Protocol Study

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Development and implementation of anxiety management program for women under gynecological surgery with spinal anesthesia: Protocol of action research study

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Abstract:

BACKGROUND: Anxiety is the most common health problem and the second leading cause of disability worldwide. Patients undergoing surgery often experience anxiety. It is necessary to use appropriate interventions to achieve the best results. The aim of this study is to develop, implement, and evaluate of anxiety management program for gynecological surgery patients under spinal anesthesia.

MATERIALS AND METHODS: This participatory action research will be conducted through four phases; problem identification, planning, action, and evaluation phases in the Gonbad-e-Kavous Shahada, hospital in northeastern of Iran. These phases will be guided based on the Promoting Action on Research Implementation in Health Services framework. Participants will be included using purposive sampling method. We will use both of qualitative (semi-structured interview, observation) and quantitative (questionnaire) approaches for data collection through the study.

CONCLUSION: For anxiety management of patients, context-based interventions should be performed. Combination of multidimension approach based on health-care providers, patients, and environment will have an effect to solve the problem in the clinical setting.

Keywords:

Action research, anesthesia, anxiety, surgery

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Introduction

Patients undergoing surgery often experience anxiety.[1] The problem can be accompanied with a wide range of emotional, psychological, and physical problems such as autonomic dysrhythmia changes, hypertension, nausea, vomiting, and severity of pain.[2] Celik and Edipoglu reported that preoperative anxiety increased hospitalization and patient mortality. Due to the therapeutic and caring nature of gynecological surgery, patients might experience severe anxiety.[3] In another study, preoperative anxiety of women undergoing cesarean section was significantly relevant to postoperative dissatisfaction.[4]

There are several factors that contribute to this problem and its complications.[5] Fear of anesthesia is one of the most important reasons for patient anxiety.[6] Some studies reported that patients under spinal anesthesia have more anxiety.[7,8] These patients are completely conscious during surgery, so they receive the external stress-provoking stimuli.[2] However, spinal anesthesia has advantages such as low risks and cost versus general anesthesia, which leads to severe anxiety in patients. In order

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to control patients' anxiety, all necessary care must be taken.[9]

Reducing preoperative anxiety is part of nursing care.[10] This is reported that systematic approaches are rarely used in order to solve the problem.[11,12] Although pharmacological methods can be decreased patient's anxiety, complementary interventions are used without any side effects such as cardiovascular and respiratory complications.[13,14] These strategies such as music therapy, aromatherapy, acupressure, relaxation techniques, or educational interventions can alleviate patients' anxiety.[10] It is necessary to provide context-based interventions in order to access the best results. Participatory action research (PAR) method is a useful approach for identifying problems and potential solutions in the context.[15] There is a challenging issue in clinical settings as an existing gap between theory and practice.[16] Clinical trial studies, despite valuable points, not have a context-based approach. Action research studies can be used as one of the solutions to this problem.[17]

This is necessary to improve patient care by implementing evidence-based practice.[18] The Promoting Action on Research Implementation in Health Services (PARIHS) framework is one of the best frameworks that guide the implementation of evidence-based practice. The first version was inductively produced by Harvey and Kitson in 1998.[19] PARIHS framework consists of three main factors: context, evidence, and facilitation.[11]

Translating and using research in practice is complex and involves the planned changes of individuals, teams, and organizations. There are no simple solutions to the complex problems of health care. The PARIHS framework was developed to demonstrate the complex interaction of a number of factors influencing the successful implementation of evidence in practice.[19,20] Therefore, this can be very useful as a systematic method to solve the patients' anxiety problem.

Objectives

The purpose of the proposed study is to develop, implement, and evaluate of anxiety management program for gynecological surgery patients under spinal anesthesia.

Materials and Methods

Study design and setting

This PAR study will be conducted through four phases: problem identification, planning, action, and evaluation phases that will be guided based on the PARIHS framework. The setting of the study is the Gonbad-e-Kavous Shahada, hospital in northeastern of Iran, that is referral gynecological surgery center in Golestan province. This operation room (OR) has three active OR and about 150–200 elective surgeries per month. About 80% of patients are undergoing surgery with spinal anesthesia (based on adherence to patient satisfaction and surgical conditions). There are 31 staffs working there: 11 nurse anesthetists, 11 surgery technicians, 4 anesthesiologists, and 5 gynecologists

Study participants and sampling

Study participants will consist of patients (who are under gynecological surgery with spinal anesthesia) and multidisciplinary team (researchers and health-care providers as anesthesia nurses, surgery technicians, matron, head nurse of OR, anesthesiologists, and gynecologists).

