता है। मैं इन व्यक्तियों को अपने रिकॉर्ड तक पहुंचने की अनुमति देता हूँ/ देती हूँ । मैं उपरोक्त अध्ययन में भाग लेने के लिए सहमत हूँ।

(हस्ताक्षर / बाएं अंगूठे का निशान)

दिनांक:

स्थान:

प्रतिभागी का नाम:

पुत्र / पुत्री / पति / पत्नीकानाम:

पूरा डाक पता:

ANNEXURE- 8

Participant Information Sheet

Project Title:

Effectiveness of an Individualized Communication Protocol on Clinical Outcomes of Comatose Patients in selected Intensive Care Unit of Tertiary Care Hospital..

IEC No:

Sponsor Name:

Language: English

Principal Investigator: Ms Pooja Thakur

Designation: Nursing Tutor

Hospital: Himalayan Institute of Medical Sciences

Mobile Number: 9719776044

Introduction:

I am Ms Pooja Thakur inviting you to participate in this research study. Please read this information sheet carefully. Your participation in this research study is voluntary and you can take time to reflect on whether you want to participate or not. You have the full rights to enquire about the details of research. If you don't understand any information or concepts before you give your written consent for participation, I will take time to explain you as long as you go along. Until you receive the satisfying clarifications to the asked doubts or questions, don't sign the informed consent form.

By signing the consent form, you will become the participant and adhere to the requirements of this study.

Purpose

The aim of the present study is to develop and implement the Individualized Communication Protocol and to evaluate its effect on clinical outcomes of comatose patients admitted in intensive care unit.

OBJECTIVES OF THE STUDY

Primary Objectives:

1. To develop Individualized Communication Protocol for staff nurses to be used for comatose patients.
2. To evaluate the effectiveness of Individualized Communication Protocol on knowledge of staff nurses working in ICU.
3. To evaluate the effectiveness of Individualized Communication Protocol on practice of the staff nurses working in ICU.
4. To evaluate the effectiveness of Individualized Communication Protocol implemented by nurses working in ICU on clinical outcomes of comatose patients in terms of physiological adverse events, level of consciousness, level of agitation and sedation and pain level.

Secondary Objectives:

5. To find out correlation of pre-test knowledge and pre-test practice of nurses working in ICU.
6. To find out association between level of knowledge of nurses working in ICU with their selected socio-demographical variables.
7. To find out association between level of practice of nurses working in ICU with their selected socio-demographical variables
- 8 To assess the opinion of nurses working in ICU regarding acceptability of Individualized Communication Protocol.

Who can take part

Comatose patients with GCS score $\leq 8/15$

Inclusion Criteria:

The sample will consist of patients who:

1. have age between 18 to 65 years
2. are on Mechanical Ventilation.
3. presents with GCS score $\leq 8/15$

Exclusion Criteria: All Patient were excluded from the study who:

1. Had history of impaired hearing.
2. Were diagnosed Injury of the Auditory pathways.
3. Were induced Coma by infusion of Neuromuscular Blockade.

What will happen during the study (Plan of Action)

Comatose patients who are admitted in intensive care units will be consecutively recruited into two groups. One group will be receiving the intervention and other group will not. The group which will not receive the intervention will be received standard routine care. Your patient will be continuing all the medication or treatments from your doctor apart from the intervention. Your patient baseline information, physiological parameters, responsiveness, sedation level and pain will be assessed.

Tool 1: Baseline proforma

Tool 2: Physiological adverse event assessment tool

Tool 3: Full Outline of Un-Responsiveness (FOUR) scale

Tool 4: The Richmond Agitation–Sedation Scale (RASS).

Tool 5: Behavioural Pain Scale (BPS)

Expected duration of study participation -The total duration for the data collection is 6 month

Potential risks and discomforts: The study does not involve any actual /potential risks to your patients.

What are the potential benefits of participating in the study:

Study helps to reduce intense feelings of insecurity anxiety and isolation in comatose patient also incidences of ICU psychosis and delirium. It will also boost their chances of survival and enhances early recovery of the patients.

Incorporating communication in the nursing standards will ensure that patients are treated with dignity which will help in improve patient outcomes.

What are the alternative treatments available: Alternative treatment not applicable?

Cost of participating in the study: No costs involved

Confidentiality of information:

All the information that you provide during the study will be kept confidential and

will be utilized only for the study purpose Information from the study records including patient name, address, medical records, results of tests, study results will be kept confidential and will be reviewed only by authorized personnel from the sponsor or their representative, Ethics Committee or regulatory bodies. The data will not be made available to another individual unless you specifically give permission in writing.

Voluntary participation:

Your participation in this study is voluntary; you may decline to participate at any time and you need not give any reason for the same, and such withdrawal shall be without penalty and without loss of benefits to which you are otherwise entitled.

Provision of free treatment for research related injury:

Not applicable in this study since there is no potential risk associated with the study

Financial Consideration:

Nothing will be charged or you will not receive any incentive for participating in the study. If you any further questions, please contact:

Alternatives to participation:

You are free not to participate in the study or to withdraw from the study at any time without penalty or loss of benefits.

Whom to contact in case of any questions:

If you experience adverse effects as a result of participating in this study, you may contact the principal investigator Pooja Thakuras detailed above.

This research project is reviewed and approved by Institutional Ethical Committee Himalayan Institute of Medical Sciences, Jolly grant, Dehradun. This is a committee whose task it is to make sure that research participants are protected from harm.

If you have any questions about the informed consent process or your rights as a participant, the Principal Investigator shall give you contact details of the Member Secretary of Institutional Ethics Committee.

Principal Investigator:

MS. Pooja Thakur

Swami Rama Himalayan University

प्रतिभागी सूचना शीट

अध्ययन / परियोजना का शीर्षक: तृतीयक देखभाल अस्पताल की चयनित गहन देखभाल इकाई में कॉमाटोज रोगियों के नैदानिक परिणामों पर एक व्यक्तिगत संचार प्रोटोकॉल की प्रभावशीलता।

आ ई ई सी नंबर:

प्रायोजक का नाम:

भाषा-हिन्दी

प्रधान अन्वेषक: सुश्री पूजा ठाकुर

पदनाम: नर्सिंग ट्यूटर

अस्पताल: स्वामी राम हिमालयन विश्वविद्यालय

मोबाइलनंबर:9719776044

परिचय:

मैं सुश्री पूजा ठाकुर आपको को इस शोध अध्ययन में भाग लेने के लिए आमंत्रित कर रही हूँ। कृपया इस सूचना पत्र को ध्यान से पढ़ें। इस शोध अध्ययन में आपकी भागीदारी स्वैच्छिक है और आप इस पर विचार करने के लिए समय निकाल सकते हैं कि आप भाग लेना चाहते हैं या नहीं। अनुसंधान के विवरण के बारे में पूछताछ करने के लिए आपके पास पूर्ण अधिकार हैं। यदि आप भागीदारी के लिए अपनी लिखित सहमति देने से पहले किसी भी जानकारी या अवधारणाओं को नहीं समझते हैं, तो मुझे आपको समझाने में समय लगेगा जब तक आप साथ हैं। जब तक आपको पूछे गए संदेह या सवालों के संतोष जनक स्पष्टीकरण नहीं मिलते हैं, तब तक सूचित सहमति फॉर्म पर हस्ताक्षर नहीं करेंगे। सहमति फॉर्म पर हस्ताक्षर करके, आप भागीदार बन जाएंगे और इस अध्ययन की आवश्यकताओं का पालन करेंगे।

अध्ययन

का

उद्देश्य:

वर्तमान अध्ययन का उद्देश्य व्यक्तिगत संचार प्रोटोकॉल को विकसित और कार्यान्वित करना है और गहन देखभाल इकाई में भर्ती होने वाले कोमाटोज रोगियों के नैदानिक परिणामों पर इसके प्रभावका आकलन करना है।

कौन भाग ले सकता है

कॉमाटोज़ मरीज जिनका जी सी एस स्कोर < 8/15 से कम है।

शामिल करने के मापदंड: सैंपल में ऐसे मरीज शामिल होंगे जो

1. 18 से 65 वर्ष के बीच की आयु हो
2. मैकेनिकल वेंटिलेशन पर हैं।
3. जी सी एस स्कोर < 8/15 से कम है।

बहिष्करण मानदंड:

सभी रोगी को अध्ययन से बाहर रखा गया है।

1. बिगड़े हुए श्रवण का इतिहास है।
2. श्रवण मार्ग के चोट का निदान किया गया।
3. न्यूरोमस्क्युलर नाकाबंदी दवाओं के द्वारा कोमा को प्रेरित किया गया।

अध्ययन के दौरान क्या होगा) कार्य योजना(

गहन देखभाल इकाइयों में भर्ती होने वाले कोमाटोज रोगियों को लगातार दो समूहों में भर्ती किया जाएगा। एक समूह हस्तक्षेप प्राप्त करेगा और अन्य समूह नहीं करेगा। जो समूह हस्तक्षेप प्राप्त नहीं करेगा, उसे मानक नियमित देखभाल प्राप्त होगी। आपका रोगी हस्तक्षेप के अलावा आपके चिकित्सक से सभी दवाया उपचार जारी रखेगा। आपकी रोगी आधारभूत जानकारी, शारीरिक मापदंडों, जवाबदेही, बेहोश करने की क्रिया स्तर और दर्द का आकलन किया जाएगा।

उपकरण 1: बेसलाइन प्रोफार्मा

उपकरण 2: शारीरिक प्रतिकूल घटना मूल्यांकन उपकरण

उपकरण 3: अन-रिस्पॉन्सिबिलिटी (FOUR) स्केल की पूर्ण रूपरेखा

उपकरण 4: रिचमंड एग्रेसन-सेडेशन स्केल (RASS)

उपकरण 5 व्यवहार दर्द स्केल (BPS)

अध्ययन की भागीदारी की अपेक्षित अवधि-डेटा संग्रह के लिए कुल अवधि

6 महीने है

संभावित जोखिम और असुविधाएँ: अध्ययन में आपके रोगियों के लिए कोई वास्तविक / संभावित जोखिम शामिल नहीं है।

अध्ययन में भाग लेने से लाभ :

अध्ययन से असुरक्षा की चिंता को कम करने में मदद मिलती है और कोमा टोज रोगी में अलगाव भी आई सी यू मनोविकृति और प्रलाप की घटनाएँ हैं। यह उनके जीवित रहने की संभावनाओं को भी बढ़ाएगा और रोगियों की शीघ्र वसूली को बढ़ाएगा। नर्सिंग मानकों में संचार को शामिल करने से यह सुनिश्चित होगा कि रोगियों को गरिमा के साथ व्यवहार किया जाता है जो रोगी परिणामों को बेहतर बनाने में मदद करेगा।

उपलब्ध वैकल्पिक उपचार क्या हैं: वैकल्पिक उपचार लागू नहीं है।

अध्ययन में भाग लेने की लागत: कोई लागत शामिल नहीं है।

जानकारी की गोपनीयता:

अध्ययन के दौरान आपके द्वारा प्रदान की जाने वाली सभी जानकारी को गोपनीय रखा जाएगा और इसका उपयोग केवल अध्ययन के उद्देश्य के लिए किया जाएगा। मरीज का नाम, पता, चिकित्सा रिकॉर्ड, परीक्षण के परिणाम, अध्ययन के परिणाम सहित अध्ययन के रिकॉर्ड की जानकारी गोपनीय रखी जाएगी और प्रायोजक या उनके प्रतिनिधि, एथिक्स कमेटी या नियामक निकायों के अधिकृत कर्मियों द्वारा ही समीक्षा की जाएगी। जब तक आप विशेष रूप से लिखित में अनुमति नहीं देते हैं, तब तक डेटा किसी अन्य व्यक्ति को उपलब्ध नहीं कराया जाएगा।

स्वैच्छिक भागीदारी:

इस अध्ययन में आपकी भागीदारी स्वैच्छिक है; आप किसी भी समय भाग लेने के लिए अस्वीकार कर सकते हैं और आपको इसके लिए कोई कारण देने की आवश्यकता नहीं है, और इस तरह की वापसी दंड के बिना और उन लाभों के नुकसान के बिना होगी जिनके आप अन्यथा हकदार हैं।

अनुसंधान से संबंधित हानी के लिए मुफ्त उपचार का प्रावधान :

इस अध्ययन में लागू नहीं है क्योंकि अध्ययन से संबंधित कोई संभावित जोखिम नहीं है।

वित्तीय विचार: कुछ भी शुल्क नहीं लिया जाएगा या आपको अध्ययन में भाग लेने के लिए कोई प्रोत्साहन नहीं मिलेगा।

भागीदारी के विकल्प: आप किसी भी समय दंड या लाभ के नुकसान के बिना अध्ययन में भाग लेने या अध्ययन से पीछे हटने के लिए स्वतंत्र हैं।

किसी भी प्रश्न के मामले में किस से संपर्क करें:

यदि आप इस अध्ययन में भाग लेने के परिणाम स्वरूप प्रतिकूल प्रभाव अनुभव करते हैं, तो आप ऊपर विस्तृत रूप से प्रधान अन्वेषक पूजा ठाकुर से संपर्क कर सकते हैं।

इस शोध परियोजना की समीक्षा और अनुमोदन संस्थागत नैतिक समिति स्वामी राम हिमालयन

विश्वविद्यालय
द्वारा किया जाता है। यह एक समिति है जिसका कार्य यह सुनिश्चित करना है कि अनुसंधान
प्रतिभागियों को नुकसान से बचाया जाए।

प्रधान अन्वेषक:

सुश्री पूजा ठाकुर,
स्वामी राम हिमालयन विश्वविद्यालय

ANNEXURE- 9
RESEARCH TOOLS

Tool I

SOCIO-DEMOGRAPHIC AND CLINICAL VARIABLES
CHARACTERISTICS OF COMATOSE PATIENT

Code No:

1. Age(in Year)
2. Gender: Male Female
3. Marital status: Married Unmarried Widow
4. Level of Education:
5. Place of Living: Rural Urban
6. Occupation:

Clinical Variables

7. Medical Diagnosis
8. Admission to ICU from Ward/ Emergency.
9. Level of Consciousness (LOC) (GCS- Score) on Admission to ICU
10. On Mechanical Ventilation (MV) Yes/No
11. ICU length of stay
12. APACHE II Score on Admission -

TOOL II: PHYSIOLOGICAL VARIABLES OF THE PATIENTS

Instruction: This tool will be used to record the physiological parameters after monitoring the Comatose Patients for each Morning /Evening shift.

S.No.	Physiological Variables	Date		Date		Date		Date		Date		Date		Date		
		M	E	M	E	M	E	M	E	M	E	M	E	M	E	
1	Temperature (Degree Fahrenheit)															
2	Heart rate (Beats per Min)															
3	Respiratory rate (cycle/min)															
4	Oxygen saturation (%)															
5	Non Invasive Blood Pressure															
6	Ventilatory distress: severe ventilator															
7	blood glucose level (BGL)mg/dl															

Key =M- Morning / E-Evening

Tool III: FULL OUTLINE OF UN-RESPONSIVENESS (FOUR) SCALE
Instructions: From Item number 1 to 4. Kindly tick (✓) the most appropriate response in each category after observing the Comatose Patients for each Morning /Evening shift.

S.N O	Components/ Description /Score	Date		Date		Date		Date		Date		Date		Date		
		M	E	M	E	M	E	M	E	M	E	M	E	M	E	
	Observation															
1.	Eye response Eyelids open or opened, tracking, or blinking to command +4 Eyelids open but not tracking +3 Eyelids closed but open to loud voice+2 Eyelids closed but open to pain+1 Eyelids remain closed with pain 0															
2.	Motor response (upper extremities) Thumbs-up, fist, or peace sign +4 Localizing to pain+3 Flexion response to pain+2 Extension response to pain+1 No response to pain or generalized myoclonus status 0															
3.	Brainstem reflexes Pupil and corneal reflexes present+4 One pupil wide and fixed +3 Pupil OR corneal reflex absent +2 Pupil AND corneal reflexes absent +1 Absent pupil, corneal, and cough reflexes 0															

1.	Respiration pattern Not intubated, regular breathing pattern +4 Not intubated, Cheyne-Stokes breathing pattern +3 Not intubated, irregular breathing +2 Breathes above ventilatory rate +1 Breathes at ventilator rate or apnea 0																
		Total Score-	16														

Key=Morning -M/ Evening -E

INTERPRETATION:

The maximum score for the four items is 4. The total score ranges from 0 to 16.

