Original article
An experimental study to assess the effectiveness of self instructional module (SIM) on knowledge regarding cord blood banking and stem cell therapy among antenatal women in selected health care institutions of Pune city

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ABSTRACT

Introduction: Stem cells are a primitive cell type found in all animals and are capable of both self-renewal and differentiation. It is this capacity for self-renewal and for differentiation into repair cells that offers great potential for regenerative medicine. Background: Cord blood banking and stem cell therapy are fields where there are various researches going on. But knowledge regarding the same is very poor among general public i.e. parents, women etc. Purpose of the study was to assess the effectiveness of Self Instructional Module (SIM) on knowledge regarding cord blood banking & stem cell therapy among antenatal women in selected health care institutions of Pune city Material and method: A Quasi-experimental Pre test post test control group design with Non probability Purposive Sampling method. The tool consisted of section I (demographic data), and section II (structured knowledge questionnaire) to assess the knowledge on cord blood banking & stem cell therapy. Result: Majority 44% of the control group and 62% of the experimental group participants are in the age group of 21 to 25 years. 32% of participants of control group are educated up to primary level. While in the experimental group most of the participants i.e. 38% have secondary level of education. Most of the participants are housewives / homemakers i.e. 80% participants from control group and 88% participants from experimental group. 44% of the participants from both the groups had no children, 58% participants from control group and 68% from experimental group are Hindus. The mean score of experimental group is less i.e. 1.20 in pretest which has increased to 2.54; this increase is found significant which has determined the effectiveness of Self Instructional Module (SIM). Pre-interventional finding are only associated with the level of education of the participants. Conclusion: The analysis reveals that Self Instructional Module was helpful to improve the knowledge regarding cord blood banking & stem cell therapy among antenatal women.

Keywords:
cord blood banking
stem cell therapy
antenatal women
self instructional module
knowledge

Introduction
Zingiberaceae is the largest monocotyledons family in India. Zingiberals group has 52 genera and 1400 species concentrated in Indo-Malaysian region of Asia. Out of these 22 genera and 121 species reported from tropical and sub tropical regions of Asia, India represents 11 species [1], distributed in south east India, North east India, Andaman and Nicobar [2]. In Maharashtra 5 species are reported along Western Ghats in Konkan, Kolhapur, Satara, Abemadnagar, in semi evergreen forest [3]. It gets the

Stem cells are primordial cells found in all types of animals. They are able of self-renewal and differentiation. Some types of stem cell are more bound to some particular evolutionary fate than others. In contrast, the pluripotent stem cells are inconstant and retain the ability to differentiate into most different cell types. The embryonic stem cell is a perfect example of pluripotent cells. It is assumed that stem cells form reserves of restored cells to replace the cells and tissues that deteriorate over the whole life of the organism. The ability for self-renewal & differentiation into repair cells offers huge potential for regenerative medicine.1

Some researches in cord blood transplantation were based on the theory that the immune cells in the cord blood maybe immature than those found in adult bone marrow or peripheral blood. As a result, the risk of graft-versus-host disease (GVHD) after giving a cord blood transplant might be much lesser than that after a bone
marrow transplant or a peripheral blood transplant. Advantages of cord blood over bone marrow are its readily available, its lesser possibility for transmission of infectious diseases, and the negligible risk at the time of collection. This boosts the chances of hematopoietic progenitor cell (HPC) transplantation to the patients who either could not find a suitable match within the existing bone marrow donor pool or were too sick to be able to wait for the process of searching and harvesting of bone marrow from adult donors.

Since the first attempted transplants done in the late 1980s, cord blood has been used as a suitable alternative to adult bone marrow or peripheral blood. It can be used to treat leukemia, lymphoma, aplastic anemia, and inherited disorders of immunity & metabolism. Whether cord blood is as good as or better than adult graft sources in all of these situations is yet unknown. Factors that have proved to influence the result of cord blood transplantation include the cell count in the cord blood, the size of the recipient, and the degree of human leukocyte antigen (HLA) match between the donor & the recipient. Cord blood & marrow are parallel sources of HPC, each one having specific advantages & disadvantages, and that the choice between the two should be made on a case-by-case basis, depending on the condition of the patient. GVHD occurs when donor cells attack the recipient's normal tissues after transplant and can lead to organ damage. HLA stands for human leukocyte antigen, the major histocompatibility complex in humans. The closer the donor's and recipient's HLA antigens match, the less likely it is that the T cells (immune system cells) of the donated marrow will attack against the patient's body. Within a family, siblings have one-in-four chance of being HLA-identical. Outside the family, the situation is very different. HLA antigens are highly polymorphic, with hundreds of different HLA antigens found in the human population (there are roughly 750,000 possible combinations of three HLA antigens alone). To find an unrelated HLA-matched donor requires searching very large numbers of people.

**BACKGROUND OF THE STUDY**

Cord blood is a rich source of hematopoietic stem and progenitor cells available for clinical application to reconstitute the hematopoietic system and/or restore immunological function in affected individuals requiring treatment. Cord blood can be used as an alternative source for bone marrow transplantation. Its use is developing into a new field of treatment for pediatric and adult patients suffering with hematological disorders, immunological defects and specific genetic diseases.

The cells in cord blood are hematopoietic progenitor cells (HPC) and hematopoietic stem cells (HSC), which are also found in bone marrow and peripheral blood. Compared to other stem cell sources, cord blood is usually considered the safest option. Removal of stem cells from the umbilical cord is painless and completely safe for the mother and her child. Collected cord blood can be stored successfully for several decades.

For cord blood removal, the umbilical cord is cut and clamped just like in a normal birthing procedure. The only difference is that instead of discarding the umbilical cord after birth, medical staff will take the cord and remove leftover blood. The child will not lose any stem cells. Cells taken from an umbilical cord are being used in treatments for various dangerous conditions.

Because of poor knowledge about cord blood, many parents and families have mixed feelings about removing stem cells from an umbilical cord. While cord blood treatments, and stem cells in general, are still considered newer technology, dozens of diseases are currently approved for cord blood therapy by the FDA.

Cord blood HSCs have been used in treatment for more than 20 years, with over 35,000 successful transplants completed worldwide. First cord blood treatment was done in 1988, since then doctors have used umbilical cord cells as a therapy for many different illnesses. Cord blood HSCs now treat over 80 different conditions — in the past 8 years, the list of diseases treated with cord blood has doubled.

- Blood cancers like leukemia and lymphoma
- Immune system disorders like aplastic anemia
- Metabolic conditions like Hurler syndrome and Krabbe disease.

The cells are injected into a patient’s system, and then they move through the bloodstream to the affected areas like the brain, heart, or other vital organs. The cells adapt to the type of cell needed by the body, and begin multiplying. This increases the patient’s healthy blood cell count and improves their recovery time.

Stem cells can multiply an infinite amount of times. This means a single stem cell can create millions of similar cells, which can then become specialized. These specialized cells, which live inside our bodies, can become different cell types throughout their lifetime, depending on what our bodies need.

**Stem cells are different from other types of cells:**

- They can multiply through a process called cell division. This allows stem cells to increase in number and regenerate.
- Stem cells can change to assist specific organs and regenerate damaged tissue.

The two main types of cells found in the umbilical cord are hematopoietic cells and mesenchymal cells. Both of these cells are considered multi-potent, which means they may develop into different cell types over the course of their life.

Cord blood banking is the term for storing a child’s cord blood in a medical facility. Over a million units are stored in private banks, with another 500,000 registered in public facilities around the world. Expectant parents should know that birth is a one-time chance to collect and store these valuable stem cells, which can be used as a treatment for over 80 diseases.

Private banking protects your family from these dangerous conditions, while a public donation can help researchers find new treatments, or aid a family with little or no medical options.

