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Dual Clinical Collaborator: A Pragmatic Role of nurses from developing countries

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Collaboration is crucial in Professional nursing practice. Nurses act as a liaison between physicians and patients and their family members. Thus, it is vital to define the collaborative role of nurses in developing countries. The authors discuss pragmatic nurses' role by adopting the Dual Clinical Collaborator model to ensure offering the quality of care to their clients. Nursing is a healthcare profession that focuses on the care of individuals and their families to help them recover from illness and maintain optimal health and quality of life.⁽¹⁾ Health Care Professionals (HCPs) work together to provide quality health care and accomplish common goals. As healthcare delivery is becoming more complex, collaboration among healthcare workers and the patient can be a path to improve the quality of healthcare services. According to Walker and Avant's method, the conceptual definition of collaboration in nursing



Editorial



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is an intra professional or interprofessional process by which nurses come together and form a team to solve patient care or healthcare system problem with members of the team respectfully sharing knowledge and resources.⁽²⁾ Thus, collaboration is crucial in everyday professional nursing practice and should be considered a core value of nursing.⁽³⁾

Contemporary nursing practice is based on the principles of person-centred care, shared decision-making and multidisciplinary teamwork.⁽³⁾ Nurses, being the first point of contact to their clients and offering direct care, play a unique role in collaborating with health care team members and patients as well as with family members. While there is a significant transition in the role of nurses from bedside care to Advanced Nurse Practitioners, the fundamental role in collaborating with physicians and patients and their families remains the same. However, most of countries are seeking to improve health care delivery by reviewing the roles of health professionals, including nurses.⁽⁴⁾ Therefore, this concept article aims to define the pragmatic role of nurses for better communication, research and, policy purposes. Also, this paper informs the international nursing fraternity about the key issues in nursing practice in India.

Globally, nurses' roles are being greatly transformed to provide safe, ethically sound, patient-centered care.⁽⁵⁾ However, much of this transformation has occurred in developed countries such as the United States, the United Kingdom, Canada, and Australia.⁽⁶⁾ Nurses in developed countries are recognized as independent professionals with additional training and qualifications. Nurses can perform health assessments, and plan and implement nursing care interventions independently. The various roles of nurses include registered nurses, specialty nurses, advanced practice nurses, clinical nurse practitioners, nurse researchers, nurse educators, Health and Wellness counsellors etc. The reason for developing more advanced functions for nurses in these countries was to improve access to care, promote a higher

quality of care, and provide more intensive follow-up and counseling for patients with chronic illness in primary care. When the quality of care is improved, it leads to fewer complications, reduced healthcare expenditure, and prevents unnecessary hospitalizations. Another reason for these advanced roles is to enhance nurses' retention rates and enhance their career prospects.

Nurses in developing countries either work as clinical nurses in various settings or as nurse educators. The nurse practitioner role has not been formally recognized in most of the developing countries such as in India. However, initiatives by the Indian Nursing Council (INC) are underway to implement education programs for a formal nurse practitioner role.^(7,8) The role of nurses in India revolves around clinical and supervisory positions. Their role is seen chiefly as bedside care and medication administration. As the nurses gain experience over the years, the function might get shifted to a supervisory position. In a typical Indian hospital setting, we would observe a nurse doing various tasks related to the patient. The nurses provide care, maintain records and reports related to the patients. Many non-nursing roles are performed by nurses, such as billing, record keeping, inventory, laundry, diet, etc., which also diverges from their fundamental role, which is patient care.⁽⁹⁾ The role of nurses is considered to provide medications to patients and manage the hospital wards, and their role becomes stagnant over time as there are significantly fewer growth opportunities.⁽¹⁰⁾ There is a lack of leadership roles and decision making of nurses in the treatment of patients. In fact, in India, patients and families are more comfortable with nurses than doctors, which might be possible because nurses spend more time with patients than doctors. Patients are under the supervision of nurses during their time in the hospital. Hence, the role of nurses needs to be defined pragmatically.

In this article, we would like to discuss how a nurse collaborates concurrently with the patient and the doctor to maintain the first contact

care and continuity of care. We want to name this collaboration “Dual Clinical Collaboration (DCC) and the role of nurses as Dual Clinical Collaborator.” It involves collaboration between the nurse, patient, and doctor, and the nurse is the center of this collaboration. The prerequisites for any partnership to work are common goals, open communication, and mutual respect. The foremost part of it involves how the nurse receives the information from the patient, how they share this information with the doctor and the efficiency of using it for planning patient care.

During a hospital visit/stay, a patient interacts with different employees, including Doctors, nurses, and other HCPs. It is essential to make these interactions smooth and straightforward for patients and their family members. Nurses carry the influence and have the opportunity to play this role effectively as patients spend most of their time under their care and supervision. A nurse builds a trusting relationship with the patient, which helps to understand the patient’s values and beliefs. It becomes easy for the nurse to plan the care when there is clarity about the patient’s expectations from the health care providers. How effectively a patient can express his concerns depends on how well the nurse receives the information shared by the nurse. Effective collaboration with patients allows the patient and family to participate actively in the treatment process and improves their experience.

Historically, general practice has concentrated on doctors providing care; it is now necessary that we recognize how doctors and nurses can cohesively offer high-quality care. Seamless collaboration between nurses and doctors is essential for effective and efficient health care delivery. The doctor-nurse relationship, which was traditionally considered hierarchical, is now evolving into a collaborative relationship. Communication between nurses and physicians is a critical part of the information flow in healthcare. Collaboration between physicians and nurses means cooperation in work, sharing responsibilities, and making decisions to formulate

and carry out plans for patient care. A collaboration between the nurse, patient, and the doctor would only be effective if the doctor and the nurse have a good communication and awareness of each other’s roles and responsibilities. Communication between the doctor and the nurse is necessary given the interdependence of the two professions and their primary role in safe and quality patient care. It can improve patient outcomes, lower healthcare costs, increase job satisfaction, and maintain patient safety.⁽¹¹⁾ Meanwhile, the growing evidence shows that improper or poor communication can create a chronic state of conflict between nurses and physicians, leading to increased medical errors and poor outcomes.^(12,13)

Dual Clinical Collaboration (DCC) helps take advantage of the nurse and doctors’ knowledge and experience, familiarizing themselves with each other’s skills and perspectives and leading to professional development. The workload is shared, and it also leads to job satisfaction. It can also be a way to enhance leadership and decision-making in nursing. A nurse decides what kind of care their patients require and then collaborates with the health team accordingly.