A score of 0 on the FOUR scale assumes the absence of brainstem reflexes and breathing while, 16 indicates full consciousness.

Tool IV: RICHMOND AGITATION SEDATION SCALE (RASS)

Instruction: From Item number 1 to 10 Kindly tick (√) the most appropriate response after observing the Comatose Patients for each Morning /Evening shift.

S.N O	Term	Score	Date		Date		Date		Date		Date		Date		Date	
			M	E	M	E	M	E	M	E	M	E	M	E	M	E
1.	Combative	+4														
2.	Very Agitated	+3														
3.	Agitated	+2														
4.	Restless	+1														
5.	Alert and Calm	0														
6.	Drowsy	-1														
7.	Light Sedation	-2														
8.	Moderate Sedation	-3														
9.	Deep Sedation	-4														
10.	Unrousable	-5														

INTERPRETATION:

Term	Description
Combative	Overtly combative or violent; immediate danger to staff
Very agitated	Pulls on or removes tube(s) or catheter(s) or has aggressive behavior toward staff
Agitated	Frequent non purposeful movement or patient-ventilator dys synchrony
Restless	Anxious or apprehensive but movements not aggressive or vigorous
Alert and calm	Spontaneously pays attention to caregiver
Drowsy	Not fully alert, but has sustained (more than 10 seconds) awakening, with eye contact, to voice
Light sedation	Briefly (less than 10 seconds) awakens with eye contact to voice
Moderate sedation	Any movement (but no eye contact) to voice
Deep sedation	No response to voice, but any movement to physical stimulation
Unarousal	No response to voice or physical stimulation

Tool V: BEHAVIOURAL PAIN SCALE (BPS)

Instructions: From Item number 1 to 3. Kindly tick (✓) the most appropriate response in each category after observing the Comatose Patients for each Morning /Evening shift.

S. No	Term	Score	Date		Date		Date		Date		Date		Date		Date	
			M	E	M	E	M	E	M	E	M	E	M	E	M	E
1.	Facial expression															
	Relaxed	+1														
	Partially tightened (e.g., brow lowering)	+2														
	Fully tightened (e.g., eyelid closing)	+3														
	Grimacing	+4														
2.	Upper limb movements															
	No movement	+1														
	Partially bent	+2														
	Fully bent with finger flexion	+3														
	Permanently retracted	+4														
3.	Compliance with mechanical ventilation.															
	Tolerating movement	+1														
	Coughing but tolerating ventilation for most of the time	+2														
	Fighting ventilator	+3														
	Unable to control ventilation	+4														
Total Score		12														

INTERPRETATION

Each item of the three behavioral expressions is scored from 1 to 4, with higher numbers indicating higher levels of discomfort.

Each of these stages is scored from 1 to 4.

The minimum score of behavioral pain scale is 3 meaning that there is no pain.

The maximum is 12, which indicates the highest level of pain.

Blue print of area of content for Knowledge questionnaire

S.No	AREA OF CONTENT	LEVEL OF THE KNOWLEDGE DOMAIN			MAX. SCORE	%
		Recall Question No	Analytic Question No	Application Question No		
2.	Information on coma	1,11,21	9,10,12	4,14	8	33
3.	Information on general communication	2,13	6,23	3,20	6	25
4.	Information on communication skill in nurse patient relationship	5,15,16	7,8,18, 23,24	17,19	10	42
	TOTAL	8	10	6	24	
	PERCENTAGE (%)	33.3	41.7	25	100%	

Tool-VI

SECTION-A

PROFILE OF NURSES WORKING IN ICU

Instruction: Please fill appropriate option to give your

proper information. Code No-

Date:

Personal Profile

1. Age : -
2. Gender: -
3. Marital Status:
4. Professional Qualification:
5. Area of Experience: Critical area Non critical
6. Designation:
7. Years of experience in clinical : -
8. Additional Qualification (If Any): -
9. Nurse - Patient ratio (In ICU) : -

SECTION B

“KNOWLEDGE BASED QUESTIONNAIRE TO ASSESS THE KNOWLEDGE OF STAFF NURSES WORKING IN ICU

Instructions:

- Kindly read through the questions and place a right option at the appropriate column area below
- Participants are requested to answer all questions given below

1. “Coma ” is a state of: ()
 - a. Unconsciousness
 - b. Drowsiness
 - c. Delirium
 - d. Confusion

2. Communication is the : ()
 - a. Two way process
 - b. Three way process
 - c. Not a process
 - d. Sometime a process

3. In Nurse patient relationship communication should be initiated by: ()
 - a. Patient
 - b. Physician
 - c. Nurse
 - d. Family Member

4. While providing care to the Comatose patient we use therapeutic touch because ()
 - a. It makes patient comfortable.
 - b. It is always beneficial
 - c. It break the sense of isolation
 - d. All of above.

5. An important aspect for Comatose patient under Non-verbal communication is : ()
 - a. Listening
 - b. Clarification.
 - c. Empathy and intuition.
 - d. Sympathy

6. Effective communication is a one of the key determinants of the: ()
- Patient and family satisfaction.
 - Patient and nurse satisfaction
 - Patient and doctor satisfaction
 - Nurse and family satisfaction
7. Communication skills of nurse is important because it : ()
- Improve contact with patient relatives
 - Provide individualized nursing care
 - Provide Love and confidence.
 - Facilitate patient satisfaction compliance and recovery.
8. In Therapeutic Nurse patient relationship , Non Verbal communication is an essential part of: ()
- Healing process
 - Treatment process
 - Nursing process
 - Therapeutic process
9. As a Nurse which of the following do you think correct for a patient with Coma: ()
- Little memory
 - No memory
 - Half memory
 - Full memory
10. Comatose patients having GCS score below 8/15 can ()
- Remember but cannot verbalize
 - Remember and verbalize
 - Not remember and cannot verbalize
 - Not remember but can verbalize
11. Intensive care syndrome is a: ()
- Physical reaction
 - Drug reaction
 - Psychological reaction
 - Psychosocial reaction
12. Which of the following senses does the Comatose patient loose at last? ()
- Touch
 - Hearing
 - Smell
 - Sight

13. Which of the following space do you need to follow while performing care for the Comatose patient ()
- Intimate space (contact to 18 inch away)
 - Personal space (contact to 18 inch - 4 feet)
 - Social space (4 to 12 feet)
 - Public space (Greater than 12 feet)
14. The incidence of ICU syndrome in comatose minimizes through one of the following: ()
- Verbal communication by Nurses
 - Adequate treatment by anxiolytic drugs
 - Frequent patient and Family Communication
 - Verbal communication by doctors
15. Task touch means: ()
- Comforting touch
 - Caring touch
 - Reassuring touch
 - Performing touch
16. Nurse uses therapeutic touch while caring for a comatose patient because it helps in ()
- Stimulation only
 - Non-verbal communication, stimulation and healing
 - Completion of diagnostic procedure
 - Pain reduction
17. We can prevent psychological distress of Comatose patient by providing: ()
- Regular positive reinforcement
 - Maintaining privacy
 - Calm and quiet atmosphere
 - Intensive care
18. . Which of the following assists in speedy recovery of comatose patients by calling them with: ()
- Name and making them to hear unfamiliar voices
 - Bed No and surrounding them with familiar situations
 - Name and making them to hear familiar voices.
 - Bed No. and surrounding them with unfamiliar situations

19. . One of the best approach during non-verbal communication with a comatose patient is through : ()
- Social touch
 - Therapeutic touch
 - Physical touch
 - Spiritual touch
20. During therapeutic communication a Nurse feel more personal while ()
- Look around patient
 - Turning towards the patient.
 - Turning away from Patient
 - Turning toward patient while talking to others.
21. When communicating with the patient with GCS less 8/15 the nurse knows that awareness of the patient's about his external environment: ()
- Patient is aware of external environment.
 - Patient is little aware of external environment
 - Patient is fully aware of external environment.
 - Patient is aware, but not able to interpret in words.
22. Which is the most effective Stimulation for patient with Coma is: ()
- Smile.
 - Forward lean.
 - Caring touch
 - Head nodding
23. . Nurse should communicate with comatose patients: ()
- Only during change of shift
 - Only during procedure
 - During procedure, change of shift and whenever possible
 - Only when nurse is free
24. While caring for the Comatose patients the most important “Human Medicine is”: ()
- Communication Therapy
 - Surgical Therapy
 - Physiotherapy
 - Medicinal Therapy

ANSWER KEYS

1. a

2. a

3. c

4. d

5. c

6. a

7. b

8. c

9. a

10. a

11. c

12. b

13. b

14. c

15. d

16. b

17. a

18. c

19. b

20. b

21. d

22. c

23. c

24. a

SECTION-C

CHECK-LIST FOR ASSESSING STAFF NURSES PRACTICE ON COMMUNICATION

Check List

An Observation Check List for Nursing personnel practice on communication of Nurses working with Comatose patients in ICU.

Instructions:

- The investigator will observe, whether the nurse communicates to the patient with Coma or not.
- If nurse communicating then observer will put a tick mark against the column given in the check list.
- If he/she does not communicate put a cross mark ×
- The scoring will be one mark each for each column.

Results: Scoring one mark each:

If done –1 Mark

Not Done- 0 Mark

SCORE INTERPRETATION

Code No. of the Participant:

Date:

Place:

SECTION-C

Code No. of the Participant:

Date:

Place:

Communication: - Verbal and Non-Verbal Skill

S.No	Event	Done	Not Done
	ENVIRONMENTAL PREPARATION		
1	Provide privacy during communication		
2	Stand at least arm length from the patient.		
3	Maintain environment feasible for effective communication –Noise free , non-threatening environment,/ICU syndrome		
4	Create a safe comfortable environment.		
5	Communicate according to stages of development.		
	VERBAL COMMUNICATION WITH COMATOSE PATIENT		
6	Offers the patient an item to support their wellbeing/ positive reinforcement.		
7	Demonstrate soothing vocal tones		
8	Use short, simple words and sentences, repeat the content		
9	Use appropriate non-technical language		
10	Maintain Individuality of the patient.		
11	Use nonverbal cues to demonstrate understanding such as nodding, eye contact and leaning forward		
12	Call the patient by his /her name		
13	Greet the patient		
14	Introduce yourself to the patient.		
15	Orient the patient about day, time ,Place		
16	Explain the procedure to the patient		
17	Inform the patient about his/her near and dear ones saying some thing about her /his family, memories , telling a message of affection.		
18	Use abuse-free, verbal communication with clients.		
19	Communicate with hopeful word about the progress /condition regarding health.		
20	Having social conversation		
21	Communicates according to cultural background.		
22	Shows exceptional communication skill to promote patient wellbeing		
	NON VERBAL COMMUNICATION WITH COMATOSE PATIEN		
23	Maintain postures. Lean forward and smile each time when he/she spoke to patient.		
24	.Demonstrates Attentiveness while communicating with the patient.		
25	Maintain Individuality of the patient.		
26	Demonstrate appropriate pleasant/ positive facial expression		
27	Use abuse-free, non-verbal communication with clients		
28	Non Verbal Aspect: Giving Therapeutic touch while calling/caring (Caring touch ,Task touch, Protective touch, Instrumental Touch)		
29	Communicates according to cultural background		

30	Maintain professional body language while interacting with patient.		
31	Confident while communication / interactions with patient.		
	COMMUNICATION WITH PATIENT RELATIVES		
32	Talk to the patients relative in simple and understandable language		
33	Develop rapport ,trust, empathy and compassion while communicating with patients attendants.		
34	Actively listen to complaints or concern of patient family.		
35	Avoid Parallel Talk		
36	Communicates in a respectful , professional manners with family members		
37	Create a safe comfortable environment in which relatives can talk freely.		
38	Demonstrate congruence		
39	Use assertive communication with their family member.		
40	Encourage Family members to communicate “Verbally and Non Verbally’ with their patient during visiting time.		
41	Demonstrate non-judgemental listening.		
42	Encourage patient attendants to use supportive statements while meeting the patient in ICU		
43	Show Confidence in communication / interactions family member.		

SECTION-D

**OPINIONNAIRE ON ACCEPTABILITY OF INDIVIDUALIZED
COMMUNICATION PROTOCOL BY NURSES WORKING IN
ICU**

Instruction: Please read the following statements carefully and feel free to express your opinion in terms of whether you accept the statement Fully (column 1)

Partially (column 2) or

Do not accept the statement (column 3).

Please place a tick mark (✓) in the appropriate column.

Sl. No.	Statement	Accept fully	Accept Partially	Do not accept
	I find that			
1	This protocol provided me the adequate information which is required to carry out communication with comatose patient.			
2	Different aspects of this protocol are of practical use			
3	Areas of communication clearly explained in this protocol			
4	Content of protocol is easy to understand			
5	Language used in this protocol is simple			
6	This protocol is useful while communicating with comatose patient.			
7	This protocol can be implemented where Comatose patient are being taken care.			
8	Time given was sufficient to read & learn from protocol			

ANNEXURE- 10

INTERVENTION

INDIVIDUALISED COMMUNICATION PROTOCOL FOR COMATOSE PATIENTS

PREPARED BY

Ms POOJA THAKUR

INDIVIDUALIZED COMMUNICATION PROTOCOL FOR COMATOSE PATIENTS

Objectives of the session: At the end of the teacher-learning session, participants will be able to:

1. Define Communication.
2. Define comatose patients.
3. Enlist the types of communication
4. Discuss the importance of communication with comatose patients and nurses in ICU settings
5. Discuss the expected outcomes for comatose patients.
6. Enlist various components explain in detail about environmental preparation to be done before and during communication with comatose patients in ICU setting.
7. Enlist and elaborate the verbal techniques to be used in verbal communication with comatose patients.
8. Enumerate and discuss techniques to be used during non- verbal communication with comatose patients.
9. Describe the techniques of communication with relatives/ attendants of comatose patients.

Introduction of self: good morning, all. Myself, Pooja Thakur

Introduction of topic:

Today we will discuss about Communication skills for comatose patients.

Communication with critically ill patients in intensive care settings generates specific challenges for nursing staff, and demands well-developed skills. It is essential to communicate with the comatose patients by nurses to reduce stress, anxiety and feeling of social isolation.

Evidence based guidelines will help to bring uniformity in communicating with Comatose patients.

BACKGROUND

The Intensive Care Unit (ICU) is a very "intense" area and can create a great deal of tension and stress for patients and families. Effective and appropriate communication is an important part of the healing process, not only for the patient, but also for the family. Most of the critically ill patients are in the state of Coma, where they can't communicate with critical care team and with their family members.

DEFINITION-

Communication is simply the act of transferring information from one place, person or group to another. Communication has been claimed to be the foundation of all Nursing care.

“Communication is an exchange of ideas, facts, opinions or emotions of two or more persons.”

By Louis Allen

Comatose Patient: Coma is a prolonged state of deep unconsciousness, caused especially by severe injury or illness.

It refers to a patients having Glasgow Coma Scale score $\leq 8/15$ and admitted in Intensive Care Unit.

TYPES OF COMMUNICATION:

Verbal Communication: It is an essential part of the nursing process which can reduce anxiety or distress and emotionally stimulate the patient.

Verbal communication is the use of sounds and words to express yourself, which includes face-to-face, telephone, radio or television and other media.

Non Verbal communication- It is the transmission of messages or signals through a nonverbal platform such as eye contact, facial expressions, gestures, posture, covering body language, how we dress or act, where we stand. There are many subtle ways that we communicate (perhaps even unintentionally) with others. For example, the tone of voice can give clues to mood or emotional state, whilst hand signals or gestures can add to a spoken message and the distance between two individuals.