Inclusion criteria for patients will consist of the following: having elective undergoing gynecological surgery and be able to read and write.

Exclusion criteria for patients will consist of having a history of using illegal substances and psychiatric diseases. Health-care providers will be unwillingness to continue the research participating.

The participants will include in the study using the purposive sampling method. In qualitative part, it will continue until data is saturated.[21] In quantitative section, the exact number of quantitative participants cannot be exactly determined.[22,23] It estimated 30 participants in each intervention cycle of the study. Considering the total number of surgeries per month in the research hospital (average 150 surgeries), 20% of the total number of patients will be included.

Data collection tool and technique

Participatory action research phases

The study has four interrelated phases, including problem identification, planning, action (change), and evaluation [Figure 1].

Problem identification

The aim of this phase is to assess the problem in the context and identify the best solutions. In the first step, both of qualitative and quantitative studies will be done. The second step is finding the evidence interventions.

Qualitative data collection method

To explore the nature of problem in the setting and develop the strategies of program, semi-structured individual interviews and structured partially participant observation will be conducted.

Participants in the interviews will be consist of health-care providers (who have experience in caring of patients undergoing gynecological surgery with

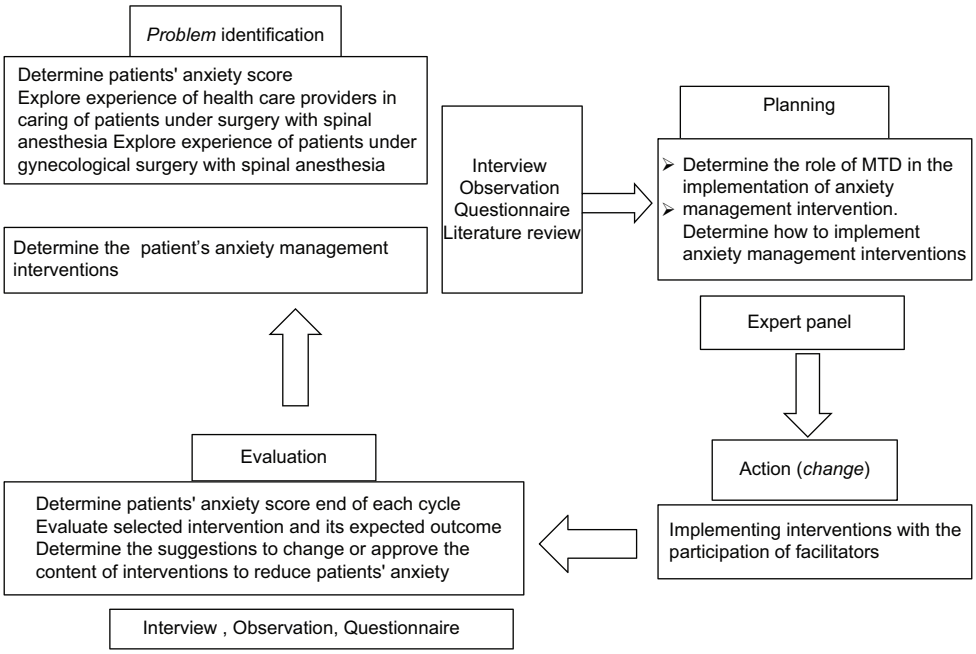

Figure 1: Study design

spinal anesthesia) and patients (who will candidates for gynecological surgery and under spinal anesthesia). A member of research team will conduct the interviews. These will be performed face to face at predetermined locations.

Health-care providers and interview

The researcher will begin the interview with a broad and open-ended question so that participants will narrate their overall experience: "Please tell about you're a work day while caring for a patient who is a candidate for surgery," then the main question will ask such as "Please tell about your experience working with an anxious patient who is a candidate for spinal anesthesia?"

Patients' interview

Questions will be started with a broad and open-ended question such as "Please tell about the day you admit to hospital?" This review will be continued with the main questions as "When I say anesthesia to you what appears to your mind?" "How do you feel about having spinal anesthesia during surgery?" "What are your main concerns or worry about your anesthesia/surgery?" and "Do you think about alleviating methods to reduce your worries?"