**Cord blood stem cells are too valuable to discard.**

With continued support from the medical community and government, many researchers believe that umbilical cord cells will become a standard treatment in the next few years.
NEED OF THE STUDY

Metabolites analysis by ESI-Q-TOF-MS revealed the presence of fatty acids, organic compounds, phenolics, alkaloids, aminopyrimidines, dipeptide and tripeptides like important metabolites (Tables 4). The major abundant metabolites identified in the Z. zerumbet ethanol extract by ESI-QTOF-MS analysis were Tamoxifen, Lecanoric acid, Oxyphencyclimine, 4-Nonylphenol, Estradiol valerate, Cedrol, Phyloquinone (Vitamin K1) of mass 371.23, 318.07, 344.20, 220.18, 356.23, 222.19 and 450.35 respectively (Fig. 1). The retention time, mass, molecularformula and the DB difference (ppm) of the major seven abundant metabolites are shown in (Table 4). The chromatogram spectra showed counts versus retention time (Fig. 2).

The rate of use of cord blood for transplantation has increased exponentially. In the United States, Europe, and Japan exceeds the use of bone marrow for childhood transplants. Researches indicate positive results in a various settings, although utilization and success is limited by several obstacles common to any form of transplantation, including the need for an HLA match (Kerman et al., 1993; Confer, 1997; Rubinstein et al., 1998; Goldberg et al., 2000; Rocha et al., 2000; de Lima and Chapmlin, 2001; Barker et al., 2001, 2003, 2005; Laughlin et al., 2001; Wagner et al., 2002; Barker and Wagner, 2003; Grewa et al., 2003).

Without a close match for HLA, HPC transplantation from any source is associated with high risk of rejection, in which the recipient’s immune cells react against the donor cells. Even with HLA compatibility, immunosuppressive therapy is required to prevent rejection and to reduce the incidence and severity of GVHD. In the case of donor-patient HLA disparity, infection is an even greater problem.6

Umbilical cord blood was once thought of as a waste product. Now, more families want information about whether to save their newborn’s cord blood. Childbirth educators may be one of the main sources that an expectant family depends on to gain more knowledge about cord blood banking in order to make an informed decision. Preserving umbilical cord blood in public banks is advisable for any family; however, it is recommended that expectant families only consider private cord blood banking when they have a relative with a known disorder that is treatable by stem cell transplants. The childbirth educator is encouraged to be well versed on the topic of cord blood banking, so that as questions from class participants arise, the topic can be explored and addressed appropriately.7

Literatures are available on various educational methods and media for practice in nursing. Planned teaching programme was found to be effective in improving attitude and knowledge on practice of mothers regarding ARIs as shown by the post-test scores of experimental group. The findings revealed that there was increase in the knowledge level of staff after structured education trials.

As the researcher felt there is lack of knowledge and awareness among people regarding cord blood banking and stem cell therapy, it was important to educate the public about the potential uses and advantages.

STATEMENT OF PROBLEM

“An experimental study to assess the effectiveness of Self Instructional Module (SIM) on knowledge regarding cord blood banking and stem cell therapy among antenatal women in selected health care institutions of Pune city.”

PURPOSE

To assess the effectiveness of Self Instructional Module (SIM) on knowledge regarding cord blood banking and stem cell therapy among antenatal women in selected health care institutions of Pune city.

OBJECTIVES

1. To assess the knowledge of antenatal women regarding cord blood banking and stem cell therapy before the Self Instructional Module (SIM) in both the groups.

2. To assess the knowledge of antenatal women regarding cord blood banking and stem cell therapy after the Self Instructional Module (SIM) in the experimental group and control group.

3. To compare the pre and post assessment of knowledge of antenatal women regarding cord blood banking and stem cell therapy.

4. To determine the effectiveness of Self Instructional Module (SIM) on knowledge regarding cord blood banking and stem cell therapy among antenatal women.

5. To associate the pre interventional findings with selected demographic variables.

ASSUMPTIONS

The study assumed that

- Women may have poor knowledge on cord blood banking & stem cell therapy
- Knowledge on cord blood banking & stem cell therapy is measurable
- Self Instructional Module (SIM) may be effective in increasing the knowledge regarding cord blood banking & stem cell therapy

OPERATIONAL DEFINITION

1) Effectiveness – In this study, it refers to change in knowledge regarding cord blood banking & stem cell therapy.

2) Self Instructional Module – In this study, it refers to a written form of valuable information systematically developed for educating the women regarding cord blood banking & stem cell therapy.

3) Knowledge – In this study it refers to the right responses of antenatal women on knowledge questionnaire regarding cord blood banking & stem cell therapy.

4) Antenatal women – In this study it refers to the women who are attending ANC clinics at selected health care institutions in Pune city, and who are in between 5 weeks to 40 weeks of gestation.
5) Cord Blood Banking - In this study it means collection and storage of the blood from within the umbilical cord after a baby is born.

6) Stem cells – In this study, Stem cells are undifferentiated biological cells that can differentiate into specialized cells and can divide to produce more stem cells.

7) Stem cell therapy – In this study, Stem-cell therapy means the use of stem cells to treat or prevent a disease or illness.

HYPOTHESIS

Hypothesis for effectiveness
There is no significant difference in the pre test and post test scores of knowledge among antenatal women regarding cord blood banking and stem cell therapy at 0.05 level of significance.

Hypothesis for association
There is no significant association between the knowledge and demographic variables at 0.05 level of significance.

CONCEPTUAL FRAMEWORK

A framework for a research study helps to organize the study and provides a context for the interpretation of the findings of the study.

Conceptual framework provides a background or foundation for a study. A conceptual framework helps to explain the relationship between concepts. The conceptual framework formalizes the thinking process, so that others may read and know the frame of reference, basic to the research problem.

Talbot (1995) proposes that, to be meaningful, a conceptual framework that influences all phases of research process must guide systematic inquiry.

Conceptualization of this study is based on “Systems Theory” A system is a group of elements that interact with another in order to achieve a goal.

This theory has 3 components – input, throughput, and output. Matter, energy and information that enter the system are called the input. The systems or subsystems use that input in a process that is referred to as throughput and the matter, energy and information released into the environment is called output.

In this study –

Input – refers to the knowledge of antenatal women, number of children, level of education, age, occupation and religion.

Throughput – refers to the administration of self instructional module (SIM) regarding cord blood banking and stem cell therapy.

- Pre-test will be taken from both experimental and control group.
- Administration of self instructional module on experimental group.
- Post – test will be done after 7th day both for experimental and control group.

Output – refers to the resultant awareness about cord blood banking & stem cell therapy.

absence of tannins and alkaloids. Therefore the active plant extract is subjected to further HRLC-MS analysis to investigate various chemical components for isolation of the therapeutic antimicrobials for detailed pharmacognosy and phytochemistry.

Conflict of interest statement
We declare that we have no conflict of interest.

Acknowledgment:
Authors are thankful to the Principal, Vivekanand Arts, Sardar Dalip Singh Commerce and Science College, Samarth Nagar, Aurangabad for providing laboratory facilities and encouragement and also wish to thank Dept. of Microbiology, Vivekanand Arts, Sardar Dalip Singh Commerce and Science College, Samarth Nagar, Aurangabad for providing pathogenic microorganisms for the present investigation.

CONCEPTUAL FRAMEWORK

GENERAL SYSTEM THEORY

DELIMITATIONS

The study was delimited to –

- Antenatal women attending ANC clinic at selected health care institutions in Pune city.
- Self made questionnaire, Self Instructional Module for knowledge assessment.

CONCLUSION

This chapter deals with the introduction, background of study, need for the study, statement of problem, assumptions, objectives, conceptual framework, & delimitations of the study.


**REVIEW OF LITERATURE**

Review of literature is an important step in research process. Review of literature means a comprehensive, complete and analytical scrutiny of publications related to the research project. Before any research can be started, literature reviews of earlier studies and experiences related to intended investigations should be done. The best part of the literature review is the contribution it makes to the new knowledge, insight and gain in knowledge of the researcher.