IMPORTANCE OF COMMUNICATION WITH COMATOSE PATIENTS IN ICU SETTING

- Communication reassures comatose patient and reduces their psychological anxiety.
- Verbal communication reduces distress and emotionally stimulate the patient.
- Orientation and reassurance during communication can reduce intense feelings of insecurity anxiety and isolation in comatose patient.
- Sensory deprivation that occurs during the hospital stay can cause psychological distress, which can be effectively reduced by verbal and nonverbal communication.
- Effective communication reduces the incidences of ICU psychosis and delirium.
- Explanations provided by nurses during verbal communication help comatose patients to feel safe, secure and less vulnerable.
- Calling comatose patients by their names in an informative and caring situation might raise patient consciousness level and boost their chances of survival.
- Communication helps to stimulate the brain's reticular activating system which helps in arousal, thus maintaining the conscious state.
- Caring touch used with verbal communication can enhance the messages comatose patients receive.
- Tactile stimulation conveys emotional support.
- Effective communication improves the psychological well-being of family members
- It improves patient and family satisfaction, compliance, trust.
- Effective communication enhances early recovery of the patients.

EXPECTED OUTCOME FOR COMATOSE PATIENT:

- Patient and Family satisfaction.
- Boosting Prognosis.
- Reduction in Mortality
- Minimizing the Duration of hospital stay
- Cost effectiveness.
- Better healing process.

COMPONENTS OF COMMUNICATION IN ICU SETTING-

1. Environmental preparation.
2. Verbal communication with comatose patients.
3. Nonverbal communication with comatose patients.
4. Communication with patient relatives

COMPONENTS OF COMMUNICATION IN ICU SETTING-

1. ENVIRONMENTAL PREPARATION

a. Provide privacy during communication

- During environment preparation, privacy to be maintained by using curtains or as per the hospital protocols

b. Stand at least arm length from the patient.

- During patient care, personal space needs to be maintained which is 8 inches to 4 feet (approximately an arm length.)

c. Maintain environment feasible for effective communication –

- Noise free, non-threatening environment, /ICU syndrome.
- Nurse should maintain noise free environment in the ICU by rectifying the issues related ventilator and cardiac monitor alarms, requesting other colleagues and health care professionals to keep the ICU area noise free by talking in low tone or not to shout in ICU setting which will prevent the incidences of ICU syndrome. Concern uses of physical restraints.

d. Create a safe comfortable environment.

- Orient the patient to any new environment or change within an existing environment to minimize safety hazards.
- Keep the number of visitors to 1 or 2 people at a time. Visits should be short. Other distractions (TV, radio) should be turned off when visiting.

e. Communicate according to stages of development.

- Nurse should consider the cognitive ability of the patient while communicating with the patient.

2. VERBAL COMMUNICATION WITH COMATOSE PATIENT

a. Offers the patient an item to support their wellbeing/ positive reinforcement.

- While communicating with comatose patients, nurse explains his /her availability for the patient's wellbeing during his /her shift.
“Nurse also motivates the patient by implementing positive reinforcement by using statements like you are doing good, your parameters are improving etc.”

b. Demonstrate soothing vocal tones

- While communicating with comatose patients, nurse should always use soothing voice by not speaking too loudly. Use short, simple words and sentences, repeat the content.
- While communicating with comatose patients, nurse have to keep in mind that most of the comatose patients have capability to hear Thus, simple words and short sentences need to be used. Repeat the context if , it seems to be important. it is recommended to use the courteous words during communication like Please, Kindly, Thanks etc.

c. Use appropriate non-technical language.

- While communicating patients, avoid using medical jargons like intubation, resuscitation etc.

d. Maintain Individuality of the patient.

- While communicating with patients, treat a patient as a dignified individual by using polite and respectful words e.g., Always call the patient by his /her name.
- Never address the patient with bed number etc.
- Use nonverbal cues to demonstrate understanding such as nodding, eye contact and leaning forward
“Nurses offer brief verbal affirmations such as “I see,” “I know,” “Sure,” “Thank you” or “I understand”.

Call the patient by his /her name, *ji*.

“While communicating with the patient, the nurse has to respectfully address the patient with his /her name..... ji”

- Greet the patient
- While meeting the needs of the patient, always start the communication by greeting the patient.
*“Good morning/Afternoon /Good Night... *Ji*”*
- Introduce yourself to the patient.
- Before performing procedure on patient, it is essential to introduce

yourself to the patient by telling your name and designation.

“My Name is.....I am a Nursing officer responsible to look after you for this shift.”

e. Orient the patient about

- Day: State the date, Day of week, weather
- Time: Tell about the time.
- Place: Explain the current location bed No., Hospital etc.
- At the beginning of each shift, nurse needs to orient the patient about time, place and person.

“Good morning/Good evening (Mr./Mrs.)__ I am.....I will be taking care of you this morning/evening / night It is now (9:00 AM/9:00 PM) on (Monday / Tuesday /Wednesday / Thursday / Friday / Saturday / Sunday) and you are at the_University Hospital.

Outside weather is very good /warm /cool. There are many doctors and nurses working here Ji. I want you to know that we’re all here to take care of you. I am here to help you come on open your eyes. If you need us, do not worry, we will always be with you”.

f. Explain the procedure to the patient

- Nurse explains the procedure each time. *That “I’m.....and now I am giving care to you.”*
- The Nurses leaned forward and smiled each time she/he spoke to the patient, maintained eye contact throughout the procedure, taped on patient shoulder and hand before and after procedure.

g. Inform the patient about his/her near and dear ones saying something about her /his family life, memories, telling a message of affection. With an optimistic perspective.

“Your Family told me they really like you and that they wish you recover quickly”

h. Use abuse-free, verbal communication with clients.

i. Communicate with hopeful word about the progress/condition regarding health:

- Some sentences about affection and her/his recovery, provide reassurance and transmit a sensation of control.

“Nurse respond calmlyji. Your condition is improving Doctors are putting best possible effort for your early recovery. Today you are looking better than yesterday. Your family members are also

praying for your early recovery. Everyone thinks of you and wants you to get better as soon as possible. Your family members love you very much and they are looking forward to be with you as soon as possible. Now rest well and do not be afraid. We are always with you.”

.....

j. Having social conversation

- Currents Affairs as per the interest of the patient
“Ji you know and sweet memories of past related to patient”.

k. Communicates according to cultural background.

- Nurse should be aware about the need culturally competent nursing care language barrier needs to be overcome by using preferred and understandable language for build the Rapport.
- Assistance from other colleagues needs to be taken is the nurse is unaware about the preferred language of the patient.
- Encourage your colleagues and other health care professionals to provide culturally competent care. If Nurse is unsure /unaware about patient cultural practices, then information could be gathered from the patient relatives.

l. Shows exceptional communication skill to promote patient’s wellbeing.

- Preferred music therapy, family members recorded voice can be used as a stimulus, encouraging any type of communication feedback from patient. In case, comatose patients regain his /her consciousness, then communication board can be used by the nurses

Communication Boards:

Communication Boards are devices that are used to help to communicate intubated patients and those who have trouble in communicating verbally.

Types of Communication Boards

The boards are categorized into two: -

1. **Low-tech**-Low technology boards could be just a sheet of paper broken up into rows and columns with different commands, verbs, adjectives, nouns, etc. with pictures.
2. **High technology** boards can be sometimes seen on I Pads, where patient can press on a button and the device speaks for the patient.

Purpose of Communication board:

To ease the communication and anxiety in mechanically ventilated conscious patients admitted to intensive care units (ICUs).

Domains for the communication chart are as following:

- ✓ Communication chart for the emergency need of the patients
- ✓ Communication chart for the basic needs of the patients
- ✓ Communication chart for the psychological needs of the patients.



3. NON-VERBAL COMMUNICATION WITH COMATOSE PATIENT

a. Maintain postures..... Lean forward and smile each time when he/she spoke to patient.

- While talking to the patient leaning forward and smiling is recommended
- Try to make eye contact as much as possible while caring for the patient.

b. Demonstrates Attentiveness while communicating with the patient. Maintain Individuality of the patient.

- While communicating with the patient use appropriate body language, gestures, facial expressions, caring touch etc. as per the age, gender, cognitive development, cultural belief etc.

c. Demonstrate appropriate pleasant/ positive facial expression

“Smile!without frowning or scowling.”

Use abuse-free, non-verbal communication with clients

- Avoid using abusive non-verbal communication like hitting the patient, intentional injury etc.

d. Non-Verbal Aspect: Giving Therapeutic touch while calling/caring

- i) Caring touch: Give comfort and Reassurance
 - Caring touch provides comfort and reassurance. caring touch can be accompanied by statement like
“Everyone who is working here is always looking after you and trying to make you feel comfortable.”
 - Ask the patient if it is okay to touch them on the wrist
- ii) Task touch: Communicating with the patient while performing procedures
- iii) Protective touch: Touch related to patient safety.
 - Procedures e.g., Positioning, Hygiene, prevention from bed sore, preventing falls etc.
- iv) Instrumental Touch:
 - Taped patient shoulder and hand before and after the procedures. Use gentle touch.

e. Communicates according to cultural background

- Keep in mind the cultural practices while dealing with the patient because every patient is unique.
- Maintain professional body language while interacting with patient.
- Confident while communication / interactions with patient.

4. COMMUNICATION WITH PATIENT RELATIVES

a. Talk to the patients relative in simple and understandable language.

- If Nurse Don't know the language ask for any other staff who know that language if possible.

Develop rapport, trust, empathy and compassion while communicating with patients' attendants.

“Nurse reassure that the patient is not aloneI am concerned about the patient's recovery”

b. Actively listen to complaints or concern of patient family.

c. Avoid Parallel Talk

- Explain the queries raised by the relatives by providing realistic hope. Explain the patient's condition thoroughly by using simple words and avoiding technical terms or medical jargons.

d. Communicates in a respectful, professional manners with family members.

- Critical care staff have to explain about the current status, so that relatives can understand that what is going on and why.

- e. **Create a safe comfortable environment in which relatives can talk freely.**
 - Nurse should provide a comfortable environment i.e., by arranging a separate room or isolated area with arrangement like furniture water where patient relatives can talk freely.
 - While conversation nurse and patient relative should face each other and eye contact to be maintained throughout the conversation.
 - Ask about patients habits, likes and dislikes which is effective for better patient outcomes from patient relatives
 - Avoid making assumptions.

- f. **Demonstrate congruence**
 - While communicating with patient attendants give feedback regarding your understanding by using terms like “is it like this”, or restating the statement.

- g. **Use assertive communication with their family member.**
 - Telling the professional boundaries, limitations and instructions without showing aggression.

- h. **Encourage Family members to communicate “Verbally and Non-Verbally’ with their patient during visiting time.**
 - Daily life event of family members and news from the home or relatives.
 - Family verbal communication covered “*spiritual support, reaffirming that the patient is not alone; concerns about the patient’s recovery; the wish for the patients to return to family life; and should not worry about external events.*”
 - While, nonverbal communication methods used by family members consisted of tapping on patient’s face and arms, maintaining eye contact, smiling, and leaning **forward during talking to the patient.**

- i. **Demonstrate non- judgmental listening.**
 - Enable the person to talk freely and comfortably about problem without feeling that he or she is being judged.
 - Reassure that you are here to listen and ready to clarify their doubts. Remain Calm and let them know its ok to take their time when communicating with you.
 - Encourage patient attendants to use supportive statements while meeting the patient in ICU
For example, "Mom, its e.g. Seema, I'm here with you and you are doing much better. Everyone is taking good care of you."

j. Show Confidence in communication / interactions family member.

Summary: Nurses often experience difficulties in communicating with comatose patients, primarily because the patient is unable to respond, lack of time, overburden etc.

This communication protocol will help the nurse participants in enhancing their communication skills specific for comatose patients.

Conclusion: -

Need to communicate with comatose patients should be addressed, emphasized and met, as it contributes to improve the overall quality of care for these patients.

ANNEXURE-11

Supplementary Data

Table No 8: Association between practice of the staff nurses with their socio-demographic variables. (N=171)

Practice of the staff nurses						
SL .No	Demographic variables of Staff Nurses		Below Median ≤21 f (%)	Above Median ≥21 f (%)	X ²	p-value
1	Age	20-29	102(100)	0	NA	NA
		30 -39	58(100)	0		
		>40	11(100)	0		
2	Total years of experience in nursing practice	<1 Years	10(100)	0	NA	NA
		1-5 Years	92(100)	0		
		6-10 Years	48(100)	0		
		>10 Years	21(100)	0		
3	Gender	Male	78(100)	0	NA	NA
		Female	93(100)	0		
4	Qualification	G.N.M	79(100)	0	NA	NA
		B. Sc Nursing	87(100)	0		
		M. Sc Nursing	5(100)	0		
5	Area of experience	Critical	147(100)	0	NA	NA
		Non Critical	5(100)	0		
		Critical/ Non Critical	19(100)	0		

Note: Chi-Square Test, NA-Not applicable p< 0.05

Table No: 12 Comparison of Physiological adverse events (Heart rate) between control and experimental group of comatose patients. (N=113)

Heart Rate of Comatose patients (Beats/Minute)								
Days	Timing	Incidences	Control Group		Experimental Group		Mann-Whitney U test	
			f	Median /IQR	f	Median /IQR	U test value	p value
Day 1 (C=58 E=55)	Morning	Bradycardia	0	110 (20)	0	100(21)	1491.50	0.541
		Normal	23		27			
		Tachycardia	35		28			
	Evening	Bradycardia	0	110 (30)	0	96(28)	1554.50	0.788
		Normal	27		27			
		Tachycardia	31		28			
Day-2 (C=58 E=55)	Morning	Bradycardia	0	96 (10)	0	100(26)	1497.00	0.394
		Normal	46		47			
		Tachycardia	12		8			
	Evening	Bradycardia	0	90 (22)	0	100(18)	1359.50	0.06
		Normal	41		47			
		Tachycardia	17		8			
Day-3 (C=57 E=52)	Morning	Bradycardia	0	92 (50)	0	112(30)	1427.00	0.695
		Normal	22		22			
		Tachycardia	35		30			
	Evening	Bradycardia	0	120 (26)	0	118(41)	1372.50	0.435
		Normal	21		23			
		Tachycardia	36		29			
Day-4 (C=52 E=45)	Morning	Bradycardia	0	98 (24)	0	98(23)	1041.00	0.281
		Normal	22		24			
		Tachycardia	30		21			
	Evening	Bradycardia	0	80 (4)	0	90(24)	1123.00	0.565
		Normal	46		38			
		Tachycardia	6		7			

Heart Rate of Comatose patients (Beats/Minute)								
Days	Timing	Incidences	Control Group		Experimental Group		Mann-Whitney U test	
			f	Median /IQR	f	Median /IQR	U test value	p value
Day-5 (C=46 E=42)	Morning	Bradycardia	0	92 (8)	0	94(15)	930.00	0.546
		Normal	41		39			
		Tachycardia	5		3			
	Evening	Bradycardia	0	90 (8)	0	90(12)	797.00	0.03
		Normal	42		31			
		Tachycardia	4		11			
Day-6 (C=36 E=34)	Morning	Bradycardia	0	110 (26)	0	100(37)	562.00	0.493
		Normal	14		16			
		Tachycardia	22		18			
	Evening	Bradycardia	0	126 (26)	0	108(22)	539.00	0.315
		Normal	17		12			
		Tachycardia	19		22			
Day-7 (C=32 E=24)	Morning	Bradycardia	0	122 (22)	0	108(31)	395.50	0.933
		Normal	15		11			
		Tachycardia	17		13			
	Evening	Bradycardia	0	130 (28)	0	96(30)	322.50	0.15
		Normal	13		14			
		Tachycardia	19		10			
Day-8 (C=19 E=18)	Morning	Bradycardia	0	106 (32)	0	104(44)	142.50	0.2
		Normal	7		10			
		Tachycardia	12		8			
	Morning	Bradycardia	0	102 (2)	0	103(27)	158.00	0.642
		Normal	7		8			
		Tachycardia	12		10			