Conclusion. Health care is dynamic; the demands of healthcare rapidly increase and require an extra workforce. While we face a shortage of healthcare workforce, we need to be innovative in utilizing the available resources. The concept of nurses collaborating with the doctor and the patient is not new, and it is something that is done daily without realization. However, it has not received due attention and needs further exploration. It provides nurses with an opportunity for professional advancement and refining their skills through clinical learning. DCC makes health services easily accessible, untroublesome to patients, helps understand their individual needs and strengthens the overall health care system. Our primary institutions can work on the curriculum such that it involves DCC, which could make it easier for future professionals to adapt to this concept swiftly.

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Nursing Care during the Perioperative within the Surgical Context

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Thematic review



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Nursing Care during the Perioperative within the Surgical Context

Abstract

The study describes basic nursing care during the perioperative. Introduces the origins of perioperative nursing, general care that must be practiced with patient in this context. During the preoperative, care related with risk assessment and preparation of patient from the emotional and physical point of view are important. The trans-operative is related with the anesthesia used, surgical position, preparation of the skin, maintenance of normothermia, among many others. The postoperative depends on the type of anesthesia and surgical procedure, emphasizing on airway permeability, hemodynamic stability, pain, and symptomatology being presented by patients until they are stable and suitable for transfer to another service or their home.

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Descriptors: perioperative period; nursing care; operating rooms; surgical procedures, operative.

Cuidado de enfermería durante el perioperatorio dentro del contexto quirúrgico

Resumen

Se describen los cuidados de enfermería básicos durante el perioperatorio. Se presentan los orígenes de la enfermería perioperatoria, los cuidados generales que se deben tener con el paciente en este contexto. En el preoperatorio es importante los cuidados relacionados con la valoración del riesgo, la preparación del paciente desde el punto de vista emocional y físico. Durante el transoperatorio se relacionan con la anestesia utilizada, la posición quirúrgica, la preparación de la piel, el mantenimiento de la normotermia, entre muchos otros. En el posoperatorio dependen del tipo de anestesia y procedimiento quirúrgico, realizando énfasis en la permeabilidad de la vía aérea, la estabilidad hemodinámica, el dolor, y la sintomatología que va presentando el paciente hasta que este estable y apto para trasladarse a otro servicio o para su casa.

Descriptor: período perioperatorio; atención de enfermería; quirófanos; procedimientos quirúrgicos operativos.

Cuidados de enfermagem no período perioperatório no contexto cirúrgico

Resumo

São descritos os cuidados básicos de enfermagem durante o período perioperatório. São apresentadas as origens da enfermagem perioperatória, bem como os cuidados gerais que devem ser tomados com o paciente nesse contexto. No pré-operatório, são importantes os cuidados relacionados à avaliação de risco e o preparo do paciente do ponto de vista emocional e físico. Durante o transoperatório, estão relacionados à anestesia utilizada, à posição cirúrgica, ao preparo da pele, à manutenção da normotermia, entre muitos outros. No pós-operatório, dependem do tipo de anestesia e procedimento cirúrgico, enfatizando a permeabilidade da via aérea, estabilidade hemodinâmica, dor e os sintomas que o paciente apresenta até que esteja estável e apto a se transferir para outro serviço ou para sua casa.

Descritores: período perioperatório; cuidados de enfermagem; salas cirúrgicas; procedimentos cirúrgicos operatórios.

Introduction

Perioperative nursing, according to history, dates to 1873 in the United States when schools of care were created. As specialization, it was recognized prior to 1889,⁽¹⁾ but the first reference of nurses in a surgical center is found in the appendix of the text *Notes on Nursing* by Florence Nightingale that states: “The surgical nurse must always be alert, always on guard, against the lack of cleanliness, musty air, lack of light...”.⁽²⁾ In 1978, the Association of Operating Room Nurses (AORN) introduced the definition of perioperative nursing, as the process of care during the perioperative, which is temporary and experienced by patients during the preoperative, trans-operative, and post-operative periods,⁽¹⁾ a concept that cleared the path for nursing to areas different from the surgical center.

Today, the number and complexity of surgical procedures have increased due to progress in surgical, anesthetic, technological, and pharmacological techniques, along with changes in the offer of health services, which favors recovery and stabilization of patients, with greater control of pain, nausea and vomiting, which has reduced hospital stays, risk of infection, and costs.⁽³⁾ Most of the time, the postoperative takes place at home, which promotes outpatient surgery and self-care.⁽⁴⁾ Nursing, within this context, requires expert knowledge on guides and care standards related with surgery, anesthesia, invasive procedures, instrumental and surgical equipment, infections, and patient safety, among others. Likewise, nursing must have human quality, excellent interpersonal and social relations in the surgical context, besides leadership and good communication.^(5,6) In this regard, the Joint Commission International continues identifying errors in communication⁽⁷⁾ and has identified it as objectives in patient safety, given that work in this context is complex and errors in communication occur when the staff is under stress, or conducting multiple tasks and when there are interruptions in communication, which can interfere with the cognitive process.⁽⁸⁾ Moreover, the staff is prone to errors when there is no comprehension of their role, or do not feel supported, respected, valued, understood, or listened to, or does not have the training to provide high-quality information to their peers and patients.^(9,10) Communication affects patient satisfaction⁽¹¹⁾ when they are not heard, or are interrupted, or when their beliefs or concerns are ignored. Additionally, if they perceive instructions difficult to follow or do not understand what they should do, it affects their compliance.⁽⁹⁾

Among the safety aspects included in the perioperative there is participation from the health staff and from the directors of the institution in patient safety in the surgical room. Nursing has led this initiative, but requires commitment from other professions. Establishing a culture of patient safety, defined as the “set of practices shared by the health staff and planned institutionally to avoid risks to patients during the pre-, intra- and post-operative periods”.