The review of literature is presented under the following areas:

I. Literature related to cord blood banking

II. Literature related to stem cell therapy

III. Literature related to effectiveness of self instructional module (SIM)

**I. Literature related to cord blood banking**

In a study titled “Cord blood collection for banking and the risk of maternal hemorrhage” by Luís Amat et al it is mentioned that after cord blood collection, stem cell separation has been performed either with a combination of monoclonal antibodies, using the negative selection Stem Sep method, or with a positive cell selection based on their surface CD34 antigens, using the Mini Macs system. An excellent recovery of hematopoietic progenitors: Burst Forming Unit Erythroid; Colony Forming Unit Granulocyte and Macrophage; and Colony Forming Unit Granulocyte, inversely related to the rising of clamping time, have been achieved with the Mini Macs system. By early clamping of umbilical cord blood, we obtained a greater number of CD34+ cells whose clonogenic activity increased with enrichment. This was particularly useful considering that the number of CD34+ stem cells contained in a unit of placental blood is enough for transplantation to a child, but not for an adult engraftment. Thus, using these methods, we can obtain a larger number of CD34+ stem cells which increases the possibility of reducing graft-versus-host disease in adult patients, producing survival rates similar to those with transplantation of bone marrow.

A study was conducted by Sudhanshu Kumar Das, et al to find the understanding among healthcare providers about the Umbilical Cord Blood Banking (UCBB) and its advantages and affordability by its longevity or viability in recent period. A cross-sectional study was conducted among 100 health care professionals; who attended OP clinics of OBG and pediatrics in NRI medical college and general hospital. Questionnaire with 20 questions was used. The Results showed that Among 100 health professionals, 67% were aware of UCBB and remaining (33%) were unaware. Advertisements were the most common source of information. The results showed that more information was needed to healthcare professionals with respect to knowledge, awareness, concerns in collection and storage of cord blood.

In another study by Louiza Z. Karagiorgou et al, to determine Greeks’ impression about umbilical cord blood, to find out the reasons for the lack of enthusiasm to donate umbilical cord blood and to allow experts to establish better induction drives to improve the donor pool. The perspectives and knowledge about umbilical cord blood of randomly selected Greek citizens were assessed by a standardized questionnaire. 48% of respondents knew about umbilical cord blood and had full knowledge about what storage/donation offers. Mass media and health professionals were the main source of information. The information from the state was considered either deficient or defunct by 85% of the people. It was concluded that Greek citizens receive information about umbilical cord blood from both the state and advertising campaigns by the Ministry of Health and Social Solidarity. A partnership between all hospitals and public umbilical cord blood banks would be desirable in order to assist access to umbilical cord blood donations.

In a study done by Elena Salvaterra, et al, it was found that despite the growing acceptance of cord blood as a therapeutically efficient biologic substance suited for the treatment of both pediatric and adult transplant recipients, undoubtedly consensus is still lacking on a number of legal and ethical issues related to specific steps of the whole cord blood collection, banking and distribution process. The main factors under discussion are ownership and autologous versus allogeneic banking. Although expectations from the public can be based on promising discoveries in the field of stem cell therapy, it is the job of politicians and stakeholders to educate citizen. It is in fact evident that no parent could expect to find an available biologic unit for their diseased child donated by other altruistic parents if the prevalent moral obligation felt by parents would be to store cord blood for their newborns. Unfortunately, recent media reports indicate that the latter opinion received support by opinion makers and other persons with high social visibility. Responsible bodies in our societies should promote educational programs to aid full understanding of all components which need to be considered so that parents can make the decision that is most advantageous for their children. Autologous cord blood banking is not the best decision at the present time.

In the study by Carlo Pafumi et al, the researchers tried to determine the effect of cord blood collection before placental expulsion on postpartum maternal blood loss. The study was conducted in a university hospital and included Spanish women who had consented to donate cord blood for public banking purposes. They measured blood volume lost during delivery by a bag collection method, as well as the need for transfusion and postpartum anemia symptoms. Deliveries at which cord blood was collected presented a significant increase in blood loss. Instrumental deliveries were associated with higher postpartum blood loss than spontaneous deliveries. Cord blood collection can increase intrapartum blood loss, especially at instrumental deliveries. Additional staffs who handle the collection are required to allow the leading obstetricians to focus on maternal care.

Cord blood can be easily collected after delivery without apparent risk for the mother and the newborn. Currently, no maternal complications associated with cord blood collection have been reported, and hence it seems to be harmless. Cord
blood collection can be performed with the placenta either ex or in utero. With the latter, there is a probability for interference in the delivery care, which might mean a risk for a higher hemorrhage rate, for example, due to a delay in perinatal repair and changed placental delivery management. Some authors have described that cord blood drainage after birth reduces the length of the third stage, but no major differences have been seen in blood loss between cord donors and a control group. Finding out the exact cause can be difficult, because anemia, malnutrition or other patient factors can disguise the clinical symptoms. Uterotonics used during the third stage and uterine massage after placental delivery matter immediately postpartum to avoid blood loss, but policies on this and the timing of cord clamping and controlled umbilical cord traction differ widely. Results suggest that cord blood collection can interfere in maternal care, especially in more complicated deliveries with a greater risk for blood loss. If the same obstetrician who is conducting the delivery is the one who performs the cord blood collection, bleeding may increase. According to the researcher, it should be mandatory that an external collector takes care of the cord blood collection, or the blood should be collected after placental expulsion, which requires better techniques for cord blood collection at that time. 

II. Literature related to stem cell therapy

In a study by Jong Kyu Hong, et. al, it is stated that Tissue engineering based on stem cells has gained interest recently. These cell behaviors are governed by soluble signals that are systemic or presented by local niche cells. The combination of stem cells and tissue engineering opens up new aspects in tissue regeneration for stem cell therapy, because of the ability to control stem cell behavior with the physical and chemical characteristics of the engineered scaffold environment.

New developments in the fields of stem cell biology, biomaterials science and engineering have been combined to produce systems by which stem cell attachment, growth and differentiation in vitro are supported and improved. The combination of tissue engineering and stem cell biology has greatly enhanced the possibility of tissue regeneration. The application of tissue engineering to stem cell therapy in vivo is highly expected to progress in the near future. Other future consideration for tissue engineering based on stem cell therapy is how to develop many methods of incorporating and producing a vascular network in a scaffold, allowing it to integrate with actual tissue or organs and restore function lost after injury. It could be achieved by co-culturing with endothelial cells or by embedding angiogenic factors such as vascular endothelial growth factors to promote angiogenesis into scaffolds. This review paper has given a good starting point for future development of tissue engineering combined with biomaterial scaffolds for stem cell therapy. 13

A study done by Franco Aversa et. al, states that transplantation of bone marrow from an HLA-matched related / unrelated donor is a likely curative treatment for patients with acute leukemia. The HLA genes are tightly linked and are inherited in a genetic unit called a haplotype. A child inherits one haplotype from each parent. For this reason, two siblings have a 25 percent chance of inheriting the same two parental haplotypes and thus of being HLA identical. Hence the overall results in terms of transplantation-related mortality and disease-free survival compare favorably with the outcome expected in patients who have the same stage of disease and who receive transplants from matched unrelated donors. The high percentage of engraftment, the elimination of GVHD, and the minimal non hematologic toxicity of the conditioning system shows that the main problem, that limited the use of marrow from relatives with only one matched haplotype have been overcome. Since almost every patient with hematologic cancer has a haplotype-mismatched relative, further studies of this strategy will increase the possibility of a cure.14