To clarify ambiguities answer from previous question, reflective question used such as "What do you mean?

All of the interviews will be recorded and transcribed immediately after the end of them. In addition to recording the interview process and participants' nonverbal messages such as tone of voice, silence, and laughter during the interview, a brief report on the interview process and its important points is provided at the end of each interview.

Observations will be conducted based on Spradley (2016) approach, dimensions that include space (the physical environment), actors (participants that involved in research and activities), activities (activities of different participants in setting), objects (physical components such as furniture), acts (special functions for individuals), events (special events), times (the sequence of events), goals (the goals of individuals for their effort and performance), and feelings (field-specific emotion).[24,25]

Quantitative data collection method

Patients, anxiety will be assessed using the Numerical Visual Analog Scale of Anxiety (NVASA): The scoring of this scale range from 0 (no anxiety) to 10 (extreme anxiety). Studies reported a positive correlation of this scale with the Spielberger questionnaire.[26]

Primary literature review

A primary review of research evidence was conducted with the aim of determining the nonpharmacological studies on anxiety management of patients undergoing surgery with spinal anesthesia. This will be completed through the study stages.

This review was conducted based on a search in databases on PubMed, Scopus, Web of Science, Proquest, and Science Direct; in addition, Google Scholar motor engineer was also reviewed. This search used the main keywords "anxiety," "anesthesia," and "surgery" from 2000 to 2021. Syntax search of each database was modified based on its specific search strategy. An

example of syntax search based on MeSH in PubMed was mentioned: Anxiety OR Stress OR Worry OR Concern AND "Spinal anesthesia" OR Anesthesia AND Surgery OR "Surgical Procedures" OR Operative OR Operating room AND Intervention. Search records were imported in the EndNote version 8 software file. Article selection and screening after removing duplicates was performed based on the following steps:[27] first, we selected related titles, then retrieved abstracts of articles, retrieved the full text of articles, selected eligible articles, and finally, extracted information from articles. After retrieving and selecting the full text of articles related to the purpose of study, other related articles that were referred to in the sources of these articles were studied by snowball sampling method [Figure 2].

Finally, from 10,450 studies, 31 eligible articles were included. We used qualitative content analysis for analyzing and interpreting sources that inform this literature review.[28] The primary categorization is presented in Table 1.

Planning

In planning phase, it is necessary to answer these questions: "How the identified data can solve the problem?" and "What is the best solution?"[59] In this stage, feasible change approaches will be determined.[60] In order to receive the best solutions, holding panels of experts with multidisciplinary team (researchers and health-care providers (will be done. According to interventional cycles of study, three meetings will be held, each with a maximum duration of 2 h, with the following objectives: agreement on the final choice of feasibility interventions based on collected data, determine the role of multidisciplinary team, and discussion about possible problems and solutions

Action

In the action phase, the best feasible and selected interventions will be implemented.[61] According to PARIHS framework, interventions will be performed based on cooperation between external and internal facilitators. Internal facilitator will be volunteers in the clinical setting. Some of the internal facilitators selection criteria are a complete understanding of clinical practice, correct knowledge of colleagues, and environment and leadership power in the organization.[19] According to our primary assessment in the study setting, internal facilitator will be a head nurse of OR, anesthesiologists, etc., Their supporting and positional power may facilitate the study implementation. In PARIHS framework, an external facilitator is an external changing agent, whose role is to develop quality improvement or educational courses. This may have academic, researching, or consultant roles. The external facilitator's role is not to implement the project but to provide the necessary support from domestic facilitators in the project, which may identify evidence and find ways to support the project.[19] In this study, external facilitators will consist of researching team to identify evidence and support the project. We will help the internal facilitation team with analysis and reporting of audit data related to problem.