⁽¹²⁾ Using surgery checklists ensures reducing damage to patients whether by adapting protocols to specificities, which must be in continuous improvement plan. Increasing the number of nurses in the surgical room to remain more time in the operations room, with greater autonomy in their work. Equilibrium of physical, material, and human resources necessary for the surgical procedure in amount and quality, with preventive maintenance plan. Technical-scientific updates through continuous education for health professionals.

Nursing care during the preoperative

This care starts from the moment patients decide to be operated and ends with their transfer to the surgical room. The surgeon explains the pathology, surgical approach, need for amputation, possible functional alterations; explains whether the surgery is urgent or not, the objectives, methods, expected benefits, potential dangers, inconvenience, probabilities of complication and makes a prognosis to make decisions.⁽¹³⁾ Patients must know their freedom to withdraw from the procedure if they wish. Patients are also seen in the pre-anesthetic consultation, which is a “clinical process that precedes the anesthetic-surgical event and consists in obtaining information from distinct sources (medical file, patient, results of laboratory exams, or others) to plan correctly the anesthetic and surgical procedure, besides offering guidance to patients and solving all their concerns”.⁽¹³⁾

The anesthesiologist must select the medications and doses indicated according with the physiological conditions and age of the patient. Nurses are responsible for their correct preparation and application. After assessing the patients, they are classified according to the following American Society of Anesthesiologists (ASA) physical status

scale:⁽¹³⁾ “ASA I: Healthy patient with localized disease; ASA II: Patient with disease independent of the cause originating the intervention; ASA III: Patient with severe systemic disease; ASA IV: Patient with severe incapacitating disease that conditions risk of death; ASA V: Moribund patient with life expectation < 24 h with or without surgery; ASA VI: Patient with brain death: organs will be donated”.

This phase of nursing care assesses the dimensions of the human being to identify problems of patients and their families, includes inquiring for antecedents and physical evaluation from which emerge actions that must have education as central to diminish anxious processes that promote post-operative recovery, besides reviewing presurgical laboratory tests and already known risk factors. During the evaluation, the peri-operative nurse obtains important information to plan the care. This must start with identifying the patient and confirming the correct site of the surgery; reviewing the clinical chart including results of laboratory exams and other diagnoses. It is necessary to understand the disease process and the procedure to be performed and evaluate the emotional state.⁽¹⁴⁾

Preoperative preparation

Surgery constitutes not only risk, given the possibility of infection and metabolic disorders, but also an emotional crisis for patients and their families, due to questions raised. Caring for children and adults includes the physical and emotional dimensions, mitigating fears of pain, death, bodily image, family separation etc. To solve these problems, it is necessary to hold preoperative meetings to facilitate anamnesis and know of doubts and concerns that can be related directly with the surgical experience.⁽¹⁵⁾ Attributes, like their listening capacity, fraternal impartial and friendly attitude stimulate trust and allow patients to familiarize with those who will care for them in the surgical room. The objectives are

related with information about the trans-operative and post-operative, involving the patient and the family in the care.⁽¹⁵⁾ Surgical and anesthetic antecedents are evaluated, as well as the support the patient has and the possible necessities in the postoperative. This phase is an opportunity to work on educational issues.

Personal antecedents. It is important to know of allergies to medications or other agents, like antiseptics, foods; in case of any of them existing, this must be made visible to the patient and in the clinical chart, also, medications being taken (for diseases or through habit), including over-the-counter drugs, many are adjusted before the surgery, by the surgeon and anesthesiologist. Current state of comorbidities, like hypertension, diabetes, pulmonary status, and asthma. It is important to inquire about personal or family antecedents of bleeding and anesthetic problems, or possibility of anemia; with women, inquire about the pregnancy, and surgical history and trauma. Uncontrolled high blood pressure is a risk factor calling for patient stabilization before admission to the surgical room.⁽¹⁶⁾ If patients suffer ischemic myocardial disease, this must be studied prior to the procedure;⁽¹⁶⁾ likewise, assess if they have stents, their type and need for platelet anti-aggregation, and the cardiologist defines the situation to the patient.⁽¹⁷⁾

Diabetes Mellitus. If the patient is controlled, risks are similar to that of non-diabetic patients. The aim is to achieve concentrations between 140 and 180 mg/dl; in uncontrolled diabetics, complications range from infections and wound healing disorders to metabolic or hydric imbalances.⁽¹⁷⁾

Respiratory disease. Infections must be treated prior to surgery. Chronic obstructive or restrictive pulmonary diseases increase risks, require evaluation and treatment prior to going into surgery. Patients who smoke, ideally, must suspend tobacco use at least two weeks before the procedure to “permit recovery of the mucociliary transport

mechanisms, reduce secretions, and lower carbon monoxide levels”.⁽¹⁶⁾ Asthmatic patients must have their disease controlled before the surgery. Training with breathing exercises is beneficial in obese patients with respiratory disease or those subjected to thoracic or abdominal procedures.

Kidney disease. In presence of nephritis, acute kidney failure, surgery is contraindicated. Chronic kidney failure is not a contraindication. If the glomerular filtration rate is < 30%, morbidity increases due to electrolyte disturbances, metabolic acidosis, high blood pressure, and uremic states that undermine life.⁽¹⁸⁾ Alcohol consumption induces reactions and tolerance against anesthetics, requiring greater doses of analgesics during the postoperative and monitoring for the possible onset of Delirium Tremens.⁽¹⁹⁾

Risk of thrombo-embolic disease. Formation of a thrombus in the venous vessels, due to prolonged rest and/or endothelial injury, causes local disturbances to obstructing pulmonary vessels.⁽²⁰⁾

Obesity. Increases anesthetic risk and makes the surgical technique difficult, thus, it must be assessed carefully.⁽¹⁶⁾ Currently, presurgical exams are requested according with the patient’s specific conditions and clinical characteristics.⁽²¹⁾

Informed consents. These are related with the surgical procedure, conducted by the surgeon; the anesthetic, performed by the anesthesiologist; and nursing that is related with all the processes and procedures carried out by the nursing staff during the perioperative period, which is under the responsibility of nursing. The consent “is a legal instrument that defines the obligations of the parties involved in the act”. Once patients are informed and have their doubts cleared, they decide to accept or reject it; in this case, potential problems are informed and written record of their refusal is included in the clinical chart. This document is signed by the patient and the caregiver or companion who accepts said procedure.⁽²²⁾