An in vivo study done by Sakai Daisuke to assess the differentiation status of mesenchymal stem cells (MSCs) transplanted to the nucleus pulposus of degenerative discs in a rabbit model. The objective of the study was to determine whether they are a suitable alternative for cell transplantation therapy for disc degeneration. Many cells that were positive for green fluorescent protein were observed in the nucleus pulposus of cell-transplanted rabbit discs 2 weeks after transplantation. In 48 weeks their number increased significantly. Biochemical and gene expression analyses showed significant restoration of total proteoglycan content and matrix-related genes compared with nontransplanted discs. MSCs transplanted to degenerative discs in rabbits proliferated and differentiated into cells expressing some of the major phenotypic characteristics of nucleus pulposus cells, suggesting that these MSCs may have undergone site-dependent differentiation. Further studies are needed to evaluate their functional role.15

This study done by Attabehfar et al, sought to evaluate the feasibility and safety of autologous bone marrow derived and cardiogenically oriented mesenchymal stem cell therapy and to identify signs of efficacy in patients with chronic heart failure. In pre-clinical heart failure models, cardiopoietic stem cell therapy improves left ventricular function and blunts pathological remodeling. The C-CURE (Cardiopoietic stem Cell therapy in heart failure) trial, a prospective, multicenter, randomized trial, was conducted in patients with heart failure of ischemic origin who received standard of care plus lineage-specified stem cells. In the cell therapy arm, bone marrow was harvested and isolated mesenchymal stem cells were exposed to a cardiogenic cocktail. Cardiopoietic stem cell therapy was found feasible and safe with signs of benefit in chronic heart failure, meritng definitive clinical evaluation. The ensuing C-CURE clinical trial addressed the feasibility and safety of autologous bone marrow-derived cardiopoietic stem cell therapy and assessed the signs of efficacy in patients with ischemic cardiomyopathy. This is the first application of guided stem cells for targeted regeneration of a failing organ. Lineage priming of bone marrow stem cells from patients with ischemic heart failure was shown to be feasible. The present C-CURE trial introduces a potential new treatment for heart failure using readily accessible bone marrow mesenchymal stem cells lineage specified to upgrade cardioregenerative aptitude.16
A study done by Gian Paolo et al, found that up to 1/3rd of patients are not susceptible to traditional revascularization and may benefit from stem cell therapies. In this meta-analysis, it was sought to determine whether autologous cell therapy is effective in the treatment of PAD. The researcher searched the English literature in Medline, Excerpta Medica and the Cochrane database for trials of autologous cell therapy in patients with PAD published before 31 January 2009. They included controlled and non-controlled, randomized and non-randomized trials using autologous bone marrow or granulocyte colony stimulating factor (G-CSF) mobilized peripheral blood cells to treat PAD. Also data was collected from trials of G-CSF monotherapy, as a control treatment. In a meta-analysis of 37 trials, autologous cell therapy was effective in improving surrogate indexes of ischemia, subjective symptoms and hard endpoints. On the other hand, G-CSF monotherapy was not associated with significant improvement in the same endpoints. Patients with thrombocytopenia obliterans showed some larger benefits than patients with atherosclerotic PAD. The intramuscular route of administration and the use of bone marrow cells seemed somewhat more effective than intrarctal administration and the use of mobilized peripheral blood cells. The procedures were well tolerated and generally safe. This meta-analysis indicates that intramuscular autologous bone marrow cell therapy is a feasible, relatively safe and effective therapeutic strategy for PAD patients, who are not suitable candidates for traditional revascularization.17

### III. Literature related to effectiveness of self instructional module (SIM)

A study done by Mr Swamy Pgn et al, aimed to evaluate the effectiveness of self instructional module (SIM) on knowledge regarding revised national tuberculosis control programme among female health workers. They used pre experimental research (one group pre-test post-test design). Purposive sampling technique was used for 30 female health workers in selected primary health centres of Tumkur district. Self administered knowledge questionnaire was used to assess the knowledge. The Results showed that there was a significant difference between pre-test and post-test knowledge of female health workers regarding revised national tuberculosis control programme. Hence SIM is considered as one of the effective teaching strategy in imparting knowledge regarding RNTCP among female health workers.18

In a study done bySheetal Udaykar et al, titled "Effect of self- Instructional Module regarding Oncology Emergencies on knowledge among nurses" was aimed to assess the effectiveness of self instructional module on oncology emergency among nurses. Quantitative research approach with one group pre test post test research design was used for 40 study samples, selected by non probability purposive sampling technique. The results suggest that there was a significant difference in the pre test and post test knowledge scores. Hence it is found that Self instructional module regarding oncological emergencies among staff nurses was effective to improve the knowledge of staff nurses.19

Mr Robin J Bhatti conducted a study aimed to determine the effectiveness of Self Instructional Module on knowledge of emergency drugs among staff nurses working in critical care units. Pre-experimental design was used to assess the knowledge level. Purposive sampling technique was used for 50 staff nurses and data collection tool was questionnaire. The results of the study suggest that the Self Instructional Module was effective in improving the knowledge of staff nurses hence improving the quality of services delivered by staff nurses. This paper reports the importance of Self Instructional Module in improvement of knowledge of staff nurses regarding emergency drugs.20

Another study conducted in Nigeria aimed to assess the effectiveness of self-instructional information on knowledge regarding office ergonomics among computer users was done by Sokunbi Ganiyu et al, 170 computer users among the staffs of selected higher educational institutions in Nigeria participated in this study. Occupational Safety and Health Administration (OSHA) workstation checklist was used to assess the level of knowledge of office ergonomics. Work Safely with Visual Display Terminal (WSVDT) booklet was used to provide instructional information on office ergonomics. Both OSHA and WSVDT were administered and collected by hand. Findings from this study showed that instructional information on computer office ergonomics increase the level of knowledge of office ergonomics among computer users in selected institution of learning in Nigeria. It also showed that level of education and duration of computer use increase with increase in the changes in the level of knowledge of computer office ergonomics among computer users.21

A study was undertaken to assess the effectiveness of self instructional module on knowledgein diarrhea among mothers in selected play schools at Chennai by P. Ester Bala. Quasi experimental pre test post test control group design was used for the study. The sample size of the study is 60 mothers of children under 5 years of age. The Results indicated that the improvement was statistically found to be significant at P<0.001 in the experimental group.22

### CHAPTER 3 RESEARCH METHODOLOGY

Research is a logical and systematic search for new and useful information on a particular topic

It is an investigation of finding solutions to scientific and social problems through objective and systematic analysis. It is a search for knowledge, that is, a discovery of hidden truths. Here knowledge means information about matters. The information might be collected from different sources like experience, human beings, books, journals, nature, etc.

Research methods are the various procedures, schemes and algorithms used in research. All the methods used by a researcher during a research study are termed as research methods. They are essentially planned, scientific and value-neutral. They include theoretical procedures, experimental studies, numerical schemes, statistical approaches, etc. Research methods help us collect samples, data and find a solution to a problem. Particularly,
scientific research methods call for explanations based on collected facts, measurements and observations and not on reasoning alone. They accept only those explanations which can be verified by experiments.

Research methodology is a systematic way to solve a problem. It is a science of studying how research is to be carried out. Essentially, the procedures by which researchers go about their work of describing, explaining and predicting phenomena are called research methodology. It is also defined as the study of methods by which knowledge is gained. Its aim is to give the work plan of research. The methodology of research indicates the general pattern of organizing the procedure of gathering valid and reliable data for an investigation.

This chapter deals with research methodology adopted to assess the effectiveness of self instructional module (SIM) on knowledge regarding cord blood banking and stem cell therapy among antenatal women in selected health care institutions in Pune city

**RESEARCH APPROACH**

The research approach adopted for this study was quantitative approach.

**RESEARCH DESIGN**

The research design refers to the overall plan for obtaining the data to fulfill the objectives of the present study. The research design selected for the present study was Quasi experimental - Pre test – post test control group design.

**Fig no 1.1: Schematic representation Quasi experimental Pre test – post test control group design**

**VARIABLES**

**Dependent Variable:-**
- In this study, the dependent variable is the level of knowledge of antenatal women.

**Independent Variable:-**
- In this study, the independent variable is the Self Instructional Module (SIM) on stem cell therapy and cord blood banking

**SETTINGS**

Setting is the most specific places where the data collection takes place. Nature of the setting influences the observations of the study.