Heart Rate of Comatose patients (Beats/Minute)								
Days	Timing	Incidences	Control Group		Experimental Group		Mann-Whitney U test	
			f	Median /IQR	f	Median /IQR	U test value	p value
Day-9 (C=14 E=14)	Morning	Bradycardia	0	96 (20)	0	94(9)	91.00	0.549
		Normal	12		13			
		Tachycardia	2		1			
	Evening	Bradycardia	0	96 (6)	0	96(22)	77.00	0.072
		Normal	14		11			
		Tachycardia	0		3			
Day-10 (C=10 E=12)	Morning	Bradycardia	0	112 (22)	0	108(23)	64.00	0.942
		Normal	4		5			
		Tachycardia	6		7			
	Evening	Bradycardia	0	112 (32)	0	100(39)	61.00	0.773
		Normal	4		6			
		Tachycardia	6		6			
Day-11 (C=9 E=12)	Morning	Bradycardia	0	100 (14)	0	86(22)	49.00	0.192
		Normal	5		10			
		Tachycardia	4		2			
	Evening	Bradycardia	0	102 (24)	0	96(20)	64.00	0.942
		Normal	3		5			
		Tachycardia	6		7			
Day-12 (C=7 E=9)	Morning	Bradycardia	0	120 (30)	0	104(34)	48.00	0.89
		Normal	2		4			
		Tachycardia	5		5			
	Evening	Bradycardia	0	112 (14)	0	90(27)	28.00	0.048
		Normal	1		6			
		Tachycardia	6		3			

Heart Rate of Comatose patients (Beats/Minute)								
Days	Timing	Incidences	Control Group		Experimental Group		Mann-Whitney U test	
			f	Median /IQR	f	Median /IQR	U test value	p value
Day-13 (C=7 E=9)	Morning	Bradycardia	0	110 (14)	0	96(32)	27.50	0.391
		Normal	2		5			
		Tachycardia	5		4			
	Evening	Bradycardia	0	98 (4)	0	98(9)	28.00	0.222
		Normal	7		7			
		Tachycardia	0		2			
Day-14 (C=7 E=9)	Morning	Bradycardia	0	96 (0.1)	0	94(7)	31.50	0.403
		Normal	7		8			
		Tachycardia	0		1			
	Evening	Bradycardia	0	100 (16)	0	100(17)	33.50	0.793
		Normal	6		8			
		Tachycardia	1		1			

Note: Mann-Whitney U test, $p < 0.05$, C=Control group, E=Experimental group

Table No :13 Comparison of Physiological adverse events (blood pressure) between control and experimental group of comatose patients. (N=113)

Blood Pressure of Comatose patients (mmHg)								
Days	Timing	Incidences	Control Group		Experimental Group		Mann-Whitney U test	
			f	Median (IQR)	f	Median (IQR)	U test Value	p value
Day-1 (C=58 E=55)	SBP Morning	Hypotensive	1	110(10)	1	120(10)	1536.500	0.45
		Normal	55		50			
		Hypertensive	2		4			
	DBP Morning	Hypotensive	1	80(10)	4	80(10)	1481.000	0.92
		Normal	56		51			
		Hypertensive	1		0			
	SBP Evening	Hypotensive	0	130(20)	2	130(10)	1513.000	0.186
		Normal	56		52			
		Hypertensive	2		1			
	DBP Evening	Hypotensive	3	80(20)	2	80(10)	1566.500	0.195
		Normal	53		53			
		Hypertensive	2		0			
Day-2 (C=58 E=55)	SBP Morning	Hypotensive	2	120(0)	1	120(15)	1567.000	0.695
		Normal	54		54			
		Hypertensive	2		0			
	DBP Morning	Hypotensive	3	70(10)	1	70(15)	1568.500	0.652
		Normal	54		54			
		Hypertensive	1		0			
	SBP Evening	Hypotensive	2	120(10)	1	120(10)	1568.000	0.663
		Normal	55		53			
		Hypertensive	1		1			
	DBP Evening	Hypotensive	3	70(10)	1	70(10)	1568.500	0.669
		Normal	54		54			
		Hypertensive	1		0			

Blood Pressure of Comatose patients (mmHg)								
Days	Timing	Incidences	Control Group		Experimental Group		Mann-Whitney U test	
			f	Median (IQR)	f	Median (IQR)	U test Value	p value
Day-3 (C=57 E=52)	SBP Morning	Hypotensive	0	130(10)	0	120(20)	1482.000	0.999
		Normal	57		52			
		Hypertensive	0		0			
	DBP Morning	Hypotensive	2	60(10)	0	70(15)	1456.000	0.578
		Normal	54		52			
		Hypertensive	1		0			
	SBP Evening	Hypotensive	2	120(0)	0	120(15)	1482.000	0.988
		Normal	53		52			
		Hypertensive	2		0			
	DBP Evening	Hypotensive	2	70(0)	1	70(10)	1458.500	0.615
		Normal	55		51			
		Hypertensive	0		0			
Day-4 (C=52 E=45)	SBP Morning	Hypotensive	1	120(0)	1	120(10)	1193.000	0.539
		Normal	50		45			
		Hypertensive	1		0			
	DBP Morning	Hypotensive	1	70(20)	1	70(15)	1193.000	0.356
		Normal	50		45			
		Hypertensive	1		0			
	SBP Evening	Hypotensive	1	130(0)	1	130(0)	1193.000	0.563
		Normal	50		45			
		Hypertensive	1		0			
	DBP Evening	Hypotensive	2	60(20)	1	70(25)	1216.000	0.951
		Normal	49		45			
		Hypertensive	1		0			

Blood Pressure of Comatose patients (mmHg)								
Days	Timing	Incidences	Control Group		Experimental Group		Mann-Whitney U test	
			f	Median (IQR)	f	Median (IQR)	U test Value	p value
Day-5 (C=46 E=42)	SBP Morning	Hypotensive	1	120(0)	1	120(10)	923.000	0.987
		Normal	43		41			
		Hypertensive	1		0			
	DBP Morning	Hypotensive	1	70(10)	1	70(10)	943.500	0.961
		Normal	44		41			
		Hypertensive	0		0			
	SBP Evening	Hypotensive	2	120(0)	1	110(15)	944.000	0.981
		Normal	42		41			
		Hypertensive	1		0			
	DBP Evening	Hypotensive	4	60(10)	1	60(10)	883.500	0.195
		Normal	41		41			
		Hypertensive	0		0			
Day-6 (C=36 E=34)	SBP Morning	Hypotensive	1	130(0)	0	130(5)	612.000	0.999
		Normal	34		34			
		Hypertensive	1		0			
	DBP Morning	Hypotensive	3	80(10)	0	80(5)	561.000	0.088
		Normal	33		34			
		Hypertensive	0		0			
	SBP Evening	Hypotensive	1	120(0)	0	120(5)	612.000	0.999
		Normal	34		34			
		Hypertensive	1		0			
	DBP Evening	Hypotensive	3	70(10)	0	70(10)	561.000	0.088
		Normal	33		34			
		Hypertensive	0		0			
Day-7 (C=32 E=24)	SBP Morning	Hypotensive	1	120(10)	0	120(10)	384.000	0.999
		Normal	30		24			
		Hypertensive	1		0			
	DBP Morning	Hypotensive	2	70(10)	0	70(20)	360.000	0.216
		Normal	30		24			
		Hypertensive	0		0			
	SBP Evening	Hypotensive	2	130(0)	0	130(0)	372.000	0.311
		Normal	29		24			
		Hypertensive	1		0			
	DBP Evening	Hypotensive	2	60(20)	0	60(25)	360.000	0.216
		Normal	30		24			
		Hypertensive	0		0			

Blood Pressure of Comatose patients (mmHg)								
Days	Timing	Incidences	Control Group		Experimental Group		Mann-Whitney U test	
			f	Median (IQR)	f	Median (IQR)	U test Value	p value
Day-8 (C=19 E=18)	SBP Morning	Hypotensive	0	130(10)	0	130(15)	162.000	0.33
		Normal	18		18			
		Hypertensive	1		0			
	DBP Morning	Hypotensive	0	80(10)	0	80(0)	171.000	0.988
		Normal	19		18			
		Hypertensive	0		0			
	SBP Evening	Hypotensive	0	120(0)	0	120(10)	162.000	0.888
		Normal	18		18			
		Hypertensive	0		0			
	DBP Evening	Hypotensive	1	70(0)	0	70(10)	153.000	0.317
		Normal	17		18			
		Hypertensive	0		0			
Day-9 (C=14 E=14)	SBP Morning	Hypotensive	0	130(0)	1	130(10)	84.500	0.335
		Normal	13		13			
		Hypertensive	0		0			
	DBP Morning	Hypotensive	0	60(20)	0	70(10)	91.000	0.966
		Normal	13		14			
		Hypertensive	0		0			
	SBP Evening	Hypotensive	0	120(10)	1	70(10)	78.000	0.355
		Normal	12		13			
		Hypertensive	0		0			
	DBP Evening	Hypotensive	0	120(10)	1	70(10)	78.000	0.335
		Normal	12		13			
		Hypertensive	0		0			
Day-10 (C=10 E=12)	SBP Morning	Hypotensive	0	120(0)	0	120(10)	60.000	0.999
		Normal	10		12			
		Hypertensive	0		0			
	DBP Morning	Hypotensive	0	70(10)	0	70(10)	60.000	0.856
		Normal	10		12			
		Hypertensive	0		0			
	SBP Evening	Hypotensive	0	110(0)	0	110(5)	60.000	0.987
		Normal	10		12			
		Hypertensive	0		0			
	DBP Evening	Hypotensive	0	60(10)	0	60(15)	60.000	0.964
		Normal	10		12			
		Hypertensive	0		0			

Blood Pressure of Comatose patients (mmHg)								
Days	Timing	Incidences	Control Group		Experimental Group		Mann-Whitney U test	
			f	Median (IQR)	f	Median (IQR)	U test Value	p value
Day-11 (C=9 E=12)	SBP Morning	Hypotensive	0	120(10)	0	120(5)	54.000	0.856
		Normal	9		12			
		Hypertensive	0		0			
	DBP Morning	Hypotensive	0	80(10)	0	80(0)	54.000	0.963
		Normal	9		12			
		Hypertensive	0		0			
	SBP Evening	Hypotensive	0	-	0	-	54.000	0.964
		Normal	0		0			
		Hypertensive	9		12			
	DBP Evening	Hypotensive	0	-	0	130(15)	54.000	0.556
		Normal	0		0			
		Hypertensive	9		12			
Day-12 (C=7 E=9)	SBP Morning	Hypotensive	0	110(0)	0	110(10)	45.000	0.453
		Normal	7		9			
		Hypertensive	0		0			
	DBP Morning	Hypotensive	0	60(0)	0	60(15)	45.000	0.456
		Normal	7		9			
		Hypertensive	0		0			
	SBP Evening	Hypotensive	0	-	0	120(15)	45.000	0.366
		Normal	7		9			
		Hypertensive	0		0			
	DBP Evening	Hypotensive	0	70(0)	0	70(15)	45.000	0.147
		Normal	7		9			
		Hypertensive	0		0			
Day-13 (C=7 E=9)	SBP Morning	Hypotensive	0	130(0)	0	130(10)	31.500	0.569
		Normal	7		9			
		Hypertensive	0		0			
	DBP Morning	Hypotensive	0	70(0)	0	70(10)	31.500	0.258
		Normal	7		9			
		Hypertensive	0		0			
	SBP Evening	Hypotensive	0	-	0	110(0)	31.500	0.597
		Normal	7		9			
		Hypertensive	0		0			
	DBP Evening	Hypotensive	0	60(0)	0	60(5)	31.500	0.985
		Normal	7		9			
		Hypertensive	0		0			

Blood Pressure of Comatose patients (mmHg)								
Days	Timing	Incidences	Control Group		Experimental Group		Mann-Whitney U test	
			f	Median (IQR)	f	Median (IQR)	U test Value	p value
Day-14 (C=7 E=9)	SBP Morning	Hypotensive	0	130(10)	0	120(20)	31.500	0.654
		Normal	7		9			
		Hypertensive	0		0			
	DBP Morning	Hypotensive	0	70(0)	0	70(5)	31.500	0.987
		Normal	7		9			
		Hypertensive	0		0			
	SBP Evening	Hypotensive	0	110(0)	0	110(15)	31.500	0.966
		Normal	7		9			
		Hypertensive	0		0			
	DBP Evening	Hypotensive	0	60(0)	0	60(10)	31.500	0.988
		Normal	7		9			
		Hypertensive	0		0			

Note: Mann-Whitney U test, $p < 0.05$, SBP-Systolic Blood Pressure, DBP-Diastolic Blood Pressure, C=Control group, E=Experimental group

Table No: 14 Comparison of Physiological adverse events (temperature) between control and experimental group of comatose patients. (N=113)

Temperature of Comatose patients(Degree Fahrenheit)								
Days	Timing	Incidences	Control group		Experimental Group		Mann-Whitney U test	
			f	Median /IQR	f	Median /IQR	U test Value	p value
Day-1 (C=58 E=55)	Morning	Hypothermia	3	97.6(1)	0	98.2(1)	1595.000	0.969
		Normal	52		55			
		Hyperthermia	3		0			
	Evening	Hypothermia	1	97.6(1)	0	98.2(1)	1592.000	0.989
		Normal	53		52			
		Hyperthermia	4		3			
Day-2 (C=58 E=55)	Morning	Hypothermia	2	97.7(0.3)	0	98.2(1)	1594.000	0.99
		Normal	52		53			
		Hyperthermia	4		2			
	Evening	Hypothermia	1	98.6(1)	0	97.9(1)	1512.500	0.183
		Normal	53		55			
		Hyperthermia	4		0			
Day-3 (C=57 E=52)	Morning	Hypothermia	0	98.9(2)	0	98.2(1)	1404.000	0.095
		Normal	54		52			
		Hyperthermia	3		0			
	Evening	Hypothermia	2	98.7(1)	0	98.3(1)	1431.500	0.498
		Normal	50		51			
		Hyperthermia	5		1			
Day-4 (C=52 E=45)	Morning	Hypothermia	2	97.7(0.2)	0	98(0.3)	1222.000	0.936
		Normal	48		47			
		Hyperthermia	2		0			
	Evening	Hypothermia	2	97.8(1)	0	98.2(0.2)	1222.000	0.856
		Normal	48		47			
		Hyperthermia	2		0			
Day-5 (C=46 E=42)	Morning	Hypothermia	0	97.5(1)	0	98(0.3)	967.500	0.334
		Normal	45		43			
		Hyperthermia	1		0			
	Evening	Hypothermia	0	97.6(0.2)	0	98.3(1)	989.000	0.996
		Normal	46		43			
		Hyperthermia	0		0			

Temperature of Comatose patients(Degree Fahrenheit)								
Days	Timing	Incidences	Control group		Experimental Group		Mann-Whitney U test	
			f	Median /IQR	f	Median /IQR	U test Value	p value
Day-6 (C=36 E=34)	Morning	Hypothermia	1	98(1)	0	97.8(1)	595.000	0.314
		Normal	32		35			
		Hyperthermia	3		0			
	Evening	Hypothermia	0	98.6(0.1)	0	98.1(1)	630.000	0.855
		Normal	36		35			
		Hyperthermia	0		0			
Day-7 (C=32 E=24)	Morning	Hypothermia	0	98.9(0.2)	0	98.4(1)	387.500	0.377
		Normal	31		25			
		Hyperthermia	1		0			
	Evening	Hypothermia	1	98.7(1)	1	98.2(1)	372.500	0.318
		Normal	29		24			
		Hyperthermia	2		0			
Day-8 (C=19 E=18)	Morning	Hypothermia	0	97.6(0.1)	0	98.2(1)	171.000	0.999
		Normal	19		18			
		Hyperthermia	0		0			
	Evening	Hypothermia	0	97.6(0.2)	0	97.8(1)	162.000	0.33
		Normal	18		18			
		Hyperthermia	1		0			
Day-9 (C=14 E=14)	Morning	Hypothermia	0	97.7(0.1)	0	98.2(1.1)	98.000	0.334
		Normal	14		14			
		Hyperthermia	1		0			
	Evening	Hypothermia	1	98.6(1)	0	97.9(1)	98.000	0.334
		Normal	14		14			
		Hyperthermia	0		0			
Day-10 (C=10 E=12)	Morning	Hypothermia	0	98.9(0.2)	0	98.3(1)	60.000	0.888
		Normal	10		12			
		Hyperthermia	0		0			
	Evening	Hypothermia	1	98.7(1)	0	98.2(1)	54.000	0.233
		Normal	9		12			
		Hyperthermia	0		0			
Day-11 (C=9 E=12)	Morning	Hypothermia	0	97.7(0.2)	0	98(1)	54.000	0.99
		Normal	9		12			
		Hyperthermia	0		0			
	Evening	Hypothermia	0	97.8(0.3)	0	98.3(0.3)	49.500	0.386
		Normal	9		11			
		Hyperthermia	0		1			