Physical preparation. It is necessary to bear in mind the following aspects in patients:

Preparation of the skin. To suppress transient flora and inhibit resident flora, thus, eliminating one of the sources of surgical infection, This is achieved by bathing and asepsis of the surgical area.⁽²³⁾ The presurgical bath is done with antiseptic soap, focusing on contaminated areas, like the navel, perineum, inguinal folds, and armpits, the previous day or the day of the intervention, including washing the hair with shampoo.^(23,24) If the procedure is in the head, two baths with 4% chlorhexidine are recommended.⁽²³⁾

Hair removal from the operative area. The current trend consists of making a very sparse trichotomy, avoiding lacerations because they are infectious foci. It should be done with an electric razor, and disposable heads, or with depilatory cream, after testing for sensitivity,^(25,26) immediately before the surgery (2 h before) and outside the surgical room. Do not use adhesive bandages tape to remove the hair because it can cause microaggressions that permit colonization with bacteria; patients must be educated not to shave the surgical zone.⁽²³⁾

Preoperative fasting. If the patient requires special preparation, the specifications appear in the medical orders. General anesthesia increases danger of bronchial aspiration when the patient is urgent and fasting time is unknown.⁽²⁷⁾ In children, this risk is prevented by educating the family. Fasting of clear liquids must be of 2 h, breast milk 4 h, non-human infant formula 6 h, light food 6 h, and normal diet at least 8 h.⁽²⁸⁾

Hematic products: in surgeries with prognosis of blood loss, the request must be verified with the blood bank and the patient must be classified with cross tests and sufficient reserve of hematic products.

Dressing and preparation of the patient: on arrival to the surgery service, street clothes are substituted by surgical gown, turban or disposable

cap and surgical leggings. The patient is brought to the operating room without makeup, to be able to see the color of the integuments. All types of prosthetics, contact lenses, piercings and jewelry are removed.

Patency of venous line: a good gauge catheter, minimum 18, is installed in the back of the hand and/or forearm away from flex sites to provide a pathway to administer medications and solutions. Likewise, the patient is weighed because drug doses depend on weight.

Preparation of the colon: Elective surgery of the colon requires mechanical preparation. The objective is to arrive to surgery with an empty intestine and free of pathogenic germs. If required, it will be ordered by the treating surgeon for its preparation.⁽²⁹⁾

Safety indicators: it is necessary to verify the patient, surgery, and correct side to prevent unwanted events. In addition, these are confronted with the clinical chart, surgery programming and other exams, like imaging, and other identification mechanisms.

Education for the postoperative: plays a very important role in the patient's recovery and these must be taught breathing exercises, like coughing; active and passive exercises of upper and lower limbs; changes of position, early ambulation, management of catheters and drains, how to get up, among many others. The educational interventions have positive effects on knowledge, satisfaction, physical, mental, and social aspects, quality of life, knowledge of self-care practices.⁽³⁰⁾

Emotional preparation. It helps to minimize negative emotions related with the surgery; ideally, this starts three weeks before such. The surgical intervention is a trigger and stimulus that impacts the human being's emotional dimension and can bring unpleasant consequences that can lead to preoperative trauma.⁽³¹⁾ For some patients, surgery can cause concern and anxiety

throughout the perioperative process, in part, due to lack of experience with surgical procedures. Anxiety can also be based on the fear of pain and the anesthesia.⁽³²⁾ Lack of information, not only of the surgical procedure, but of the anesthesia and its complications, fear of the side effects, and the potential risk of death are aspects that can trigger anxiety.⁽³³⁾

Anxiety is manifested with increased state of alertness, heart rate, blood pressure, muscle tension, and respiratory disorders.⁽³⁴⁾ Superficial bodily signs may include pale skin, sweating, shivering, and dilated pupils.^(35,36) The surgical intervention reactivates memories of traumatic situations, previous personal surgical experiences or of significant relatives that can represent a stressful event and generate concerns, like death, physical dependence, not returning from the anesthesia, pain, disease, recovery and separation from the family generate emotional responses, like anxiety, depression and stress that make the post-operative recovery much slower and complicated. Hence, preparing the patients and providing them with information, will allow them to understand what they expect to find during the perioperative period.⁽³³⁾

Tranquility can also be manifested and this is because their body and their environment are not governed by themselves, rather, there is a spiritual or material period that governs them, which can be called destiny, God, supernatural, or whatever.^(32,37) That period "is manifested in the hands of the surgeon and the accompanying staff. Prayer or profound dialogue with God It is to request and entrust that everything turns out well, since it is from Him that everything is expected, in Whom one trusts and to Whom life is given".^(38,39) "It is through spirituality that they find hope, relief and inner peace during this process; these findings are compatible with other studies that examined the association among religious participation, spirituality and health and found that religious participation and spirituality are associated with better health results".⁽⁴⁰⁻⁴²⁾ The person entering

surgery must confront multiple stressful elements, like personal, physiological, psychological, and environmental factors.⁽⁴¹⁾

Emotional needs are determined by the capacity to adapt to situations that represent danger, fear, and anxiety and every emotional adaptation process demands a process of information.⁽⁴²⁾ Psychological support is quite important, it is necessary to banish the ghost of bad luck or the idea that something bad will happen. When things are done right, good indication and preparation, adequate surgical technique, the end result of an operation should be favorable. Hence, the following should be considered:⁽⁴³⁾

Information: education/teaching the patient reduces pre-operative anxiety. Explaining the procedures and activities of nursing care and the feelings they will experience in the pre-, intra- and post-operative.

Psychosocial support: interactions intensify behavior mechanisms related with anxiety and fears and provide emotional wellbeing.

Training of skills: practice guided by specific measures makes the post-operative period simpler, accelerates recovery, and helps to prevent complications.