The research setting will be

- Kamala Nehru Hospital, Pune
- Smt. Kashibai Nawale Medical College & General Hospital, Pune

The settings for the study were selected for the following reasons:
- Availability of the sample
- Administrative approval and expectation of co-operation from the authority
- Feasibility of conducting the study in terms of time and distance
- Familiarity with the setting
- Easy accessibility

**POPULATION**

Target: - All antenatal women attending ANC clinic.

Accessible: - All antenatal women attending ANC clinic at selected health care institutions of Pune city.

**SAMPLE**

Samples are antenatal women attending ANC clinic at selected health care institutions of Pune city.

**SAMPLE SIZE**

In this study, the sample size is 100. i.e. 50 in control group and 50 in experimental group.

**SAMPLING TECHNIQUES**

The sampling technique adopted for the present study is Non probability Purposive Sampling

**DEVELOPMENT AND DESCRIPTION OF SIM**

After review of research and non research literature related to cord blood sampling and stem cell therapy the self instruction module was prepared by the researcher. It includes the following steps–

- Preparation of the first draft of the self instructional module.
- Establishment of content validity of the self instructional module.
- Preparation of final draft of the self instructional module.
- Linguistic validation: translation of English tool and self instructional module to Marathi was done. Language experts were involved in respective translation.

**DATA COLLECTION TOOLS AND TECHNIQUES**

The most important and crucial aspect of any investigation is the collection of appropriate information which provide necessary data for study.
Table no 1.1: description the tool.

<table>
<thead>
<tr>
<th>Tool no</th>
<th>Tools</th>
<th>Variables to be measured</th>
<th>Technique method</th>
</tr>
</thead>
<tbody>
<tr>
<td>Section 1</td>
<td>Structured questionnaire</td>
<td>Demographic variable</td>
<td>Pen and paper</td>
</tr>
<tr>
<td>Section 2</td>
<td>Structured Questionnaire</td>
<td>Knowledge Level</td>
<td>Pen and paper</td>
</tr>
</tbody>
</table>

DEVELOPMENT OF TOOL

- Reviewed various research and non research articles on areas related to study.
- Guidelines was from guide and co – guide
- Informal discussions with peer group and other teachers and concerned people in the field of Obstetrics and Gynaecology
- Preparation of blueprint
- Expert opinion was sought for ascertaining the clarity and appropriateness of the tools
- Plan for scoring
- First drafts of tools were prepared and given to the guide and co – guide for correction
- All the tools were given for validation to 21 experts from various fields
- After taking opinion from experts final draft of the tools were prepared.
- Final scoring plan were developed
- Establishment of content validity
- Translation of tool from English to Marathi was done with the help of respective experts.
- Reliability of the tool done by test retest method.
- Pre testing of tool was done

Fig 1.2: Schematic Representation
DESCRIPTION OF TOOL

- Section 1: Demographic Data – 5 Questions
  - Structured questionnaire was developed to collect demographic data.
  - It consists of 5 items which include age, education, occupation, number of children, and religion

- Section 2: Structured Questionnaire to assess the knowledge on cord blood Banking and Stem cell therapy – 15 Questions
  - The structured questionnaire regarding knowledge about cord blood Banking and Stem cell therapy. It consists of 15 items
  - Scoring – there were 4 options for each item. Out of the 4 options only one is the correct response.
  - Each correct response will carry “1” mark. Wrong response will carry “0” marks.
  - Respondents with score 12 and above will be considered to be having excellent knowledge. Those having a score between 11 to 8 will be considered to have good knowledge, and those getting a score of 7 to 4 will be considered having average knowledge, and those who score less than or equal to 3 will be considered to have poor knowledge regarding cord blood Banking and Stem cell therapy.

VALIDITY

Validity refers to getting results that accurately reflect the concept of being measured. A valid measure refers to the degree to which an instrument measures what it is supposed to be measuring. In practice, validity can also refer to the success of the research in retrieving “valid” results.

Content validity refers to the degree to which the test actually measures or is specifically related to the traits for which it was designed. Identifying the universe of content is not an easy task. It is, therefore, usually suggested that a panel of experts in the field be studied to identify a content area. (Polite, 1999)

The content of data collection tool was sent for its validity in terms of relevance and accuracy to a list of experts along with scoring sheet.

To ensure the content validity, the tool was given to 21 experts. Out of those 15 were received back with their valuable suggestions and comments on the study tool. The experts were from different fields - 3 expert from the field of medical surgical nursing, 3 expert from community health Nursing, 1 expert from child health nursing and 14 experts were obstetrics & gynecological health nursing specialty.

The Content of the tool was having 2 sections – section 1 (demographical data) and section 2 (knowledge questionnaire)

Following Suggestion were given by the experts.
1. Add more questions in section 2
2. Rephrase a few questions
3. Arrange the questions according to the SIM.
4. Add some details regarding facilities providing cord blood banking in Pune.

These above mentioned suggestions were discussed with guide and relevant ones are enclosed in the study. Hence, the content validity of the research tool was ensured.

RELIABILITY

Reliability is the stability and repeatability of the data collection instrument. Reliable instruments obtain consistent results when reused. Test having a high co-efficient of reliability, errors of measurement are reduced to a minimum. Reliability of the tool may be raised by increasing the number of items.

Reliability has to do with the quality of measurement. In its everyday sense, reliability is the “consistency” or “repeatability” of measures. Reliability is the consistency of a set of measurements or measuring instrument. Reliability does not imply validity. That is reliable measure is measuring something consistently, but not necessarily what it is supposed to be measuring. Reliability is the extent to which the measurements of a test remain consistent over repeated tests of the same subject under identical condition.

The reliability was done using Test-Retest method; co-efficient was calculated using “Karl Pearson’s correlation coefficient formula”. The items were coded and the reliability was calculated. The reliability co-efficient was found to be 0.85, which is significant.

The reliability result was $r = 0.85$. If values is greater than 0.70, then the test is reliable. Hence the tool is reliable. The final form of tool consisted of 15 items where each item was given ‘one score’. The purpose was to determine the clarity of the items, presence of ambiguous items and the difficulty in understanding scientific terms and to ensure the reliability and feasibility of the tool. A few modifications of items in terms of clarification, use of simple words were made to the tool to make it simpler to understand.

ETHICAL CONSIDERATIONS

Ethical permission
- Permission taken from ethical committee of BVDU College of Nursing, Pune
- Informed consent from each of the participants.

Administrative permission
- Permission taken from Medical Director, Bharati Hospital And Research Centre, Pune
- Permission taken from Medical Director, Bharati Ayurveda hospital, Pune
- Permission taken from Dean, Smt. Kashibai Navale Medical College & General hospital, Pune
- Permission from Health Director, Pune Municipal Corporation, for carrying out the research study at Kamala Nehru Hospital and Sonawane Maternity Home, Pune

PILOT STUDY
- On 10 women attending ANC Clinic at Bharati Ayurveda Hospital, Pune.
- Consent from research participants was taken.
• Data collection was done by self structured questionnaire.
  
• The process of the pilot study was started on 31/07/2017.
  
• Questionnaire was administered to samples for experimental and control group.
  
• Post test done on 8th Aug 2017.

Problems faced during pilot study

• Did not get permission from Bharati hospital and research centre, Pune.
  
• Some ANC women did not come on 7th day for post test.
  
• There were some drop outs i.e. 10%

FINAL DATA COLLECTION PROCEDURE

• Ethical approval.
  
• Permission from the concerned health care institutions.
  
• Explain procedure to the mothers.
  
• Consent of subject.
  
• Tool – administration (20–30 minutes) and before giving Self Instructional Module (SIM).
  
• Self Instructional Module (SIM)
  
• Post test - will be conducted after 7 days of giving the Self Instructional Module (SIM).
  