Temperature of Comatose patients(Degree Fahrenheit)								
Days	Timing	Incidences	Control group		Experimental Group		Mann-Whitney U test	
			f	Median /IQR	f	Median /IQR	U test Value	p value
Day-12 (C=7 E=9)	Morning	Hypothermia	0	97.7(0.4)	0	98.3(1)	40.500	0.72
		Normal	7		8			
		Hyperthermia	0		1			
	Evening	Hypothermia	0	98.6(0.2)	0	97.9(1)	45.000	0.889
		Normal	7		9			
		Hyperthermia	0		0			
Day-13 (C=7 E=9)	Morning	Hypothermia	0	98.9(0.3)	0	98.3(0.2)	31.500	0.999
		Normal	7		9			
		Hyperthermia	0		0			
	Evening	Hypothermia	0	98.7(0.4)	0	98.5(1)	31.500	0.788
		Normal	7		9			
		Hyperthermia	0		0			
Day-14 (C=7 E=9)	Morning	Hypothermia	0	-	0	98.2(1)	31.500	0.997
		Normal	7		9			
		Hyperthermia	0		0			
	Evening	Hypothermia	0	-	0	-	31.500	0.999
		Normal	7		9			
		Hyperthermia	0		0			

Note: Mann-Whitney U test, $p < 0.05$, C=Control group, E=Experimental group

Table No:15 Comparison of Physiological adverse events (respiratory rate) between control and experimental group of comatose patients. (N=113)

Respiratory rate of Comatose patients (Breaths/Minute)								
Days	Timing	Incidences	Control Group		Experimental group		Mann-Whitney U test	
			f	Median (IQR)	f	Median (IQR)	U test Value	p value
Day-1 (C=58 E=55)	Morning	Bradypnea	0	14(6)	0	17(6)	1595.000	0.984
		Normal	58		55			
		Tachypnoea	0		0			
	Evening	Bradypnea	0	20(5)	0	17(5.5)	1595.000	0.785
		Normal	58		55			
		Tachypnoea	0		0			
Day-2 (C=58 E=55)	Morning	Bradypnea	0	18(12)	0	18(9)	1595.000	0.365
		Normal	58		55			
		Tachypnoea	0		0			
	Evening	Bradypnea	0	14(4)	0	18(3.5)	1595.000	0.876
		Normal	58		55			
		Tachypnoea	0		0			
Day-3 (C=57 E=52)	Morning	Bradypnea	0	2(0)	0	22(8)	1482.000	1.0
		Normal	57		52			
		Tachypnoea	0		0			
	Evening	Bradypnea	0	18(7)	0	20(4.5)	1482.000	1.0
		Normal	57		52			
		Tachypnoea	0		0			
Day-4 (C=52 E=45)	Morning	Bradypnea	0	16(6)	0	16(2)	1192.500	0.9
		Normal	52		45			
		Tachypnoea	0		0			
	Evening	Bradypnea	0	15(10)	0	16(3)	1192.500	0.9
		Normal	52		45			
		Tachypnoea	0		0			

Respiratory rate of Comatose patients (Breaths/Minute)								
Days	Timing	Incidences	Control Group		Experimental group		Mann-Whitney U test	
			f	Median (IQR)	f	Median (IQR)	U test Value	p value
Day-5 (C=46 E=42)	Morning	Bradypnea	0	16(5)	0	17(2.5)	966.000	0.888
		Normal	46		42			
		Tachypnoea	0		0			
	Evening	Bradypnea	1	14(2)	0	14(4.5)	945.000	0.339
		Normal	45		42			
		Tachypnoea	0		0			
Day-6 (C=36 E=34)	Morning	Bradypnea	0	20(12)	0	18(10)	612.000	0.344
		Normal	36		34			
		Tachypnoea	0		0			
	Evening	Bradypnea	0	20(50)	0	20(3.50)	612.000	0.31
		Normal	36		34			
		Tachypnoea	0		0			
Day-7 (C=32 E=24)	Morning	Bradypnea	0	22(9)	0	24(8)	384.000	0.555
		Normal	32		24			
		Tachypnoea	0		0			
	Evening	Bradypnea	0	17(40)	0	17(2.50)	384.000	367
		Normal	32		24			
		Tachypnoea	0		0			
Day-8 (C=19 E=18)	Morning	Bradypnea	0	16(2)	0	18(2)	171.000	0.999
		Normal	19		18			
		Tachypnoea	0		0			
	Evening	Bradypnea	0	18(2)	0	18(2)	144.000	0.988
		Normal	18		16			
		Tachypnoea	0		0			

Respiratory rate of Comatose patients (Breaths/Minute)								
Days	Timing	Incidences	Control Group		Experimental group		Mann-Whitney U test	
			f	Median (IQR)	f	Median (IQR)	U test Value	p value
Day-9 (C=14 E=14)	Morning	Bradypnea	0	16(7)	0	21(2)	98.000	0.777
		Normal	14		14			
		Tachypnoea	0		0			
	Evening	Bradypnea	0	16(9)	0	20(3)	98.000	0.477
		Normal	14		14			
		Tachypnoea	0		0			
Day-10 (C=10 E=12)	Morning	Bradypnea	0	16(8)	0	22(5)	60.000	0.246
		Normal	10		12			
		Tachypnoea	0		0			
	Evening	Bradypnea	0	18(7)	0	22(4)	60.000	0.953
		Normal	10		12			
		Tachypnoea	0		0			
Day-11 (C=9 E=12)	Morning	Bradypnea	0	22(8)	0	22(7)	54.000	0.741
		Normal	9		12			
		Tachypnoea	0		0			
	Evening	Bradypnea	0	21(8)	0	21(1)	54.000	0.322
		Normal	9		12			
		Tachypnoea	0		0			
Day-12 (C=7 E=9)	Morning	Bradypnea	0	22(6)	0	21(5)	45.000	0.984
		Normal	7		9			
		Tachypnoea	0		0			
	Evening	Bradypnea	0	22(12)	0	22(8.50)	45.000	0.844
		Normal	7		9			
		Tachypnoea	0		0			

Respiratory rate of Comatose patients (Breaths/Minute)								
Days	Timing	Incidences	Control Group		Experimental group		Mann-Whitney U test	
			f	Median (IQR)	f	Median (IQR)	U test Value	p value
Day-13 (C=7 E=9)	Morning	Bradypnea	0	26(8)	0	24(10)	31.500	0.776
		Normal	7		9			
		Tachypnoea	0		0			
	Evening	Bradypnea	0	24(12)	0	22(11)	31.500	0.853
		Normal	7		9			
		Tachypnoea	0		0			
Day-14 (C=7 E=9)	Morning	Bradypnea	0	28(12)	0	18(13)	31.500	0.876
		Normal	7		9			
		Tachypnoea	0		0			
	Evening	Bradypnea	0	22(8)	0	22(8)	31.500	0.799
		Normal	7		9			
		Tachypnoea	0		0			

Note: Mann-Whitney U test, $p < 0.05$, C=Control group, E=Experimental group

Table No:16 Comparison of Physiological adverse events (Oxygen saturation) between control and experimental group of comatose patients. (N=113)

Oxygen saturation of Comatose patients (Percent)								
Days	Timing	Incidences	Control Group		Experimental Group		Mann-Whitney U test	
			f	Median (IQR)	f	Median (IQR)	U test Value	p value
Day-1 (C=58 E=55)	Morning	Desaturation	2	96(4)	0	100(4)	1481.500	0.185
		Subnormal	1		7			
		Normal	55		48			
	Evening	Desaturation	0	100(1)	0	98(3)	1419.500	0.023
		Subnormal	1		7			
		Normal	57		48			
Day-2 (C=58 E=55)	Morning	Desaturation	0	100(1)	0	98(3)	1531.000	0.455
		Subnormal	4		6			
		Normal	54		49			
	Evening	Desaturation	0	100(2)	1	100(2.50)	1523.000	0.494
		Subnormal	7		8			
		Normal	51		46			
Day-3 (C=57 E=52)	Morning	Desaturation	1	99(1)	1	99(4)	1390.500	0.245
		Subnormal	2		5			
		Normal	54		46			
	Evening	Desaturation	1	98(1)	0	98(2.50)	1378.000	0.053
		Subnormal	3		0			
		Normal	53		52			
Day-4 (C=52 E=45)	Morning	Desaturation	0	97(1)	0	97(2)	1201.500	0.814
		Subnormal	5		5			
		Normal	47		41			
	Evening	Desaturation	0	98(2)	0	98(2)	1136.000	0.125
		Subnormal	1		4			
		Normal	51		42			

Oxygen saturation of Comatose patients (Percent)								
Days	Timing	Incidences	Control Group		Experimental Group		Mann-Whitney U test	
			f	Median (IQR)	f	Median (IQR)	U test Value	p value
Day-5 (C=46 E=42)	Morning	Desaturation	1	98(3)	0	98(3.50)	940.500	0.595
		Subnormal	1		3			
		Normal	44		39			
	Evening	Desaturation	1	96(2)	0	96(2)	886.500	0.277
		Subnormal	6		3			
		Normal	39		39			
Day-6 (C=36 E=34)	Morning	Desaturation	0	99(1)	0	99(2)	579.000	0.335
		Subnormal	3		1			
		Normal	33		33			
	Evening	Desaturation	0	100(2)	0	100(4)	579.000	0.335
		Subnormal	3		1			
		Normal	33		33			
Day-7 (C=32 E=24)	Morning	Desaturation	0	98(2)	0	99(3)	391.000	0.708
		Subnormal	2		1			
		Normal	30		23			
	Evening	Desaturation	0	99(0)	0	99(2.50)	332.000	0.081
		Subnormal	1		4			
		Normal	31		20			
Day-8 (C=19 E=18)	Morning	Desaturation	1	98(1)	0	97(2)	162.000	0.563
		Subnormal	1		1			
		Normal	17		17			
	Evening	Desaturation	0	97(2)	0	97(1)	170.500	0.969
		Subnormal	1		1			
		Normal	18		17			

Oxygen saturation of Comatose patients (Percent)								
Days	Timing	Incidences	Control Group		Experimental Group		Mann-Whitney U test	
			f	Median (IQR)	f	Median (IQR)	U test Value	p value
Day-9 (C=14 E=14)	Morning	Desaturation	0	98(2)	0	98(0)	98.000	0.334
		Subnormal	1		0			
		Normal	14		14			
	Evening	Desaturation	0	99(1)	0	99(0)	97.500	0.301
		Subnormal	0		1			
		Normal	15		13			
Day-10 (C=10 E=12)	Morning	Desaturation	0	98(0)	0	98(0)	60.000	0.999
		Subnormal	0		0			
		Normal	10		12			
	Evening	Desaturation	0	97(1)	0	97(0)	54.000	0.273
		Subnormal	1		0			
		Normal	9		12			
Day-11 (C=9 E=12)	Morning	Desaturation	0	99(1)	0	99(1)	54.000	0.996
		Subnormal	0		0			
		Normal	9		12			
	Evening	Desaturation	0	97(1)	0	97(0)	54.000	0.989
		Subnormal	0		0			
		Normal	9		12			
Day-12 (C=7 E=9)	Morning	Desaturation	0	99(1)	0	99(1)	40.000	0.999
		Subnormal	0		0			
		Normal	7		9			
	Evening	Desaturation	0	100(1)	0	100(1)	45.000	0.292
		Subnormal	0		0			
		Normal	7		9			

Oxygen saturation of Comatose patients (Percent)								
Days	Timing	Incidences	Control Group		Experimental Group		Mann-Whitney U test	
			f	Median (IQR)	f	Median (IQR)	U test Value	p value
Day-13 (C=7 E=9)	Morning	Desaturation	0	99(1)	0	99(2.5)	45.000	0.999
		Subnormal	0		0			
		Normal	7		9			
	Evening	Desaturation	0	98(1)	0	98(0)	31.500	0.987
		Subnormal	0		0			
		Normal	7		9			
Day-14 (C=7 E=9)	Morning	Desaturation	0	97(2)	0	97(0)	28.000	0.378
		Subnormal	0		1			
		Normal	7		8			
	Evening	Desaturation	0	98(0)	0	98(0.5)	31.500	0.954
		Subnormal	0		0			
		Normal	7		9			

Note: Mann-Whitney U test, $p < 0.05$, C=Control group, E=Experimental group

Table No: 17 Comparison of Physiological adverse events (blood glucose level) between control and experimental group of comatose patients. (N=113)

Blood Glucose level of Comatose patients (mg/dL)								
Days	Timing	Incidences	Control Group Control group		Experimental Group		Mann-Whitney U test	
			f	Median /IQR	f	Median /IQR	U test Value	P value
Day 1 (C=58 E=55)	Morning	Hypoglycaemia	0	161(77)	0	152(55.5)	1079.500	0.432
		Normal	15		32			
		Hyperglycaemia	43		23			
	Evening	Hypoglycaemia	1	131(25)	0	124(24)	1462.000	0.367
		Normal	37		32			
		Hyperglycaemia	20		23			
Day-2 (C=58 E=55)	Morning	Hypoglycaemia	0	146(84)	0	134(49)	1454.000	0.322
		Normal	36		39			
		Hyperglycaemia	22		16			
	Evening	Hypoglycaemia	0	152(50)	0	125(52)	1336.000	0.078
		Normal	18		26			
		Hyperglycaemia	40		29			
Day-3 (C=57 E=52)	Morning	Hypoglycaemia	0	140(21)	0	134(12.50)	1363.500	0.378
		Normal	36		37			
		Hyperglycaemia	21		15			
	Evening	hypoglycaemia	0	156(53)	0	156(25.50)	1263.500	0.119
		Normal	19		25			
		Hyperglycaemia	38		27			
Day-4 (C=52 E=45)	Morning	Hypoglycaemia	0	123(32)	0	123(17)	1084.000	0.256
		Normal	30		32			
		Hyperglycaemia	22		14			
	Evening	Hypoglycaemia	0	134(18)	0	136(28.50)	1218.500	0.996
		Normal	37		33			
		Hyperglycaemia	15		13			

Blood Glucose level of Comatose patients (mg/dL)								
Days	Timing	Incidences	Control Group Control group		Experimental Group		Mann-Whitney U test	
			f	Median /IQR	f	Median /IQR	U test Value	P value
Day-5 (C=46 E=42)	Morning	Hypoglycaemia	0	147(12)	0	148(35.50)	650.000	0.005
		Normal	10		22			
		Hyperglycaemia	34		20			
	Evening	Hypoglycaemia	1	159(79)	0	161(69)	764.000	0.112
		Normal	18		26			
		Hyperglycaemia	25		16			
Day-6 (C=36 E=34)	Morning	Hypoglycaemia	0	135(21)	0	135(30.50)	504.000	0.137
		Normal	18		23			
		Hyperglycaemia	17		11			
	Evening	Hypoglycaemia	0	135(14)	0	135(49.50)	494.000	0.098
		Normal	26		18			
		Hyperglycaemia	9		16			
Day-7 (C=32 E=24)	Morning	Hypoglycaemia	0	141(44)	0	165(41.50)	263.000	0.03
		Normal	9		14			
		Hyperglycaemia	22		10			
	Evening	Hypoglycaemia	0	138(19)	0	138(5.50)	321.000	0.287
		Normal	19		18			
		Hyperglycaemia	12		6			
Day-8 (C=19 E=18)	Morning	Hypoglycaemia	0	135(28)	0	147(27)	135.000	0.317
		Normal	12		9			
		Hyperglycaemia	6		9			
	Evening	Hypoglycaemia	0	127(35)	0	127(26.50)	162.000	0.999
		Normal	11		11			
		Hyperglycaemia	7		7			