In addition, emotional care includes physical presence that implies listening and explaining; physical contact that expresses feelings of comprehension, interest, trust and significance of active presence; visual contact during verbal or non-verbal communication; providing guidance to promote self-care; assisting with physical presence and empathic attitude in situations of explicit or implicit vulnerability, both of the patient and of the relative; providing interventions to potentiate control of thought processes so that negative beliefs are substituted for positive attitudes; capacity to understand and respond affectively and adequately to the physical, emotional, and spiritual needs of the patient, expressed verbally

and non-verbally; keeping adequate distance and providing trust and intimacy for patients to express themselves; providing adequate and individualized information according to the patient's and family's situation; facilitating visits from a priest, chaplain or pastor according to their religion.⁽⁴⁴⁾ Patients must demonstrate they understand the surgical experience and must receive pre-operative education and for the post-operative; knowing the time of the surgery; knowing the post-operative unit and the location of the family during the surgical intervention and after recovery; knowing the monitorization and treatments foreseen in the post-operative; knowing the resumption of their activities and the measures to relieve pain, as well as permitting to express their feelings regarding the surgery.

Nursing care in the trans-operative

Within the surgical context, care is offered with high technology, thus, it is essential to have good knowledge of medical devices. The operating table is narrow and through its sections, it can be adapted to the surgical procedure and the patient's conditions. This is located in the center, under a ventilation and illumination system in the operations room.⁽⁴⁵⁾ The purpose of the ventilation system is to keep temperature from 18 to 25 °C with humidity > 50%, and carry out 25 air replacements per hour to reduce the air's microbial content and dilute anesthetic gases.⁽⁴⁶⁾ Noise is common in the surgical room due to medical equipment (surgical drills, hammers, among others), telephones, alarms, music, intra-professional communication.⁽¹⁴⁾

The surgical team is comprised of members from different professions, like specialists in anesthesiology, surgery; circulating and instrumental staff. The circulating staff can be nurse specialist in surgical care, nurse, or nursing

aide.⁽⁴⁷⁾ All work together to perform the surgical procedure and optimize patient care. The care provided in the surgical room is characterized by efficiency exigencies;⁽⁴⁸⁾ organizational barriers and shortage of staff hinder contact with patients, satisfying their needs and expectations, making it necessary to adapt the care to the patient's conditions during the short time prior to the anesthesia or sedation.⁽⁴⁹⁾

Care in this context should be centered on the person, seeing the human being as an independent person, with dignity and in need, emphasizes the individual will and abilities of the person.⁽⁵⁰⁾ Various studies describe the surgery staff as healers of the patient's anxiety during a surgical procedure⁽⁵¹⁻⁵⁴⁾ by perceiving them as serious and competent, which generates trust and tranquility in patients.⁽⁵⁴⁾ The staff's attitude affects the patient's concerns and anxiety, intraoperative soothing properties took place when the staff had a positive and friendly attitude in dealing with the patient and among them.

In this phase, there is disturbing commotion that generates anxiety for patients upon seeing the physicians in surgery, noting the instruments with which they will be operated or observing any surgical compress or bloody gauze. This anxiety can determine the need for more anesthesia and, hence, risks. Patients awake during the surgical procedure hear everything in the surgical room, such as conversations by the staff and the noise related to the procedure that can be annoying.⁽³²⁾ A high level of noise in the surgical room can lead to post-operative sleep disorders. Anxiety experience throughout the process can provoke increased post-operative pain, nausea and vomiting, as well as delayed post-operative recovery and hospitalization. Post-operative pain increases because anxiety creates diminished tolerance and pain threshold, which – in turn – prolongs the patient's post-operative recovery in hospital or other care center.⁽³⁵⁻⁵⁵⁾

Touch and contact have been shown to reduce anxiety^(24,25,54-57) through massage, or by holding

their hands, besides being described as anxiolytic, and diminishes systolic blood pressure.⁽⁵²⁾ Anti-stress balls also help, which can be squeezed in case of perceived concern or anxiety.⁽⁵¹⁾ Part of the patient's comfort in surgery is that of having a heating blanket; it contributes to feeling that the surgical team prioritizes the patient's physical comfort and the heat contributes to relaxation that relieves anxiety.⁽⁵⁴⁾ Sound distractions during surgery have been used and patients appreciate such positively; these relieve anxiety and aid in normal heart rate,^(58,59) blood pressure, and respiratory frequency.^(54,58,59)

Patient's preparation in the surgical room. The surgical team: instrumentation, circulating staff and physicians, simultaneously, work on preparing the patient for the surgical event, again identifying the patient, confirming the surgery: patient, procedure and site of intervention; position in the surgical table, monitoring physiological constants: heart rate electrocardiographic record, non-invasive blood pressure, pulse oximetry, capnography continuously to spot disorders, bearing in mind that no monitoring apparatus substitutes clinical judgement. Other preparations include preservation of normothermia, taking precautions to avoid deep venous thrombosis, as well as disinfecting the feet⁽⁶⁰⁾ among many others, which represents exposure and manipulation of the patient's body. Prior to starting any surgical procedure, it must be ensured that all the anesthetic and surgical material and equipment are available for the surgical event.

Anesthesia. For the procedure, patients must be subjected to some type of anesthesia: general, local or regional. With general anesthesia, the patient is unconscious through the administration of different types of medications, anesthetics, analgesics and, if necessary, muscle relaxants. Local anesthesia is used to anesthetize a small area of the body, while with regional anesthesia the body area is broader. With local and regional anesthesia, the patient is awake during the surgical procedure, probably sedated.⁽⁶¹⁾ Activities

are aimed at protecting the patients' safety and wellbeing, like their necessities through monitoring the activities of the members of the surgical team and constant revision of prevalent conditions in the surgical room: appropriate asepsis, temperature, humidity, and lighting, availability and proper functioning of equipment and instrumentation.

Venous and arterial lines. The patient's characteristics and comorbidities, the surgical procedure and possible recovery in the intensive care unit require continuous invasive monitoring of the patient, given that it allows observing physiological changes. Arterial catheterization allows continuous monitoring of systolic, diastolic and mean arterial pressure (MAP);⁽⁶²⁾ also, central venous catheter to monitor central venous pressure, fluids in large volumes, administration of medications, insertion of catheters in the pulmonary artery, no peripheral access, among many others.⁽⁶³⁾ Generally, once the patient has been anesthetized, catheters are inserted after skin asepsis in the corresponding areas.