• The final data collection was done between 10th Aug 2017 to 4th Sept 2017.
  
• Pre test for experimental group was conducted on 10th Aug 2017 in Smt. Kashibai Navale Medical College & General Hospital, Pune; Self instructional module was given to the participants immediately after the pre test.
  
• Post test for experimental group was conducted on 17th Aug 2017.
  
• Pre test for control was conducted on 28th Aug 2017 in Kamala Nehru Hospital.
  
• Post test was conducted on 4th Sept 2017.

PLAN FOR DATA ANALYSIS

Analysis of the data will be done using descriptive and inferential statistics. (The organised data will be represented by tabular and graphical form.)

Statistical Analysis:

1. Demographic data of the respondents will be done by Descriptive analysis (frequency and percentage distribution, mean, median, S.D., etc.)

2. Association of the knowledge will be done by using parametric and non parametric tests, Co-efficient of co-relation, Chi–Square test.

PLAN FOR DATA DISSEMINATION

The findings of the study will be presented in the group meeting and copy will be circulated to hospital administrators for their comments. Improvement and standardisation can be undertaken.

CONCLUSION

This chapter deals with the methodology adopted for the present study. It includes research approach, research design, variables under study, setting, population, sample and sampling technique, selection and development of data collection tools, description of the self instructional module (SIM).

CHAPTER 4
ANALYSIS AND INTERPRETATION OF DATA

This chapter dealt with the analysis and interpretation of data which were based on the information collected from the antenatal women of the selected health care institutions of Pune city and by evaluating the effectiveness of the information booklet on cord blood banking & stem cell therapy. Data analysis is the phase of a study that includes tabulating, coding, and classifying, data gathered in accordance with the research design to perform quantitative or qualitative analysis. The purpose of data analysis is to impose some order on a large body of information so that data can be synthesized, interpreted and communicated.

Data collected was analyzed statistically to fulfill the objectives of the study and to test the hypotheses formulated. For this purpose, descriptive and inferential statistics is used, since both of these statistics have their own significance. Data analysis and interpretation for this study is organized according to objectives of the study.

Interpretation refers to the process of making sense of the result and of examining the implications of the finding with in boarder context.

The researcher had broken down data into constituent part to obtain answers to research questions and to test research hypothesis. Data was collected through structured questionnaire.

On the basis of the objectives of the study analysis and interpretation of data were done by using descriptive and inferential statistics. The objectives of the study were

1. To assess the knowledge of antenatal women regarding cord blood banking and stem cell therapy before the Self Instructional Module (SIM) in both the groups.

2. To assess the knowledge of antenatal women regarding cord blood banking and stem cell therapy after the Self Instructional Module (SIM) in the experimental group and control group.

   1. To compare the pre and post assessment of knowledge of antenatal women regarding cord blood banking and stem cell therapy.

   2. To determine the effectiveness of Self Instructional Module (SIM) on knowledge regarding cord blood banking and stem cell therapy among antenatal women.

   3. To associate the pre intervention findings with selected demographic variables.
ORGANIZATION AND PRESENTATION OF DATA

The data had been organized and presented under the following heading.

Section I: Findings related to the demographic characteristics of the sample

Section II: Findings related to assessment of the knowledge of antenatal women regarding cord blood banking and stem cell therapy before the Self Instructional Module (SIM) in both the groups.

Section III: Findings related to the assessment the knowledge of antenatal women regarding cord blood banking and stem cell therapy after the Self Instructional Module (SIM) in the experimental group and control group.

Section IV: Findings related to the comparison of the pre and post assessment of knowledge of antenatal women regarding cord blood banking and stem cell therapy among antenatal women.

Section V: Findings related to the effectiveness of Self-Instructional Module (SIM) on knowledge regarding cord blood banking and stem cell therapy among antenatal women.

Section VI: Findings related to the association between pre interventional knowledge and selected demographic variables.

SECTION I:

To describe the demographic variables of the sample.

The following graphs describe the age distribution of the participants in both the control and group. N = 100; n1 = 50, n2 = 50

Figure 1.3 shows that almost 44% of the participants in the control group and 62% of the participants of the experimental group are in the age group of 21 to 25 years. Only 10% of participants from control group and 6% of participants from experimental group are in the age group of 31 to 35 years. 24% from control group & 22% participants from experimental group are in the age group of 18 to 20 yrs. Remaining 10% from experimental group and 22% from control group are in the age group of 26 to 30 yrs.

The following graphs describe the education distribution of the participants in both; the control and experimental group. N = 100; n1 = 50, n2 = 50

Fig 1.4: Distribution of control and experimental group participants according education (in percentage).

Fig 1.4 shows that all the participants had received at least primary education. 32% of participants of control group are educated up to primary level while 18% of participants from experimental group have primary education. In the experimental group most of the participants i.e. 38% have secondary level of education while 30% participants from control group have secondary education.

16% of participants of control group and 30% of participants of experimental group are having education up to higher secondary level. 12% of participants of both the groups have education up to graduate level. Only 10% participants from control group and 2% participants from experimental group have education up to post graduate level or above.

The following graphs describe the occupation distribution of the participants in both; the control and experimental group. N = 100; n1 = 50, n2 = 50

Fig 1.3: Distribution of control and experimental group participants according age (in percentage).
According to Fig 1.5 most of the participants are housewives/homemakers. i.e. 80% participants from control group and 88% participants from experimental group. Only 2% of participants from control group are govt. employees. 4% participants from both the groups are private sector employees. 14% participants from control group and 8% participants from experimental group are self-employed.

The following graphs describe the distribution of the participants according to the number of children in both; the control as well as experimental group. N = 100; n1 = 50, n2 = 50

Fig 1.6 shows that 44% of the participants from both the groups were primi mothers, i.e. had no children. Whereas only 2% of the participants from the experimental group had more than 2 children. 38% of the participants from the control group & 42% participants from the experimental group had only one child.

The following graphs describe the distribution of the participants according to the number of children in both; the control as well as experimental group.

<table>
<thead>
<tr>
<th>Knowledge Score</th>
<th>Control group (n=50)</th>
<th>Experimental group (n=50)</th>
</tr>
</thead>
<tbody>
<tr>
<td>f</td>
<td>%</td>
<td>f</td>
</tr>
<tr>
<td>Poor (0-3)</td>
<td>37</td>
<td>43</td>
</tr>
<tr>
<td>Average (4-7)</td>
<td>11</td>
<td>7</td>
</tr>
<tr>
<td>Good (8-11)</td>
<td>2</td>
<td>0</td>
</tr>
<tr>
<td>Excellent(12-15)</td>
<td>0</td>
<td>0</td>
</tr>
</tbody>
</table>

Table 1.2 revealed that experimental group participants 43(86%) had poor knowledge whereas in control group participants 37(74%) had poor knowledge. None of the participants from control group had excellent knowledge and in an experimental not single participant had good knowledge.

These arithmetic calculations were tested for central tendency mean, median and standard deviation to find out the distribution of sample. The table below depicts the measures of central tendency.

<table>
<thead>
<tr>
<th>Statistics</th>
<th>Control group (n=50)</th>
<th>Experimental group (n=50)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mean</td>
<td>2.1800</td>
<td>1.2000</td>
</tr>
<tr>
<td>Median</td>
<td>1.0000</td>
<td>.0000</td>
</tr>
<tr>
<td>Std. Deviation</td>
<td>2.37065</td>
<td>1.85144</td>
</tr>
<tr>
<td>Variance</td>
<td>8.620</td>
<td>3.429</td>
</tr>
</tbody>
</table>
Table 1.3 depicts that in control group Mean ($\mu$) = 2.1800 where as Experimental group Mean ($\mu$) = 1.2000. The difference between two $\mu$ is -0.98. The calculated $p = 0.023 < 0.05$ this reveals that two group $\mu$ is significantly different in terms of pre test knowledge. Hence we reject null hypothesis that there is no significant difference in the pre test scores of knowledge of antenatal women regarding cord blood banking and stem cell therapy at 0.05 level of significance. This result can be interpreted that participants from control group and experimental group do not follow the normal distribution. Hence the researcher of this study has decided to use non parametric statistical test to assess the effect of intervention on knowledge of antenatal women regarding cord blood banking and stem cell therapy.