Blood Glucose level of Comatose patients(mg/dL)								
Days	Timing	Incidences	Control Group Control group		Experimental Group		Mann-Whitney U test	
			f	Median /IQR	f	Median /IQR	U test Value	P value
Day-9 (C=14 E=14)	Morning	Hypoglycaemia	0	150(43)	0	164(52)	84.000	0.411
		Normal	3		5			
		Hyperglycaemia	11		9			
	Evening	Hypoglycaemia	0	146(91)	0	132(85)	84.000	0.453
		Normal	5		7			
		Hyperglycaemia	9		7			
Day-10 (C=10 E=12)	Morning	Hypoglycaemia	0	124(3)	0	125(9)	47.000	0.288
		Normal	8		7			
		Hyperglycaemia	2		5			
	Evening	Hypoglycaemia	0	186(66)	0	186(31.50)	47.000	0.2
		Normal	3		1			
		Hyperglycaemia	7		11			
Day-11 (C=9 E=12)	Morning	Hypoglycaemia	0	138(19)	0	138(8.50)	51.000	0.754
		Normal	7		10			
		Hyperglycaemia	2		2			
	Evening	Hypoglycaemia	0	123(28)	0	123(25)	49.500	0.704
		Normal	6		7			
		Hyperglycaemia	3		5			
Day-12 (C=7 E=9)	Morning	Hypoglycaemia	0	153(29)	0	159(15)	44.000	0.908
		Normal	2		1			
		Hyperglycaemia	5		8			
	Evening	Hypoglycaemia	0	136(8)	0	136(13)	39.000	0.521
		Normal	5		8			
		Hyperglycaemia	2		1			

Blood Glucose level of Comatose patients (mg/dL)								
Days	Timing	Incidences	Control Group Control group		Experimental Group		Mann-Whitney U test	
			f	Median /IQR	f	Median /IQR	U test Value	P value
Day-13 (C=7 E=9)	Morning	Hypoglycaemia	0	129(26)	0	129(14.50)	30.500	0.503
		Normal	5		7			
		Hyperglycaemia	2		2			
	Evening	Hypoglycaemia	0	119(16)	0	119(21)	35.500	0.931
		Normal	7		8			
		Hyperglycaemia	0		1			
Day-14 (C=7 E=9)	Morning	Hypoglycaemia	0	102(20)	0	103(75)	21.000	0.101
		Normal	7		6			
		Hyperglycaemia	0		3			
	Evening	Hypoglycaemia	0	119(0)	0	119(13.50)	28.000	0.378
		Normal	7		8			
		Hyperglycaemia	0		1			

Note: Mann-Whitney U test, $p < 0.05$, C=Control group, E=Experimental group

Table No 19: Comparison of clinical outcomes (level of consciousness) between control and experimental group of comatose patients. (N=113)

Level of consciousness of comatose patients							
Days	Timing	Control group		Experimental group		Mann-Whitney U Test	p value
		Mean	Median (IQR)	Mean	Median (IQR)	U Test	p value
Day-1 (C=58,E=55)	Morning	4.29	5.00(1)	4.44	4.00(1)	1558.00	0.821
	Evening	4.29	5.00(1)	4.44	4.00(1)	1558.00	0.821
Day-2 (C=58,E=55)	Morning	4.29	5.00(1)	4.44	4.00(1)	1579.50	0.925
	Evening	4.29	5.00(1)	4.44	4.00(1)	1486.00	0.511
Day-3 (C=57,E=52)	Morning	4.71	5.00(1)	5.11	5.00(1)	898.50	0.001
	Evening	5.57	5.00(3)	6.44	6.00(3)	855.50	0.001
Day-4 (C=52,E=45)	Morning	6.29	6.00(2)	6.89	7.00(3)	690.50	0.001
	Evening	6.29	6.00(2)	6.89	7.00(3)	647.00	0.001
Day-5 (C=46,E=42)	Morning	6.57	6.00(2)	7.44	8.00(4)	528.00	0.001
	Evening	7.00	6.00(5)	7.78	9.00(3)	453.00	0.001
Day-6 (C=36,E=34)	Morning	6.71	6.00(5)	8.67	9.00(4)	248.50	0.001
	Evening	7.29	7.00(5)	8.67	9.00(4)	272.00	0.001
Day-7 (C=32,E=24)	Morning	7.71	8.00(5)	9	9.00(4)	217.00	0.002
	Evening	7.71	8.00(5)	9.11	9.00(4)	216.50	0.002
Day-8 (C=19,E=18)	Morning	7.71	8.00(5)	9.89	11.00(5)	73.00	0.003
	Evening	8.00	8.00(6)	10.11	11.00(5)	91.00	0.005
Day-9 (C=14,E=14)	Morning	8.14	9.00(6)	10.56	12.00(4)	59.50	0.015
	Evening	8.14	9.00(6)	10.56	12.00(5)	61.50	0.018
Day-10 (C=10,E=12)	Morning	8.14	9.00(6)	10.56	12.00(5)	37.50	0.072
	Evening	8.14	9.00(6)	10.56	12.00(5)	37.50	0.072
Day-11 (C=9, E=12)	Morning	7.57	7.00(6)	11.11	12.00(3)	26.50	0.023
	Evening	8.14	9.00(6)	11.33	12.00(4)	29.00	0.037
Day-12 (C=7, E=9)	Morning	8.57	9.00(6)	11.44	12.00(4)	23.50	0.024
	Evening	8.57	9.00(6)	11.56	12.00(3)	22.00	0.018
Day-13 (C=7,E=9)	Morning	8.71	10.00(6)	11.67	13.00(3)	18.00	0.047
	Evening	8.71	10.00(6)	11.89	13.00(3)	17.50	0.042
Day-14 (C=7, E=9)	Morning	8.86	10.00(7)	12	13.00(3)	17.50	0.042
	Evening	8.86	10.00(7)	12	13.00(3)	17.50	0.042

Note: FOUR: Full Outline of Unresponsiveness, Mann-Whitney U test, p < 0.05, *statistically significant, C=Control group, E=Experimental group

Table No 20: Comparison of clinical outcomes (sedation level) between control and experimental group of comatose patients. (N=113)

Level of agitation & sedation of the comatose patients							
Days	Timing	Control group		Experimental group		Mann-Whitney U test	
		Mean	Median (IQR)	Mean	Median (IQR)	U Test Value	p value
Day-1 (C=58,E=55)	Morning	0.14	1.00(5)	-1.44	-3.00(5)	1434.00	0.343
	Evening	-3	-4.00(1)	-1.44	-3.00(5)	805.00	0.001
Day-2 (C=58,E=55)	Morning	-3.86	-4.00(0)	-2.11	-3.00(3)	761.50	0.001
	Evening	-3.86	-4.00(0)	-2.67	-3.00(1)	721.00	0.001
Day-3 (C=57,E=52)	Morning	-2.67	-4.00(0)	-2.56	-3.00(2)	610.00	0.001
	Evening	-3.86	-4.00(0)	-2.89	-3.00(2)	572.50	0.001
Day-4 (C=52,E=45)	Morning	-3.71	-4.00(1)	-2.56	-3.00(1)	483.50	0.001
	Evening	-2.56	-4.00(1)	-2.44	-3.00(1)	486.00	0.001
Day-5 (C=46,E=42)	Morning	-3.71	-4.00(1)	-2.33	-2.00(1)	381.50	0.001
	Evening	-3.57	-4.00(1)	-2.11	-2.00(2)	470.00	0.001
Day-6 (C=36,E=34)	Morning	-3.43	-3.00(1)	-2	-2.00(1)	274.50	0.001
	Evening	-3	-3.00(0)	-1.78	-2.00(1)	304.50	0.001
Day-7 (C=32,E=24)	Morning	-2.71	-3.00(1)	-1.67	-2.00(1)	223.00	0.003
	Evening	-2.71	-3.00(1)	-1.67	-2.00(1)	217.50	0.002
Day-8 (C=19,E=18)	Morning	-2.71	-3.00(1)	-1.33	-2.00(2)	60.00	0.001
	Evening	-2.57	-3.00(1)	-1.22	-2.00(2)	58.50	0.001
Day-9 (C=14,E=14)	Morning	-2.29	-2.00(1)	-0.89	-1.00(1)	47.00	0.017
	Evening	-2	-2.00(0)	-0.89	-1.00(1)	56.00	0.047
Day-10 (C=10,E=12)	Morning	-2	-2.00(0)	-0.78	-1.00(1)	37.00	0.11
	Evening	-1.86	-2.00(1)	-0.44	-1.00(2)	35.00	0.081
Day-11 (C=9, E=12)	Morning	-1.71	-2.00(1)	-0.44	-1.00(2)	32.50	0.104
	Evening	-1.57	-1.00(1)	-0.44	-1.00(2)	36.00	0.166
Day-12 (C=7, E=9)	Morning	-1.43	-1.00(1)	-0.56	-1.00(1)	21.50	0.032
	Evening	-1.43	-1.00(1)	-0.56	-1.00(1)	19.00	0.02
Day-13 (C=7,E=9)	Morning	-1.29	-1.00(1)	-0.56	-1.00(1)	14.50	0.05
	Evening	-0.86	-1.00(2)	-0.44	0.00(1)	23.50	0.351
Day-14 (C=7, E=9)	Morning	-0.71	-1.00(1)	-0.44	0.00(1)	25.50	0.476
	Evening	-0.71	-1.00(1)	-0.44	0.00(1)	25.50	0.476

Note: RASS: Richmond agitation sedation scale, Mann-Whitney U test, p < 0.05,*statistically significant, C=Control group, E=Experimental group

Table No -21: Comparison of clinical outcomes (behaviour pain scales) between control and experimental group of comatose patients(N=113)

Level of pain of the comatose patients							
Days	Timing	Control group		Experimental group		Mann-Whitney U test	
		Mean	Median (IQR)	Mean	Median (IQR)	U Test Value	p value
Day-1 (C=58,E=55)	Morning	8.14	8.00(2)	6.67	7.00(3)	1503.00	0.592
	Evening	5.57	5.00(1)	4.89	5.00(2)	1323.50	0.104
Day-2 (C=58,E=55)	Morning	5.14	5.00(3)	4.67	5.00(2)	1287.00	0.067
	Evening	5	5.00(2)	4.89	5.00(2)	1364.00	0.165
Day-3 (C=57,E=52)	Morning	5.29	5.00(2)	4.56	4.00(1)	1366.50	0.451
	Evening	4.86	5.00(2)	4.78	5.00(1)	1344.00	0.374
Day-4 (C=52,E=45)	Morning	4	4.00(2)	4.67	5.00(1)	1066.00	0.423
	Evening	4.14	4.00(2)	4.44	4.00(1)	992.50	0.168
Day-5 (C=46,E=42)	Morning	5.14	5.00(2)	4.33	4.00(1)	460.50	0.001*
	Evening	5.43	5.00(3)	4.44	4.00(1)	358.00	0.001*
Day-6 (C=36,E=34)	Morning	5.43	6.00(2)	4.22	4.00(1)	198.00	0.001*
	Evening	5.43	6.00(1)	4.33	4.00(1)	142.00	0.001*
Day-7 (C=32,E=24)	Morning	5.29	5.00(1)	4.22	4.00(1)	153.50	0.001*
	Evening	5.29	5.00(1)	4.33	4.00(1)	118.00	0.001*
Day-8 (C=19,E=18)	Morning	5	5.00(2)	4	4.00(2)	61.00	0.001*
	Evening	5.29	6.00(2)	4	4.00(2)	67.50	0.002*
Day-9 (C=14,E=14)	Morning	5.57	5.00(2)	3.56	3.00(1)	21.50	0.001*
	Evening	5	5.00(2)	3.44	3.00(1)	16.50	0.001*
Day-10 (C=10,E=12)	Morning	5.14	5.00(0)	3.33	3.00(1)	2.50	0.001*
	Evening	5.29	5.00(1)	3.44	3.00(1)	8.00	0.001*
Day-11 (C=9, E=12)	Morning	5.14	5.00(2)	3.44	3.00(1)	10.00	0.001*
	Evening	5.29	5.00(1)	3.56	3.00(1)	11.50	0.002*
Day-12 (C=7, E=9)	Morning	4.86	5.00(0)	3.67	4.00(1)	7.00	0.001*
	Evening	5.43	6.00(1)	3.56	3.00(1)	4.50	0.001*
Day-13 (C=7,E=9)	Morning	5.29	5.00(1)	3.22	3.00(0)	2.50	0.001*
	Evening	5.14	5.00(1)	3.33	3.00(1)	3.50	0.002*
Day-14 (C=7, E=9)	Morning	5.14	3.00(1)	3.22	3.00(1)	0.00	0.001*
	Evening	5.14	3.00(1)	3.22	3.00(1)	0.00	0.001*

Note: Behavioural pain scale, Mann-Whitney U test, $p < 0.05$,*statistically significant, C=Control group, E=Experimental group

Table No. 27(a) Association between heart rate of comatose patients with their selected socio-demographical variables. (N=113)

Heart Rate of the Patients					
Demographic variables	Bradycardia heart rate ≤60 beats/minute	Normal 60-100 beats/minute	Tachycardia ≥100 beats/minute	Fischer Exact Test	p-value
1. Age					
a. 18-25 years	0	2	4	1.283	0.879
b. 26-35 years	0	4	7		
c. 36-45 years	0	11	10		
d. 46-55 years	0	13	15		
e. 56-65 years	0	20	27		
2. Gender					
a. Male	0	38	44	0.531	0.528
b. Female	0	12	19		
3. Marital status					
a. Unmarried	0	2	2	0.056	0.599
b. Married	0	48	61		
4. Level of education					
a. No formal education	0	3	2	2.754	0.626
b. Till 5th	0	9	6		
c. 10th	0	18	24		
d. 12th	0	17	25		
e. Graduate	0	3	6		
5. Place of living					
a. Rural	0	24	30	0.002	0.559
b. Urban	0	26	33		
6. Occupation					
a. House wife	0	13	22	3.469	0.656
b. Self employed	0	9	10		
c. Private job	0	14	15		
d. Government job	0	7	4		
e. Retired	0	6	11		
f. Students	0	1	1		

Note: Fischer Exact Test , $p < 0.05$

Table No. 27(b) Association between heart rate of comatose patients with their clinical variables. (N=113)

Heart Rate of the Patients					
Clinical variables.	Bradycardia heart rate ≤60 beats/minute	Normal 60-100 beats/minute	Tachycardia ≥100 beats/minute	Fischer Exact test	p- value
1. Diagnosis				4.432	0.335
a.Neurologic disorder	0	21	35		
b.Respiratory disorder	0	8	11		
c.Cardiac disorder	0	3	5		
d. Metabolic disorder	0	12	9		
e. Renal disorder	0	6	3		
2.Length of ICU Stay				9.868	0.552
a.2-5 days	0	14	28		
b.6-10 days	0	50	0		
c.11-14 days	0	8	13		
3. GCS SCORE				4.727	0.442
a.3	0	31	41		
b.4	0	3	9		
c.5	0	7	6		
d.6	0	4	5		
e.7	0	4	2		
f.8	0	1	9		
4.APACHE-II score (Prognosis)				6.309	0.090
a.15-19(25% deathrate)	0	4	5		
b.20-24(40% death rate)	0	18	10		
c.25-29(55% death rate)	0	20	36		
d.30-34(75% death rate)	0	8	20		

Note: Fischer Exact Test , $p < 0.05$

Table No. 28(a) Association between temperature of comatose patients with their selected socio-demographical variables. (N=113)