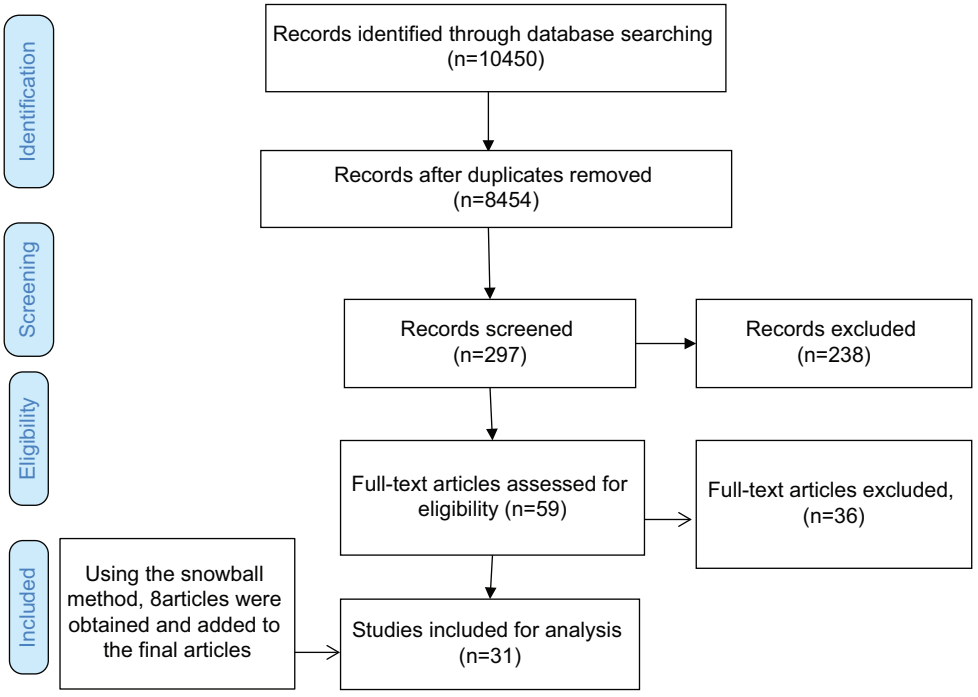

Figure 2: Primary search results and screening study

Table 1: Recommended interventions based on primary literature review

Category	Subcategory	Condensed code
Patient-based interventions	Patient education	Written education,[29,30] computer-based education using real operating room photos[31] and, video-based education[32-34]
	Preoperative patient counseling	Preanesthesia clinic consultation,[35] preoperative nursing visit[36]
	Psychological support	Motivational interviewing,[37] guided imagery[38]
	Music therapy	Preoperative music therapy using by headphones[12,39,40] and speakers[41]
	Touch therapy	Holding patient's hands,[42-44] acupressure[45]
	Aromatherapy	Inhalation of rose oil[46] and Lavender[47]
	Novel technology interventions	Use of virtual 3D glasses during surgery[48] Clinical application of virtual reality application[49,50]
	Patient companion's support	Nursing intervention on family members[51]
	Orientation tour	Familiarity with the operating room and special care units[52,53]
Health-care providers-based interventions	Music therapy for health-care providers	Music therapy utilizing based on mix of eastern and western songs[54]
	Changing health-care provider behavior	Multi-intervention on health-care provider behavior[55,56]
Environmental-based interventions	Environment art therapy	Utilization of ornamental indoor plants[57] and colors and art in patient rooms[58]
	Utilization of nature plants	

Due to PAR nature methods, implementation process of interventions will be determined during the study process. It is not possible to mention the exact details of the action phase in the protocol study, but it was reported recommended interventions based on our primary literature review.

Evaluation

In this study, evaluation will be done in two dimensions that consist of effectiveness of interventions process and overall outcome.

At the end of each phase of the intervention, patients' anxiety will be evaluated using the NVASA (Numerical Visual Analog Scale of Anxiety) scale to assess the overall effectiveness of the study.

In order to determine the effectiveness of interventions evaluation, the overall outcome of anxiety management interventions on patients' anxiety will be discussed in the group meetings of researchers and health-care providers. In this way, the final result of this step at the end of each cycle will be a decision to approve, continue, or modify the selected interventions. New interventions will be done based on group meetings of the researchers and health-care provider's suggestions. If there will be significant changes in any part of the intervention program, research will be passed to the next cycle. The cycles will be continued until expected change is achieved in new patient groups.

Data analyzing

The PAR impact will be assessed using qualitative and quantitative approaches assessing before–after changes in important outcomes.