**SECTION III:**

To assess the knowledge of antenatal women regarding cord blood banking and stem cell therapy after the Self Instructional Module (SIM) in the experimental group and control group.

Table 1.4: Post-test knowledge scores of control group and experimental group antenatal women regarding cord blood banking and stem cell therapy.

<table>
<thead>
<tr>
<th>Scores</th>
<th>Control group (n=50)</th>
<th>Experimental group (n=50)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Marks</td>
<td>F</td>
<td>%</td>
</tr>
<tr>
<td>Poor (0-3)</td>
<td>46</td>
<td>92</td>
</tr>
<tr>
<td>Average (4-7)</td>
<td>4</td>
<td>8</td>
</tr>
<tr>
<td>Good (8-11)</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Excellent (12-15)</td>
<td>0</td>
<td>0</td>
</tr>
</tbody>
</table>

As participants from control, group and experimental group do not follow the normal distribution the Effect of Self Instructional Module (SIM) was assessed by applying the Mann-Whitney Utest. The Mann-Whitney U test is a non-parametric test is used to test the null hypothesis. The table below represents U statistics of post-test knowledge of antenatal women regarding cord blood banking and stem cell therapy after the Self Instructional Module (SIM) in the experimental group and control group.

**SECTION IV:**

To compare the pre and post assessment of knowledge of antenatal women regarding cord blood banking and stem cell therapy.

Table 1.6: Comparison of pre and post assessment of knowledge of antenatal women regarding cord blood banking and stem cell therapy.

<table>
<thead>
<tr>
<th>Statistics</th>
<th>Pretest Knowledge</th>
<th>Posttest Knowledge</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Control group</td>
<td>Experimental group</td>
</tr>
<tr>
<td>Mean</td>
<td>2.18</td>
<td>2.06</td>
</tr>
<tr>
<td>Median</td>
<td>1.00</td>
<td>0.00</td>
</tr>
<tr>
<td>Std. Deviation</td>
<td>2.37</td>
<td>1.85</td>
</tr>
</tbody>
</table>

As participants from control, group and experimental group do not follow the normal distribution the Effect of Self Instructional Module (SIM) was assessed by applying the Mann-Whitney U test. The Mann-Whitney U test is a non-parametric test to assess the effect of intervention on knowledge of antenatal women regarding cord blood banking and stem cell therapy.

**SECTION V:**

To determine the effectiveness of Self-Instructional Module (SIM) on knowledge regarding cord blood banking and stem cell therapy among antenatal women.

Table 1.7: Mann-Whitney U test for assessment of post-test knowledge of antenatal women regarding cord blood banking and stem cell therapy.

<table>
<thead>
<tr>
<th>Statistics</th>
<th>Control group (n=50)</th>
<th>Experimental group (n=50)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mean</td>
<td>2.0600</td>
<td>2.5400</td>
</tr>
<tr>
<td>Median</td>
<td>0.0000</td>
<td>3.0000</td>
</tr>
<tr>
<td>Std. Deviation</td>
<td>1.462</td>
<td>2.233</td>
</tr>
<tr>
<td>Variance</td>
<td>2.139</td>
<td>4.98</td>
</tr>
</tbody>
</table>

*significant finding at 0.05 level of significance

Table 1.7 shows that Mann-Whitney U test was conducted to determine whether there was a difference in the post knowledge scores of experimental and control group and if so is that difference is statistically significant. Above table depicts mean rank of experimental group is 59.68 verses control group 41.32. The rank average of the posttest scores of the experimental group women 2984 while the women in the control group had a posttest score rank average of 2006. The analyses had shown significant difference between the rank averages of the groups’ posttest knowledge scores; Calculated Mann-Whitney U = 791; $Z = P = 0.001 < 0.05$ indicated that Self Instructional Module (SIM) regarding cord blood banking and stem cell therapy had a significant effect on the knowledge level of experimental group. Hence, null hypothesis is rejected that, there is no significant difference in the post test scores of knowledge of antenatal women regarding cord blood banking and stem cell therapy at 0.05 level of significance.

**SECTION IV:**

To associate the pre interventional findings with selected demographic variables.

Table 1.8: Association between pre interventional with selected demographic variables.

<table>
<thead>
<tr>
<th>Variables</th>
<th>Value</th>
<th>p</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age</td>
<td>25.522a</td>
<td>0.377</td>
</tr>
<tr>
<td>Education</td>
<td>65.368a</td>
<td>0.006**</td>
</tr>
<tr>
<td>Number of children</td>
<td>30.987a</td>
<td>0.154</td>
</tr>
<tr>
<td>Occupation</td>
<td>29.983a</td>
<td>0.185</td>
</tr>
<tr>
<td>Religion</td>
<td>11.135a</td>
<td>0.988</td>
</tr>
</tbody>
</table>
**Pre-interventional finding are associated with educational level of participants**

The results presented in Table 1.8 indicates that there is no statistically significant association between the pretest knowledge score with selected demographic variables; such as age the probability of the chi-square test statistic (chi-square=35.252) p=0.377, more than the alpha level of significance of 0.05 ; education (chi-square=60.350) p=0.006 which is < than the alpha level of significance of 0.05 hence concluded as the pre interventional findings of pretest scores and educational level of participants are associated with each other. In other terms we reject the null hypothesis and accepts the H3 ; number of children (chi-square=30.987) p=0.154 ;and occupation (chi-square=29.983) was p = 0.185; religion (chi-square=11.135) p=0.988 . Hence, except educational level of women participants of this study the Chi square findings accept the null hypothesis that there is no significant association between the pre interventional findings related to pretest knowledge scores with selected demographic variable at 0.05 level of significance.

**CONCLUSION**

This chapter deals with analysis and interpretation of data collection from 100 antenatal women who were attending ANC clinic in Smt. Kashibai Navale Medical College & Hospital, Pune and Kamala Nehru Hospital, Pune. The control group (n=50) was selected from Kamala Nehru Hospital, Pune; whereas the experimental group was taken from Smt. Kashibai Navale Medical College & Hospital, Pune. Statistical tests employed were frequency and percentage distribution, mean, median, standard deviation, paired t test, Mann Whitney U test, and chi square test for association. Test results of the statistical test shows that the self instructional module (SIM) on cord blood banking & stem cell therapy was found to be effective in improving knowledge of the antenatal women. Knowledge scores were found to be associated with the level of education of the antenatal women.

**CHAPTER 5**

**DISCUSSION, CONCLUSION & RECOMMENDATIONS**

This chapter deals with the major finding of the study, conclusion, implications for nursing practice, nursing education, nursing administration and nursing research and discussion followed by its limitations. This chapter concludes with recommendations for future research in this field.

**MAJOR FINDINGS OF THE STUDY**

Major finding of the study of the study were summarized below:

I. Findings related to the sample characteristics

1. Almost 44% of the participants in the control group and 62% of the participants of the experimental group are in the age group of 21 to 25 years. Only 10% of participants from control group and 6% of participants from experimental group are in the age group of 31 to 35 years.

2. All the participants had received at least primary education. 32% of participants of control group are educated up to primary level. While in the experimental group most of the participants i.e. 38% have secondary level of education.

3. Most of the participants are housewives / homemakers i.e. 80% participants from control group and 88% participants from experimental group.

4. 44% of the participants from both the groups were primi mothers i.e. had no children.

Whereas only 2% of the participants from the experimental group had more than 2 children.

5. 58% participants from control group and 68% from experimental group are Hindus.

There are no Christians in both the groups.