Surgical positions. The objective is to obtain an optimal exposure of the region to be operated, access to venous catheters, and monitoring devices monitorization. Attention should be paid to the patient's comfort and safety, as well as to the circulatory, respiratory, musculoskeletal and neurological structures. It must be a time of great attention, being frequently performed routinely and often underestimated. The body in a certain position exerts external pressure on the patient's tissue that, at capillary pressures > 32 mm Hg, causes occlusion of blood flow that inhibits tissue perfusion and produces tissue ischemia.⁽⁶⁴⁾ It is recognized that 23% of intraoperative pressure lesions are acquired in procedures lasting more than three hours;⁽⁶⁴⁾ besides, patients remain still during the surgery and cannot change position or feel pain caused by remaining in a position during a prolonged period or even manifest verbally their discomfort in a given position. Patients under local anesthesia might not feel pain or might not be able to communicate where the pain is

felt;⁽⁶⁵⁾ thereby, they depend on nursing and members of the surgical team to advocate for them. Many times, with a given position, uniform distribution of body weight is not allowed, which leads to the risk of tissue damage. Skin areas over bony prominences are particularly vulnerable to pressure lesions (PL), above all in individuals with low weight; this is why risks must be identified and start their prevention.⁽⁶⁵⁾

The procedure and status of the patient determine the equipment to use to provide the position to the patient; the staff should check that the surgical table has all its accessories and performs all its movements. Once the patient is anesthetized, said patient is placed in the position required for the surgical procedure, prior identification of potential risks evaluating the patient's needs and characteristics, like weight, height, and age.⁽⁶⁶⁾ The most common surgical positions are dorsal decubitus, Trendelenburg, reverse Trendelenburg, batrachian, lithotomy, prone position, Kraske (jackknife), lateral decubitus, Fowler or semi-Fowler. Each position produces physiological and anatomical alterations and can produce pressure zones.⁽⁶⁷⁾

Avoiding pressure lesions during the intra-operative: surgical patients are vulnerable to their development as a result of multiple risk factors:

Intrinsic to the patient: the skin's capacity against pressure and cutting and shearing forces, adjusted to old age; medications; comorbidities, like cancer, vascular or cardiovascular disease and diabetes mellitus; low body mass index; low systemic blood pressure; low hemoglobin and hematocrit levels; poor nutritional state with low albumin levels; and diminished blood pressure.⁽⁶⁸⁾

Extrinsic to the patient: the conditions of procedures performed to solve a condition through a surgical intervention⁽⁶⁹⁾ depend on physical and environmental factors and include shearing, friction, humidity, position and duration of the surgery. Often, these lesions are not present in the

immediate post-operative and can take up to five days to become visible.⁽⁶⁵⁾ Foam-based materials, specifically D33 sealed foam, redistribute the body interface pressure on operating tables more effectively.⁽⁷⁰⁾

Surgical site infection (SSI), generates great consternation for patients and relatives and as a high cost for health systems. Thereby, its prevention must be a priority for everyone. The risk factors that can cause it are related with prolonged hospital stay before or after the surgery, unsubstantiated prescription of antimicrobials, deficient antiseptic cleaning of the patient's skin prior to the surgery, and others oversights, like lack of hand hygiene.⁽⁷¹⁾ Likewise, intrinsic risks exist related with patients, like their comorbidity diseases, nutritional state, smoking, obesity, and aging.⁽⁷²⁾ Considering that a patient with SSI has five more times the risk of dying than an uninfected patient, and his/her additional care generates costs close to 2,625 US Dollars, coupled with the loss of expectation of health, surveillance, prevention, and control strategies result necessary in this type of infection associated to healthcare.⁽⁷³⁾

Prophylactic antibiotics. Risk of infection depends on the magnitude of the wound's contamination wound and the host's resistance. Efforts are made to control the sterile technique, but host and procedural factors make it a problem, so each hospital dictates the rules on the subject; the prophylactic antibiotic is selected according to spectrum, pharmacokinetics, toxicity, frequency of adverse secretions and the possibility of achieving good concentrations in a single dose, and costs. The most-used are cephalosporins. Their effectiveness depends on the moment of administration and on the time maintained. It should be administered 1 h before the surgical event and more than 24 to 48 h is not justified.⁽⁷³⁾ The infections committee at each hospital formulates its own protocols and methods to carry out the practice, adjusted to economic resources and characteristics of the population.⁽⁷⁴⁾

Preparation of the skin for surgery. Before starting antiseptics, there is surgical hand washing for 2 to 5 minutes, as recommended by the World Health Organization,⁽⁷⁵⁾ and use of sterile gloves. At the same time, the skin is examined to identify the presence of

organic matter or dirt (this must be removed with gauze and non-sterile gloves) and report and register any alteration, like nevi, warts or other. The effectiveness of antiseptics depends on the skin being clean, free of organic material and waste. In preparing the skin, emphasis is placed on the most contaminated areas: navel, armpits, folds, subungual region, foreskin, and others. Preparation of clean and contaminated areas for the procedure is performed separately to avoid microorganisms in the incision site^(23,24), like when there are stomas. Remember that povidone iodine is inactivated by organic material.⁽²³⁾ Likewise, before starting the preparation of the skin, verify the surgical site to avoid preparing an area and performing the surgery on a mistaken site.⁽²³⁾ Different antiseptic products have been used, these should not be irritating, but of broad spectrum, fast action, and residual effect. Antiseptics, like chlorhexidine should not be applied in the auricle and ear canal; in mucous membranes, the concentration decreases.^(23,24) Each institution creates its own policies for the antiseptics used, their concentrations and areas where these are used.