Temperature of the Patients					
Demographic variables	Hypothermia T≤97F	Normothermia 97F-99F	Hyperthermia T≥99F	Fischer Exact test	p-value
1. Age				11.79	0.048
a. 18-25 years	0	5	1		
b. 26-35 years	0	10	1		
c. 36-45 years	2	18	1		
d. 46-55 years	0	28	0		
e.56-65years	1	46	0		
2. Gender				0.985	0.807
a. Male	3	77	2		
b. Female	0	29	2		
3. Marital status				1.378	1.000
a. Unmarried	0	4	0		
b. Married	3	102	3		
4.Level of education				13.934	0.023
a. No formal education	1	4	0		
b. Till 5th	0	15	0		
c. 10th	0	41	1		
d. 12th	2	40	0		
e. Graduate	0	7	2		
5. Place of living				0.839	0.845
a. Rural	2	51	1		
b. Urban	1	56	2		
6. Occupation				8.886	0.594
a. House wife	0	33	2		
b. Self employed	2	17	0		
c. Private job	1	27	1		
d. Government job	0	11	0		
e. Retired	0	17	0		
f. Students	0	2	0		

Note: Fischer Exact Test , p< 0.05

Table No. 28(b) Association between temperature of comatose patients with their selected clinical variables. (N=113)

Temperature of the Patients					
Clinical variables	Hypothermia T≤97F	Normothermia 97F -99F	Hyperthermia T≥99F	Fischer Exact test	p- value
1. Diagnosis				5.399	0.731
a. Neurologic disorder	3	51	2		
b. Respiratory disorder	0	19	0		
c. Cardiac disorder	0	8	0		
d. Metabolic disorder	0	21	0		
e. Renal disorder	0	8	1		
2.Length of ICU Stay				20.675	0917
a.2-5 days	1	39	2		
b.6-10 days	0	50	0		
c.11-14 days	0	21	0		
3. GCS SCORE				9.201	0.693
a.3	2	67	3		
b.4	0	12	0		
c.5	0	13	0		
d.6	0	9	0		
e.7	1	5	0		
f.8	0	1	0		
4.APACHE II score (Prognosis)				4.847	0.516
a.15-19(25 % death rate)	0	8	1		
b. 20-24(40% death rate)	1	27	0		
c. 25-29(55% death rate)	1	53	2		
d.30-34(75% death rate)	0	19	0		

Note: Fischer Exact Test , p< 0.05

Table No. 29 (a) Association between systolic blood pressure of comatose patients with their selected socio-demographical variables. (N=113)

Systolic blood pressure of the patients					
Clinical variables	Hypotension SBP≤95 mmHg	Normotensive SBP-90-140 mmHg	Hypertension SBP≥140 mmHg	Fischer Exact test	p- value
1. Age				3.582	0.990
a. 18-25 years	0	6	0		
b. 26-35 years	0	10	1		
c. 36-45 years	0	20	1		
d. 46-55 years	1	26	1		
e.56-65years	1	43	3		
2. Gender				1.246	0.520
a. Male	1	77	4		
b. Female	1	28	2		
3. Marital status				1.263	1.000
a. Unmarried	0	4	0		
b. Married	2	101	6		
4. Level of education				4.794	0.847
a. No formal education	0	5	0		
b. Till 5th	0	14	1		
c. 10th	1	38	3		
d. 12th	1	40	1		
e. Graduate	0	8	1		
5. Place of living				0.770	0.839
a. Rural	1	51	2		
b. Urban	1	54	4		
6. Occupation				7.835	0.784
a. House wife	1	32	2		
b. Self employed	0	18	1		
c. Private job	0	28	1		
d. Government job	1	9	1		
e. Retired	0	16	1		
f. Students	0	2	0		

Note: Fischer Exact Test , p< 0.05

Table No. 29(b) Association between systolic blood pressure of comatose patients with their selected clinical variables. (N=113)

Systolic Blood Pressure of the Patients					
Clinical variables	Hypotension SBP<9 5 mmHg	Normotensive SBP-90-140 mmHg	Hypertension SBP≥140 mmHg	Fischer Exact test	p- value
1. Diagnosis				5.085	0.746
a. Neurologic disorder	1	50	5		
b. Respiratory disorder	1	17	1		
c. Cardiac disorder	0	8	0		
d. Metabolic disorder	0	21	0		
e. Renal disorder	0	9	0		
2.Length of ICU Stay				22.206	0.709
a.2-5 days	1	39	2		
b.6-10 days	0	50	0		
c.11-14 days	0	21	0		
3. GCS SCORE				9.961	0.567
a.3	1	67	4		
b.4	1	10	1		
c.5	0	13	0		
d.6	0	8	1		
e.7	0	6	0		
f.8	0	1	0		
4. APACHE II score (Prognosis)				5.978	0.329
a.15-19(25 % death rate)	0	9	0		
b. 20-24(40 % death rate)	20	24	4		
c. 25-29(55% death rate)	2	52	2		
d.30-34(75% death rate)	0	20	0		

Note: Fischer Exact Test , p< 0.05

Table No. 30(a) Association between diastolic blood pressure of comatose patients with their selected socio-demographical variables. (N=113)

Diastolic blood pressure of the patients					
Demographic variables	Hypotension DBP≤60 mmHg	Normotensive DBP 60 -90mmHg	Hypertension DBP≥90 mmHg	Fischer Exact test	p- value
1. Age				6.270	0.816
a. 18-25 years	0	6	0		
b. 26-35 years	0	11	0		
c. 36-45 years	1	19	1		
d. 46-55 years	1	27	0		
e.56-65years	3	44	0		
2. Gender				1.075	0.721
a. Male	3	78	0		
b. Female	2	29	1		
3. Marital status				1.966	1.000
a. Unmarried	0	4	0		
b. Married	5	103	1		
4. Level of education				5.429	1.000
a. No Formal education	0	5	0		
b. Till 5th	1	14	0		
c. 10th	2	40	0		
d. 12th	2	39	1		
e. Graduate	0	9	0		
5. Place of living				1.216	0.828
a. Rural	3	51	0		
b. Urban	2	56	1		
6. Occupation				11.075	0.457
a. House wife	2	33	0		
b. Self employed	1	18	0		
c. Private job	1	28	0		
d. Government job	1	9	1		
e. Retired	0	17	0		
f. Students	0	2	0		

Note: Fischer Exact Test , p< 0.05

Table No. 30(b) Association between diastolic blood pressure of comatose patients with their selected clinical variables. (N=113)

Diastolic blood pressure of the patients					
Clinical variables	Hypotension ≤60 mmHg	Normotensive 60 -90mmHg	Hypertension ≥90 mmHg	Fischer Exact test	p- value
1. Diagnosis				9.443	0.270
a. Neurologic disorder	1	54	1		
b. Respiratory disorder	1	18	0		
c. Cardiac disorder	0	8	0		
d. Metabolic disorder	1	20	0		
e. Renal disorder	2	7	1		
2.Length of ICU Stay				29.056	0.391
a.2-5 days	1	39	2		
b.6-10 days	0	50	0		
c.11-14 days	1	20	0		
3 GCS SCORE				11.654	0.650
a.3	3	68	1		
b.4	0	12	0		
c.5	1	12	0		
d.6	0	9	0		
e.7	1	5	0		
f.8	0	1	0		
4. APACHE II score (Prognosis)				4.203	0.803
a.15-19(25 % death rate)	0	9	0		
b. 20-24(40 % death rate)	1	26	1		
c. 25-29(55% death rate)	3	53	0		
d.30-34(75% death rate)	1	19	0		

Note: Fischer Exact Test , $p < 0.05$

Table No. 31(a) Association between oxygen saturation of comatose patients with their selected socio-demographical variables. (N=113)

Oxygen Saturation of the patients					
Demographic variables	Desaturation ≤90%	Normal 95≤%	Sub normal 90to 94%	Fischer Exact test	p-value
1. Age				4.531	0.873
a. 18-25 years	0	5	1		
b. 26-35 years	0	11	0		
c. 36-45 years	0	19	2		
d. 46-55 years	1	25	2		
e.56-65years	1	43	3		
2. Gender				0.463	1.000
a. Male	2	74	6		
b. Female	0	29	2		
3. Marital status				3.429	0.313
a. Unmarried	0	3	1		
b. Married	2	100	7		
4. Level of education				9.945	0.173
a. No formal education	0	4	1		
b. Till 5th	0	15	0		
c. 10th	2	39	1		
d. 12th	0	36	6		
e. Graduate	0	9	0		
5. Place of living				0.329	1.000
a. Rural	1	49	4		
b. Urban	1	54	4		
6. Occupation				9.390	0.514
a. House wife	0	32	3		
b. Self employed	1	18	0		
c. Private job	0	26	3		
d. Government job	0	11	0		
e. Retired	1	14	2		
f. Students	0	2	0		

Note: Fischer Exact Test , p< 0.05

Table No. 31(b) Association between oxygen saturation of comatose patients with their selected clinical variables. (N=113)

Oxygen Saturation of the patients					
Clinical variables	Desaturation ≤90%	Normal 95≤%	Sub normal 90to 94%	Fischer Exact test	p- value
1. Diagnosis				7.825	0.348
a. Neurologic disorder	1	53	2		
b. Respiratory disorder	0	16	3		
c. Cardiac disorder	0	8	0		
d. Metabolic disorder	1	17	3		
e. Renal disorder	0	9	0		
2.Length of ICU Stay				30.975	0.027
a.2-5 days	0	40	2		
b.6-10 days	0	50	0		
c.11-14 days	1	16	4		
3. GCS SCORE				8.269	0.790
a.3	1	65	6		
b.4	0	11	1		
c.5	1	11	1		
d.6	0	9	0		
e.7	0	6	0		
f.8	0	1	0		
4.APACHE II score(Prognosis)				3.669	0.743
a.15-19(25 % death rate)	0	8	1		
b. 20-24(40 % death rate)	0	27	1		
c. 25-29(55% death rate)	1	50	5		
d.30-34(75% death rate)	1	18	1		

Note: Kruskal Wallis test, p < 0.05

Table No. 32(a) Association between blood glucose Level of comatose patients with their selected socio-demographical variables. (N=113)

Blood glucose level of the patients					
Demographic variables	Hypoglycaemia BGL < 70 mg/dl	Normal range 70-180 mg/dl	Hyperglycaemia ≥180 mg/d	Fischer Exact test	p-value
1. Age				2.369	0.692
a. 18-25 years	0	3	3		
b. 26-35 years	0	5	6		
c. 36-45 years	0	9	12		
d. 46-55 years	0	14	14		
e. 56-65 years	0	16	31		
2. Gender				0.812	0.398
a. Male	0	32	50		
b. Female	0	15	16		
3. Marital status				0.470	0.446
a. Unmarried	0	1	3		
b. Married	0	46	63		
4. Level of education				2.385	0.678
a. No formal education	0	1	4		
b. Till 5th	0	8	7		
c. 10th	0	19	23		
d. 12th	0	16	26		
e. Graduate	0	3	6		
5. Place of living				0.346	0.573
a. Rural	0	24	30		
b. Urban	0	23	36		
6. Occupation				3.406	0.670
a. House wife	0	16	19		
b. Self employed	0	7	12		
c. Private job	0	13	16		
d. Government job	0	6	5		
e. Retired	0	5	12		
f. Students	0	0	2		


Note: Fischer Exact test , p < 0.05

**Table No. 32(b) Association between blood glucose level of comatose patients with their selected clinical variables.
(N=113)**

Blood glucose level of the patients					
Clinical variables	Hypoglycaemia < 70 mg/dl	Normal range 70-180 mg/dl	Hyperglycaemia ≥180 mg/d	Fischer Exact test	p- value
1. Diagnosis				13.317	0.008
a. Neurologic disorder	0	17	39		
b. Respiratory disorder	0	7	12		
c. Cardiac disorder	0	3	5		
d. Metabolic disorder	0	12	9		
e. Renal disorder	0	8	1		
2.Length of ICU Stay				9.054	0.639
a.2-5 days	0	38	4		
b.6-10 days	0	50	0		
c.11-14 days	0	16	5		
3. GCS SCORE				4.801	0.431
a.3	0	29	43		
b.4	0	4	8		
c.5	0	4	9		
d.6	0	6	3		
e.7	0	3	3		
f.8	0	1	0		
4.APACHE-II score (Prognosis)				8.214	0.040*
a.15-19(25 % death rate)	0	3	6		
b. 20-24(40 % death rate)	0	17	11		
c. 25-29(55% death rate)	0	23	33		
d.30-34(75% death rate)	0	4	16		

Note: Fischer Exact test , p < 0.05 ,*statistically significant

ANNEXURE-12






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Effectiveness of training program on Individualized Communication Protocol regarding communication with comatose patient on knowledge and practice of nurses working in selected Intensive Care Unit at a tertiary care hospital

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 Pooja Thakur
 Poojathakurrksh@gmail.com
 Ph.D Scholar, Swami Rama Himalayan University, Dehradun, Uttarakhand

 Sanchita Pugazhendi
 Professor & Dean, Himalayan College of Nursing, Swami Rama Himalayan University, Dehradun, Uttarakhand



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Effectiveness of training program on Individualized Communication Protocol regarding communication with comatose patient on knowledge and practice of nurses working in selected Intensive Care Unit at a tertiary care hospital

Pooja Thakur

Ph.D Scholar, Swami Rama Himalayan University, Dehradun, Uttarakhand
Corresponding author email: Poojathakur.rksh@gmail.com

Dr. Sanchita Pugazhendi

Professor & Dean, Himalayan College of Nursing, Swami Rama Himalayan University, Dehradun, Uttarakhand
Email: spugazhendi@srhu.edu.in

Dr. Kamli Prakash

Professor & Head of Department (Medical & Surgical Nursing) Himalayan College of Nursing Swami Rama Himalayan University, Dehradun, Uttarakhand
Email: kamliprakash@srhu.edu.in

Abstract---Introduction: Effective communication is a keystone of the nurse patient relationship. Communicating with comatose patients is always challenging for healthcare professionals. In order to provide quality nursing care, we need to communicate with patients whether conscious or unconscious. This study was aimed to evaluate the effectiveness of training program on knowledge and practice of nurses working in ICUs regarding Individualized Communication Protocol with comatose patients. Methods: A quantitative pre-experimental research approach was used with one group Pre-Test- Post-Test-only Design. Total enumeration sampling technique was used to select 171 Staff Nurses from the selected ICUs. A structured questionnaire containing knowledge and skill items were used to assess knowledge and practice related to communication. Result revealed that there was significant improvement in knowledge post test score (20.09 ± 3.21) after intervention as compared to pretest scores (13.23 ± 2.96 with p-value of 0.0001. Data also represented significant improvement in practice posttest score (30.96 ± 4.46) as compared to pretest score

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Results and Discussion

Participants mean age was (29.22±5.945) years. The analysis of findings in table (1) showed that the mean age of staff Nurses were (29.22±5.94) it might be associated with interest of young generation to joining in the profession. These findings are supported by Abbas, Mohammed⁵ who found that the majority of nurses (48%) of the study sample were in the age group (26-29) years old. Also, this finding of the present study supportive evidence is available in the study by Gaffar⁷, Vyas⁸ Bagherian⁹ that showed the age of the study sample is within the age group of (23-26) years of age and within 25.1 ± 3.8 mean of age. In the area of gender both male 78 (46%) and females 93 (54%) were more or less equally participated in the study. These results were not along with the findings of the study by Abba, Mohammed⁵ in which higher percentages (75%) of nurses were males. In the area of education a large proportion of staff nurses were degree holders 82(48%) followed by 79(46 %) were diploma holder ,5 (3%) of the staff nurses were having post basic B. Sc degree and only 5 (3%) staff Nurses have completed their masters, it might be associated with in last decade the most of the staff nurses were had degree in Nursing education .These findings are supported by the study who found that half of them (55 %) were nursing bachelor's degree(9), whereas these results were contradictory by Josuva¹⁰ there were 82% of diploma holders and 18% are degree holder working in the hospital.

In duration of clinical experience majority of the staff nurses were having more or less similar experience with mean score 5.52±4.25. This finding is supported by the study done which shows that (76.7%) of nurses have (1 to 5) years of experiences in the hospital. These findings are contradictory to study conducted by Thomas (2006)¹¹ where 18 % fell under the category of 1 month -1year of the experience, 32 % having experience between 1 to 2 years, 12 % having experience between 2 year-3 year and 38% were having experience more than three years. Among all staff nurses majority 147 (86%) had experience in critical care areas and only 19 (11%) had experience of non- critical areas and 5(3%) had experience of both the areas. It might be associated with nurses would like to continue the same area of experience. With regards nurse patient ratio in Intensive care unit majority 144(84%) of nurses were following 1:2 ratio.