II. Findings related to the determination of pre test knowledge regarding cord blood banking & stem cell therapy among the antenatal women.

Findings revealed that most of the experimental group participants 43 (86%) had scores in the range between 0-3 (i.e. poor) marks out of 15 marks; whereas there were 74% (i.e. 34 ) participants from control group in the same range. None of the participants from control group obtained marks above 12 (i.e. excellent) and in the experimental group not a single participant scored 8 marks and above (i.e. only 14% participants scored average marks).

Findings show that none of the respondent had excellent (10 – 15) knowledge on cord blood banking & stem cell therapy during their pre-test.

III. Findings related to the determination of post test knowledge regarding cord blood banking & stem cell therapy among the antenatal women.

It is found that experimental group participants 31 (62%) scored in the range between 0-3 marks out of 15 marks; whereas control group participants were 46 (92%). The number of participants scoring average marks had increased in the experimental group i.e. 19 (38%)

IV. Findings related to the comparison of pre test scores and post test scores

The mean score of experimental group is less µ=1.20 in pretest which has increased to 2.54, this increase is found significant which has determined the effectiveness of Self Instructional Module (SIM) on knowledge regarding cord blood banking and stem cell therapy among antenatal women.

V. Findings related to the effectiveness of self instructional module

The analyses had shown significant difference between the rank averages of the groups’ posttest knowledge scores; it is indicated that Self Instructional Module (SIM) regarding cord blood banking and stem cell therapy had a significant effect on the knowledge level of experimental group. Hence, null hypothesis is rejected that, there is no significant difference in the post test
scores of knowledge of antenatal women regarding cord blood banking and stem cell therapy at 0.05 level of significance.

VI. Association of the knowledge on regarding cord blood banking & stem cell therapy among antenatal women with selected demographic variables

The results indicates that there is no statistically significant association between the pretest knowledge score with selected demographic variables; such as age; the probability of the chi-square test statistic (chi-square=25.522) p=0.377, more than the alpha level of significance of 0.05; education (chi-square=65.368) p=0.006 which is < than the alpha level of significance of 0.05 hence concluded as the pre interventional findings of pretest scores and educational level of participants are associated with each other. In other terms we reject the null hypothesis and accepts the H3; number of children (chi-square=30.987a) p=0.154; and occupation (chi-square=29.983) was p = 0.185; religion (chi-square=11.135a) p=0.988.

Hence, except educational level of women participants of this study the Chi square findings accept the null hypothesis that there is no significant association between the pre interventional findings related to pretest knowledge scores with selected demographic variable at 0.05 level of significance. Pre-interventional finding are only associated with the level of education of the participants.

DISCUSSION RELATED TO OTHER STUDIES

In this study it is found that self instructional module (SIM) is effective in increasing knowledge regarding cord blood banking & stem cell therapy among antenatal women. Similar findings were seen in a study done in Vinayaka Missions Hospital, Salem to assess the effectiveness of self instructional module regarding emergency management of patient with myocardial infarction on knowledge among staff nurse. Samples were 98 staff nurses selected by convenient sampling technique and data collection tool used was closed ended questionnaire. Highly significant difference was found between the pretest and posttest KS (P<0.01) but no significant association was found between the posttest KS when compared with the demographic variables of staff nurses (P<0.05).

In another study, two teaching strategies were used to improve the knowledge of mothers regarding acute respiratory infections in under-five children. The aim of the study was to determine the effectiveness of STP and SIM on knowledge regarding prevention of ARI among the two groups; and compare the effectiveness of STP and SIM on knowledge regarding prevention of ARI among the two groups. The quasi experimental two group pretest post test design was adopted. Simple random technique was adopted to select 60 mothers. The data collection tool was structured interview schedule. On the first day of data collection (pre test) for STP & SIM groups, STP was administered on the same day. On seventh day, again the same mother’s knowledge was assessed (post test) using the same tool. The mean post test knowledge score of STP was apparently higher than SIM the mean post test knowledge score respectively. Hence STP is more effective than SIM.

CONCLUSION:

On the basis of the finding of the study the following conclusions are drawn the knowledge regarding cord blood banking & stem cell therapy was ranging from poor to average in pre test knowledge score assessment. Most of the participants of both the groups scored in the range of 0-3 marks i.e. poor score. This means that both the groups i.e. experimental as well as control group participants had poor knowledge regarding cord blood banking & stem cell therapy.

After giving the self instructional module (SIM) none of the participants scored excellent i.e. in the range of 11 to 15 marks but the mean scores increased from 1.20 in pretest to 2.54 in post test. This implies that there was an increase in the level of knowledge of the antenatal women in the experimental group after giving the self instructional module (SIM).

IMPLICATION: The result obtained from the study has helped the researcher to derive implications for nursing education, nursing practice, nursing administration and nursing research.

Nursing Education

The consumers today demand quality assurance from every profession including nursing. Standard nursing care is only possible through standard education.

The nursing personnel are working in various settings and they must acquire the ability to conduct health education programmes. Therefore, knowledge regarding various method of education should be included in nursing curriculum. Specially information booklet can be referred afterwards and can be used for reinforcement of knowledge. So nursing students should be introduced so that they can use it for their own learning and educating public particularly the students.

Nursing Practice

Due to improvement of communication and information technology, people have become more aware of their health promotion and their right than the past. The consumer today is often using his/her legal and political power to demand more and better quality of health care.

On the other hand is the skyrocketing cost of health care. So, prevention is better than cure. Nurse is an important member of health team and prepares the patient to be independent for his/her self-care.

Nurses working in gynaecological unit should be well equipped with knowledge and skill and develop positive attitude to deal with physiological and psychological, social, vocational aspect of patient care. Nurses may conduct teaching programme through TV channel. Nurses can prepare structured teaching programme, or teaching material as leaflet, pamphlet, brochure etc.

As a health educator nurse’s role is significant than other category of health members. So, instead of routine teaching, nurses should concentrate on use of Self instructional module.
(SIM) in their practical fields to educate students, mothers and other community people regarding the knowledge of cord blood banking & stem cell therapy as a structured method of teaching rather than through unstructured teaching. Thus they can participate in the awareness programme regarding cord blood banking & stem cell therapy.

**Nursing Administration**

Whatever administrative action is taken, the fruit of action should reach the patients. The ultimate goal of good administration is improvement of patient care. Until the people is motivated properly a change in knowledge, attitude and practice is not possible. Administrator should arrange at least one yearly education programme for the antenatal women, couples, parents to provide adequate knowledge regarding cord blood banking & stem cell therapy.

The policies and protocols are prepared by nursing administrators. Nursing administrators may develop and use such structured IEC material to make students and community people aware regarding cord blood banking & stem cell therapy.

Nurse administrator should provide facilities in terms of personnel, time and material for such programme. Nurse administrator should arrange sufficient fund for teaching programme for printing the IEC materials such as information booklet, leaflet, pamphlet etc.

**Nursing Research**

Nursing is seeking to improve practice of its members and to enhance its professional status, strive for continual development of relevant body of knowledge. Nursing research represents an important tool for nursing profession to acquire such knowledge of professionalism, accountability, and social relevance of nursing demand. Research has a vital and significant role to play in nursing in terms of quality and cost effective care.

Emphasis should be given on research in the area of cord blood banking & stem cell therapy, Researchers should publish finding of research carried out and its implication for nursing society.

**Limitations**

- As the study was conducted at 2 hospitals in Pune city, the scope of generalization limits.
- Self-prepared tools were administered which limits the standardization.
- There was no scope for getting antenatal women’s opinion regarding self instructional module (SIM).

**Recommendations**

- A similar study can be conducted in other hospitals.
- A similar study can be done in community settings.
- A similar study can be conducted on the other group of the population like doctors, parents, staff nurses, lab technicians, etc
- A similar study can be conducted using information booklet, awareness Programme, planned teaching programme or video assisted teaching etc.