Upon ending the antiseptics, the sheets and equipment to position the patient must be protected from the antiseptic soaps used, the zone must be dry and the electrodes must not have direct contact with antiseptics to avoid reactions or adverse events in the patient.^(14,23) Usually, asepsis is carried out with sterile gloves to apply the antiseptic, unless it has a long device that does not permit contact of the non-sterile glove with the skin. It is administered by painting or rubbing the skin, no advantage has been reported of any of the methods; the time of application depends on the manufacturer, times range from 30 to 120 seconds.^(14,23)

If the area is clean, start from the incision site towards the periphery in circular manner with increasingly larger circles. In many surgical procedures, the incision site is adjacent to contaminated areas and performing the asepsis of the incision site towards the periphery, avoids contamination from these areas to the surgical site. In case the procedure involves the penis, the foreskin must be retracted and aseptised; then put into place to avoid vascular alterations.^(14,23,76) When there is a contaminated area adjacent to the surgical site, without it being part of it, it can be isolated with adhesive or fluid-resistant tape.^(14,23)

Gauzes, sponges, or applicators are used only once to avoid contamination of the incision site. A norm of asepsis in preparing the skin is to never proceed from a clean area to a contaminated area; hence, if preparing a contaminated area, prepare first the area with lower bacterial count and then the contaminated area; the technique would be from the periphery towards the incision site that is contaminated.^(10,23) If using a commercial applicator, follow the manufacturer's instructions for its use. Upon ending the preparation, make sure the patient is on a dry surface.⁽²³⁾ Traumatic open wounds are irrigated with saline solution.⁽²³⁾ When requiring asepsis of vagina in abdominal procedures, splashing from the vagina on the abdominal wall should be avoided.^(14,23)

Inadvertent hypothermia. It is defined as temperature < 36 °C during surgery; it is a preventable surgical complication.⁽⁷⁷⁾ Studies indicate incidence between 11.7% and 94.4%.⁽⁷⁷⁻⁸³⁾ Hypothermia is associated with the alteration of the metabolism of medications,⁽⁸⁴⁾ infection of the surgical site,⁽⁸⁵⁾ paralytic ileus⁽⁸⁶⁾ and post-operative cardiovascular events,⁽⁷⁹⁾ increased risk of bleeding,⁽⁸⁷⁾ increased consumption of red blood cells,⁽⁸⁸⁻⁹⁰⁾ changes in platelet function, increased oxygen demand accompanied by shivering; besides, greater use of intensive care, hospitalizations and long stays in recovery.^(77, 88, 90) Hypothermia is related with the anesthetic-surgical procedure, as with the temperature of the surgical room, duration of the surgery, administration of cold venous fluids, exposure of the bodily surface, loss of fluids and blood. It is also related with factors intrinsic to the patient, like age, sex, systemic disorders, and body mass index.^(78,91) In spite of the recommendations for maintenance of normothermia in the perioperative, this practice continues being a challenge to health professionals;⁽⁹²⁾ in Colombia, this monitoring is conducted only in 10% of surgical patients,⁽⁹³⁾ which is why interventions in hypothermia management must be a priority to guarantee safe and quality care to surgical patients.⁽⁹⁴⁾ The results of the study by Zaman *et al.*, conclude that using a warm solution (38 °C), rather than a solution at room temperature, can prevent hypothermia and reduce post-anesthetic chills in patients subjected to abdominal surgery.⁽⁹⁵⁾

Gastric emptying. The nasogastric tube is frequently used in surgeries of the upper abdomen; in cases in which it is

necessary to decompress the stomach and evacuate the fluids contained in it, the Levin catheter must be installed.

Urinary catheter. Although patients are asked to empty their bladder prior to surgery, on special cases it is necessary to install a urinary catheter as prevention of bladder distention in surgeries of the lower half of the abdomen in which a full bladder would be a mechanical obstacle for the intervention in cases in which monitoring urinary output is desired and to ensure or control the flow of urine in urological surgery. The most used is the Foley catheter and it is connected to a collection bag. Generally, it is installed when the patient is under anesthesia and ingestion and elimination control is carried out by schedule.

Nursing care during the post-operative

The challenge of post-anesthetic care with an increasingly aging population is the management of chronic diseases, health conditions, and progress in surgical interventions; increasingly, greater numbers of patients are attended with multiple comorbidities for numerous complex surgeries.⁽⁹⁶⁾ The recovery or post-anesthetic period starts when the patient is transferred to the recovery ward or post-anesthetic care unit (PACU) until the patient recovers conscience and capacity to communicate, maintaining, protecting and stabilizing their respiratory tract and achieving cardiovascular health. This period is not free of risks, hence, patients subjected to neuroaxial or general anesthesia must be cared for in specially designed areas and staffed;⁽⁹⁶⁾ it is a clinical area designed within the surgical center in which patients receive continuous care after surgery and anesthesia. These areas are served by trained individuals who provide care to patients until they are in conditions for discharge or are transferred to other clinical areas of the institution.⁽⁹⁶⁾ An anesthesiologist must be available at all times to assess and manage patients whenever clinical necessity arises, or on emergency call.

Continuous professional development is necessary to maintain standards and guarantee that knowledge, skills and update of new techniques and progress are obtained, such as management of difficult airway and pain management with pharmacological and non-pharmacological means. Basic competencies for care in this unit are related to professional ones, such as communication, professional development, clinical leadership. Clinical skills relate to evaluation and management of respiratory tract; circulation, conscience, monitoring during the immediate post-operative phase, intravenous access and balance of fluids, knowledge of pharmacology applied to peri-operative care, management of post-operative pain, nausea and vomiting and of surgical and anesthetic emergencies. Skills simulations are means through which reanimation, algorithms, and management of anesthetic and surgical emergencies can be rehearsed. These need not be of high fidelity and permit formation of the multidisciplinary team.⁽⁹⁶⁾ Patient care uses different empirical indicators, which include the Aldrete scale and the Bromage scale among others. The unit must be equipped with minimum pulse oximetry equipment, multiparameter monitors that display the electrocardiogram, non-invasive pressure, capnographs in case the patient is intubated, thermometers, crash cart, defibrillator, infusion pumps, among many others.⁽⁹⁶⁾

Transition of patient from surgical room to recovery. An integral part of the continuity of good quality care is the effective transfer of clinical information. During the peri-operative, the patient goes through multiple processes: pre-operative, intra-operative, post-anesthetic care unit and, finally, discharge to another service in the institution.⁽⁹⁶⁾ Anxiety is also present in the post-operative, Pezzim *et al.*, identified that patients with prevalent symptoms of anxiety and depression are more dependent on nursing care than asymptomatic patients.⁽⁹⁷⁾