Quantitative data

The quantitative analysis will be carried out using SPSS Statistics version 18. To measure the mean of variables, two groups will be compared by independent *t*-test or nonparametric test, Mann–Whitney U test. The Chi-square or Fisher's exact test will be used to compare the qualitative variables and the significance level is considered to be $P < 0.05$. To interpret the results, statistical significance will be set at $P < 0.05$.

Qualitative data

In the proposed study, conventional content analysis will be used. This is an appropriate approach to analyzing written, verbal, or visual data.[62] In this study, we will analyze qualitative data based on this approach. The analysis will be carried out based on the Lundman and Graneheim qualitative analytical approach in three phases of preparation, organization, and reporting. Parts of the interview will be selected and meanings and codes will be extracted from them. Codes that had meaning units similarities will be replaced next to each other to form subcategories. By contrasting the subcategories, the main categories will be created. In the formation of categories, we will attempt to create the highest homogeneity within the categories while being heterogeneous with the other identified categories.[63] We will use MAXQDA software version 11 for qualitative data organizing (In literature review, we used EndNote software version 8.1 (Thomson Reuters, Toronto, Ontario, Canada) and MAXQDA software version 11(VERBI, Berlin, Germany) for extracted data organizing).

This should be noted that the data obtained from the primary review were based on the steps of qualitative analysis that are mentioned.

Rigor of qualitative data

Taking into rigor and trustworthiness of qualitative data, Lincoln and Guba approach will be used.[64] To ensure credibility, prolonged engagement with data will be conducted, and it will be taken a long time to collect and analyze the data. Member check method will be applied that after transcription and coding process, analyzed data returned to 10 participants to ensure their accuracy. For dependability criteria, external audit technique will be used that two external nurses determine the codes and categories and compare each other. For transferability of our findings, the researchers will try to fully describe the participants, sampling method, time, and setting of data collection. Furthermore, various participants (surgical technologist, nurse anesthetist, surgical ward nurse, and head nurse of OR) will be selected to explore their experience. In this research, in order to increase the conformability, the researcher, by accurately recording all stages of the research, will be made it possible for others to review the steps so that others can read the data and be able to audit it.

Ethical consideration

This study was approved by the Center of Ethics Committee of Golestan University of Medical Sciences, Iran (code: IR.GOUMS.REC.1399.230). All participants will be explained the purpose and process of the study. They will be assured that the information obtained from them will be confidential. Participants will be explained that participation in the research is optional.

Discussion

The proposed study will help us to understand the process of changes in anxiety management program for gynecological surgery patients under spinal anesthesia. This study will focus on the development, implementation, and evaluation of interventions using PARIHS framework.

Patients undergoing spinal anesthesia often have a high level of anxiety. It was emphasized that drugs can reduce patients' stress levels. However, alternative interventions without drug side effects have been introduced.[13,14] Studies reported that numerous interventions have been used to reduce patients' anxiety.[11,65,66] Deeper information and context-based interventions are needed to achieve better results.[15]

A study reported that patient's fears were anesthesia, surgery, complications as pain and nerve damage, needle, and inability to perform daily activities after surgery from anesthesiologists' perception of patients' anxiety under regional anesthesia. Nurses' and anesthesiologists' assessments of patients' anxiety were often incorrect.[67] Procedures of nurse anesthetists and other caregivers should be performed based on responding to patients' needs, problems, and concerns.[7,10] In addition, Cueva-Ariza (2018) stated in a protocol study that the use of PAR can help integrate a new approach to providing nursing care through reflective practice and help to build nursing knowledge based on the daily practices of the people who practice it.[68]

Limitations and recommendation

Possible refusal to participate in the study of some patients and health-care providers. The researcher has obtained the satisfaction of the clinical staff before starting the study. If some patients do not cooperate and consent to participate in the study, other patients will be replaced with them.

However, we generally suggest that operational studies with a systematic approach be proposed and implemented in the future. In this way, a great improvement will be made gradually to solve clinical problems. By proposing and then conducting this study, we will solve one of the problems of patients.

Conclusion

For anxiety management of patients, context-based interventions should be performed. Combination of multidimension approach based on health-care providers, patients, and environment will have an effect to solve the problem in the clinical setting. Action research method has a contextual, participatory, and self-assessment nature, so the proposed study will be usable in managing patients' anxiety in the study setting.

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Nil.

Conflicts of interest

There are no conflicts of interest.

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