Table No: 2 revealed that there was significant improvement in knowledge post test score (20.09±3.21) after intervention as compared to pretest scores (13.23±2.96) with a p-value of 0.0001. similar kind of finding were found where knowledge score was treated as an categorical variable figure no.1 represent pretest and posttest categories of knowledge regarding communication among ICU nurses. This figure depicts that there were only 14 Staff nurses who had good knowledge regarding communication with comatose patient before administering intervention which drastically improve with a number if 141 subjects having good knowledge after intervention .Data also revealed that there were 11 participants who had below average knowledge before intervention which was reduced to zero after the intervention . The mean post test knowledge score (20.09±3.21) of the present study was higher than mean pre test knowledge score (13.23±2.96) with the mean difference of (6. 86). Difference between pre test and post test knowledge was statistically tested and it was found significant. The results were consistent with the findings of Binju et.al¹² which showed that the mean post-test knowledge score is 26.71 (89.03 %) is greater than the mean pre-

test knowledge scores 17.91 (59.70 %). It was observed that the staff nurses were rarely communicating with comatose patients.

Table no-3 revealed that there was significant improvement in practice posttest score (30.96 ± 4.46) as compared to pretest score (6.75 ± 1.57) with a p-value of 0.0001. Figure no 2 represents that all subjects were having unsatisfactory practices with respect to the communication required while providing nursing care to the comatose patients after the intervention 125 nurses were able to communicate satisfactorily with comatose patients. The mean post test practice score (30.96 ± 4.46) of the present study was higher than mean pre test practice score (6.75 ± 1.57) with the mean difference of (24.21). Difference between pre test and post test practice was statistically tested and it was found significant. These findings are supported by Helen Sheela Wilson¹³ who stated that only 11.9 % staff nurses had practice on communication with unconscious patients. Also supported by the study where the overall mean of posttest practice score (24.4) is significantly higher than overall mean of pretest score (9.9). Baker C, Melby⁶ also mentioned that most communication process activities involves informing the patient of immediate procedural matters or providing reassuring statements. Weich M¹⁴ reported that the Communication, both verbal and non-verbal, is a greatly neglected skill at present scenario. Two reasons given for this state of affairs were lack of time and lack of interest in others. Elliot Rosalind¹⁵ highlighted in his study that nurses communicate to unconscious patient is very minimal another study by K. Robin Ogle¹⁶ also indicates that nurses communicate extremely poor with patients, despite a high level of knowledge and skill with respect to communication. Tentative explanations of high stress levels, a preoccupation with physical care and technology, and the attraction to critical care areas of nurses with specific personality types are discussed as possible reasons for this findings.

Table: 4 shows there was no significant correlation found between Knowledge and Practice scores these results were contradictory with the results of Daya¹¹ where correlation between the pretest knowledge score (10.1) and practice score (9.9) were found significant and the score was 0.39. Table No 5 Shows that the knowledge scores of the staff Nurses was not significantly associated with any of their personal Profile variables i.e professional qualification, gender, area of experience and nurse patient ratio in ICU. Table no 6 shows a weak negative correlation was found between age and knowledge score of the staff nurses and also between years of experience and Knowledge score of the staff nurses and came to be statistical significant with p value of 0.01. This represents that as the age and year of the staff nurses increases knowledge regarding communication with comatose patients decreases. data in table no.7 indicated that no significant relationships between nurses' practice with any of their personal profile variables i. e .professional qualification, area of Experience and nurse patient ratio in ICU except gender , It was also found there was a significant association found between practice score and gender . data represented in table no.8 that females were having better practices regarding communication with comatose patients and it was significantly better as compare to males and the difference of practice score was statistically significant with p value of 0.004 the results were agreed with the findings of Daya¹¹ where shown that no association between nurses'

knowledge and ICU experience qualification, area of experience, nurse patient ratio in ICU and gender.

Limitations

The sample size is only 171 staff nurses; hence, this limits the generalization of findings beyond the study samples.

- Randomization could not be done to avoid contamination of study subjects.
- Method of Observation (Non -Participatory observation).

Conclusion

Study revealed that teaching programme was effective in improving nurse's knowledge and practice regarding Individualized Communication Protocol with comatose patients. Communication with comatose patients is an important aspect of nursing care so that individualized care can be achieved. Results strongly recommend for regular training sessions for health care professionals which help them to improve communication process by enabling them to evaluate and enhance their practice thereby helping them to render the quality services to the comatose patients

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Table No.1 : Personal Profile of Staff Nurses

(N=171)			
S. No	Personal Characteristics	Frequency (f)	Percentage (%)
1.	Age (Years)	29.22±5.945	
2.	Gender Female Male	93 78	54 46
3.	Professional Qualification GNM B.Sc (Nursing) Post Basic B.Sc (Nursing) M.Sc (Nursing)	79 82 5 5	46 48 3 3
4.	Total year of Experience in Nursing Practice	5.52±4.25	
5.	Area of Experience Critical Noncritical Critical/noncritical	147 5 19	86 3 11
6	Nurse Patient ratio in ICU 1:1 1:2	27 144	16 84

Table No- : 2 Mean, mean difference, SD difference, and paired 't' test of pretest and post-test knowledge scores of staff nurses regarding communication with comatose patients.

(N=171)

S. no	Knowledge Score	Max. score	Mean and Standard Deviation	Mean Difference	Range of Score	t Value	p-Value
1.	Pretest	24	13.23±2.96	6.86	1-19	58.27	0.0001*
2.	Posttest		20.09±3.21		10-24		

Note: Paired t -test; P value < 0.05 ,**statistically significant

Table No-: 3 Mean, mean difference, SD difference, and paired 't' test of pretest and post-test Practice scores of staff nurses regarding communication with comatose patients

(N=171)

S. No	Practice score	Max Score	Mean and Standard Deviation	Mean Difference	Range Of Score	t Value	p-Value
1.	Pretest	42	6.75±1.576	24.21	4-11	55.99	0.0001**
2	Posttest		30.96±4.461		14-40		

Note: Paired t -test; P value < 0.05,**statistically significant

Table No.4 Correlation between knowledge and practice score of staff nurses on communication with comatose patients.

(N=171)

S. No	Characteristics	Pearson Correlation (r) Value	Significance P value
1.	Knowledge score	0.027	0.722
2.	Practice score		

Note: Pearson Correlation, Not significant

Table No: 5 Association between Knowledge of the Staff Nurses on communication with comatose patients and personal profile of Staff Nurses.

(N=171)

S.No	Sample Characteristics	N	Mean ±Standard Deviation	t//F Value	P-value	
1.	Gender	Male	78	13.01±3.16	0.868 *	0.387
		Female	93	13.41±3.16		
	Knowledge		13.23±2.96			
2.	Professional Qualification	GNM(Nursing)	79	12.65±3.150	2.320 *	0.077
		B.Sc (Nursing)	82	13.62±2.774		
		Post Basic B.Sc (Nursing)	5	15.00±1.225		
		M.Sc (Nursing)	5	14.20±2.950		
3.	Area of Experience	Critical	147	13.31±2.744	0.467 *	0.627
		Non Critical	5	12.20±2.490		
		Critical/ Non Critical	19	12.89±4.508		
4.	Nurse patient ratio	1:1	27	13.41±3.682	0.341 =	0.733

Note: (α Independent t test. μ ANOVA)

Table No: 6 Correlation between Knowledge of the Staff Nurses on communication with comatose patients and personal profile of Staff Nurses.
(N=171)

S.No	Sample Characteristics		N	Mean \pm Standard Deviation	r Value	P-value
1.	Age in Years	Age	171	29.22 \pm 5.945	-0.196 ∞	0.010*
		Knowledge		13.23 \pm 2.96		
2.	Year of Experience	Year of Experience	171	5.520 \pm 4.257	-0.162 ∞	0.034*
		Knowledge		13.23 \pm 2.96		

Note :(∞ Pearson correlation; P value < 0.05, *statistically significant)

Table No 7 Association between practice of the Staff Nurses on communication with comatose patients and personal profile of Staff Nurses.
(N=171)

S.No	Sample Characteristic		N	Mean \pm Standard Deviation	t//F Value	P-value
1	Gender	Male	78	6.37 \pm 1.44	2.926 α	0.004
		Female	93	7.06 \pm 1.62		
2.	Professional Qualification	GNM	79	6.56 \pm 1.375	0.842 μ	0.473
		B.Sc (Nursing)	82	6.91 \pm 1.687		
		Post Basic B. Sc (Nursing)	5	6.60 \pm 2.074		
		M. Sc (Nursing)	5	2.280 \pm 2.28		
3	Area of Experience	Critical	147	6.76 \pm 1.560	2.217 μ	0.112
		Non Critical	5	5.40 \pm 0.894		
		Critical/ Non Critical	19	7.05 \pm 1.715		
4	Nurse patient ratio	1:1	27	6.22 \pm 1.826	-1.906 α	0.058
		1:2	144	6.85 \pm 1.511		

Note(. α Independent t test. μ ANOVA)

Table No 8 Correlation between practice of the Staff Nurses on communication with comatose patients and personal profile of Staff Nurses. (N=171)

S.No	Sample Characteristic		N	Mean ±Standard Deviation	r Value	P-value
1.	Age	Age	171	29.22±5.94	-0.196 [∞]	0.010*
		Practice		6.75±1.57		
2.	Year of Experience	Year of Experience	171	5.5208±4.257	-0.085 [∞]	0.267
		Practice				
				6.75±1.576		

Note: (∞ Pearson correlation; P value < 0.05 ,*statistically significant)

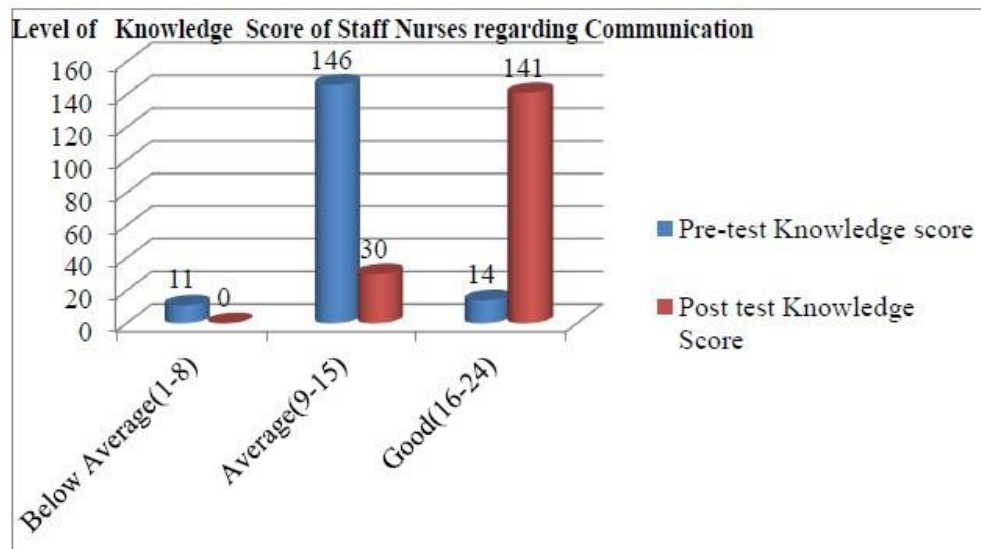


Figure No 1: Analysis of knowledge of staff nurses to depicts the level of knowledge regarding communication with comatose patients.

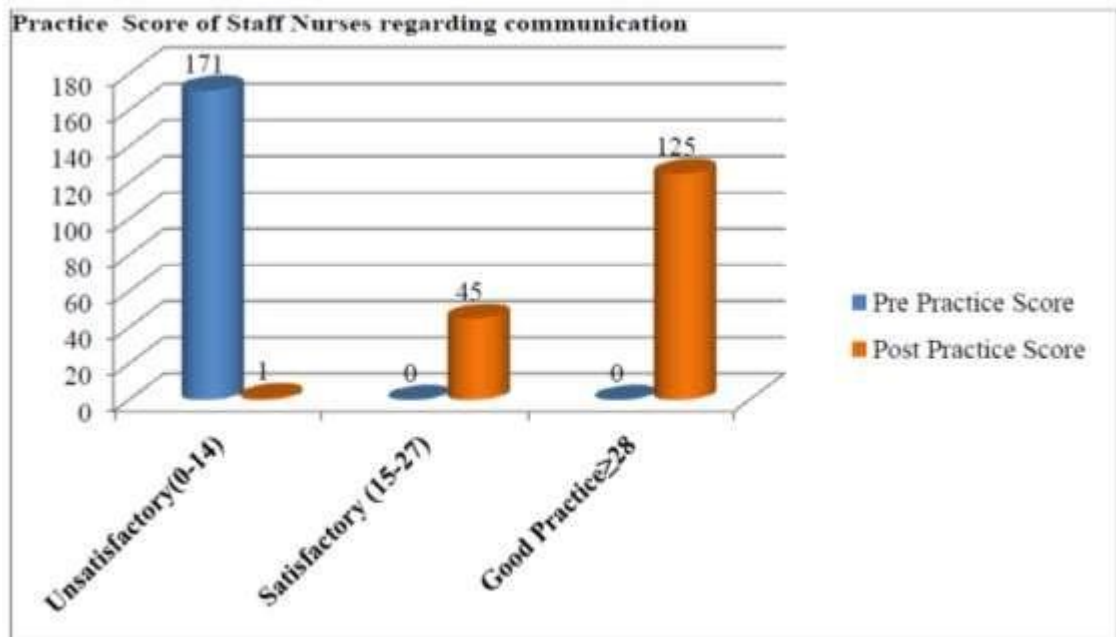


Figure No 2: Analysis of practice of staff nurses to depicts the level of practice regarding communication with comatose patients.

ANNEXURE-13





Nursing Research Society of India (NRSI)
24th National e-Conference 2021

Organized by

Yenepoya Nursing College
A Constituent College of Yenepoya (Deemed to be University)
University road, Derlakatta, Mangaluru -575018

Theme: Strengthening Nursing Scholarship through Publications

Certificate of Participation

This is to certify that **Ms. Pooja Thakur** has participated as a delegate in the e-Conference held on 26th & 27th November 2021. She has presented paper titled "A study to assess the effectiveness of training program on knowledge and practice of nurses regarding individualized communication protocol with comatose patients in selected Intensive Care Unit of Tertiary Care Hospital".

Dr. Priya Reshma Aranha
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Dr. Leena K.C
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Chairperson

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Secretary, NRSI

Dr. Assuma Beevi T M
President, NRSI

Dr. Gangadhara Somayaji K S
Registrar

Karnataka State Nursing Council has awarded.....16.....CNE credit points

ANNEXURE-14

List of Formulae used for Analysis and Interpretation

STATISTICAL TESTS

I. Arithmetic mean: $\bar{x} = \frac{\sum x}{n}$

Med(X)	
$X(\frac{n}{2})$	if n is even
$\frac{(X(\frac{n}{2}-1) + X(\frac{n}{2}+1))}{2}$	if n is odd

II. Median

III. Range: $(R) = H - L$

IV. Standard Deviation: $SD = \sqrt{\sum(x - \bar{x})^2 / n}$

V. Independent t - test: $t\text{-test} = \frac{(\bar{x}_1 - \bar{x}_2)}{SE}$

VI. Karl-Pearson's [r] correlation:

$$r = \frac{\sum(x - \bar{x})(y - \bar{y})}{\sqrt{\sum(x - \bar{x})^2 \sum(y - \bar{y})^2}}$$

$$r = \frac{\sum dx \cdot dy}{\sqrt{\sum dx^2 \cdot \sum dy^2}}$$

VII. Mann Whitney U test

$$U = NbM + \frac{N(N+1)}{2} - \sum_k \text{Rank}(x_k)$$

VIII. Fisher's Exact test

$p = \frac{(a+b)!(c+d)!(a+c)!(b+d)!}{a!b!c!d!n!}$

IX. Spearman Brown Prophecy Formula [r^2]

$$r^2 = \frac{2r}{1+r}$$