Transference of information between the surgical team in the surgical room and nursing in the post-

anesthetic unit starts once the patient's stability has been monitored and confirmed, using the suggested SBAR form (*situation, background, assessment and recommendation*)⁽⁹⁶⁾: *Situation*: name and age of patient, operation practiced; *Antecedents*: past medical history, allergies to medications, anesthetic technique (including management of respiratory tract, analgesia, antiemetics, and intravenous fluids administered), any surgical intra-operative event or significant anesthetic, or complications (like difficult airway, blood loss, cardiovascular instability, etc.); *Evaluation*: airway: permeability, device *in situ*, possible difficulties anticipated; breathing: oxygen requirement, respiratory frequency, need for capnography; circulation: stability, presence of vasoactive infusion, invasive monitoring; and: *Recommendations*: requirement of continuous monitoring: type and duration required, analgesic plan, antiemesis, management of fluids: oral intake or requirement of intravenous fluids, investigations required: blood analysis, like hemogram, etc., additional information: drains, special dressings.

Clinical challenges in post-anesthetic care. The following are among the most important:

Respiratory. For discharge from the recovery service, patients must be conscious, with unscathed reflexes and able to maintain their own respiratory tract, permeable airway and respiratory frequency. Obstruction of the respiratory tract can occur at any moment with repercussions, like pulmonary edema and hypoxemia.⁽⁹⁶⁾ Many patients arrive to the unit with a Guedell cannula or orotracheal tube; in this case, connection should be conducted to the capnograph for early detection of respiratory tract obstruction, as well as hypoventilation that results in hypercapnia. The staff must be trained in the extraction of said devices in the respiratory tract. In the case of an endotracheal tube, the responsibility for its removal rests with the anesthesiologist or such delegates this function on trained staff prepared to assume this responsibility. It is

recommended to draw up a respiratory tract care plan during the delivery of patients to the staff, in patients with risk of airway complications or with difficult respiratory tract, equipment and experienced staff must be available.⁽⁹⁸⁾ Post-operative pulmonary complications can happen to 20% of the patients undergoing an important surgery.⁽⁹⁹⁾ Early recognition of complications can minimize such by monitoring the respiratory frequency, pulse oximetry, and capnography under the circumstances described, as well as administration of oxygen.⁽⁹⁶⁾ It is also important to know the morbidity of postoperative residual curarization, which is why the nerve stimulator can be available to evaluate the residual block when clinically suspected in patients who have received neuromuscular blocking drugs.⁽⁹⁶⁾

Cardiovascular. The cardio-depressant effects of residual anesthetic agents, as well the loss of perioperative blood and changes of fluids, make patients prone to potential cardiovascular instability. Along with oxygen saturation monitoring, electrocardiographic tracing and non-invasive blood pressure measurement are minimum follow-up standards, but many patients enter the recovery ward with invasive blood pressure and central venous pressure monitoring or of other line *in situ*, which is why the staff must be trained in their use, cardiovascular stability must be achieved to comply with discharge criteria. Individualized care plans are drawn up for each patient and every intervention needs to be documented, like post-operative fluids, medications, oxygen administered and if the administration of intravenous fluids continues, it must be prescribed prior to their transfer to another service.⁽⁹⁶⁾

Post-operative nausea and vomiting. It is still a common and unpleasant experience for a third of patients and it is associated with prolonged stay in recovery and unforeseen readmissions.⁽¹⁰⁰⁾ Protocols for antiemetics can be developed in the unit and patients should not be discharged until the inconveniences of nausea and vomiting are adequately controlled.⁽⁹⁶⁾ Other inconveniences

reported by patients are thirst, and as its intensity increases, the resulting discomfort is greater. Thirst should be evaluated by the health staff, so that it is adequately treated. It is expected that the evaluation will allow some reflections on the behaviors to assume during the recovery from anesthesia, with aim of improving care and humanization of caring for surgical patients.⁽¹⁰¹⁾

Pain management. A broad range of pharmacological and non-pharmacological strategies can be used to achieve optimal management of pain during the postoperative. Epidural-type neuraxial block of peripheral nerves can be used, as well as patient-controlled analgesia, music therapy, relaxation, touch, among others. The staff must be trained to manage these patients and recognize potential side effects derived from these techniques. Specific protocols for the administration of opioid analgesia must be in place to allow timely management of postoperative pain;⁽⁹⁶⁾ music has had positive effects in pain management as non-pharmacological treatment; besides producing relaxation, distraction, and tranquility.⁽¹⁰²⁾

Specific groups of patients. Patients subjected to general anesthesia or neuraxial block must receive the same standards of care described previously.⁽⁹⁶⁾ Children must be cared for in recovery areas designed and with staff for pediatric population whenever possible. Specific teams, protocols, and algorithms for pediatric care must be available. These patients have to receive the same level of nursing care.⁽⁹⁶⁾ During this phase of the post-operative, it is important to have in mind the relatives who are in the surgical center's waiting area because this can contribute with the emergence of feelings, like anxiety, nervousness and, consequentially, stress. It is advisable to include the relative in nursing care, which includes providing information, dialogue, and respect.⁽¹⁰³⁾

Discharge from the recovery service. Discharge is ordered when the patient has fulfilled the following criteria:⁽⁹⁶⁾ recovery of protective

airway reflexes and sustained airway; respiratory frequency from 10 to 20 and regular, SpO₂ 96% or equal to the preoperative level, oxygen prescribed where indicated. Stable blood pressure and heart rate, values depend on pre-operative measurements. No inexplicable or uncontrolled arrhythmias. Level of conscience: pre-operative orientation achieved or additional evaluation conducted. Pain: controlled and postoperative analgesia prescribed; nausea and vomiting under controlled treatment and prescribed when indicated. Temperature: postpone discharge as long as the central temperature is not at 36 °C. Wound/drains/dressings: intact dressings and without evidence of excessive blood loss from the wound site or drains. Neuraxial block: spinal <T6 or epidural sensory level, sensory level at or below the level specified by the anesthesiologist. Venous access: catheter without residual medications and permeable. Medications/intravenous fluids: infusions prescribed, controlled, and dully labeled. During the perioperative, what people value is to feel safe and relational aspects, like the explanations they receive and the treatment by the professionals.⁽¹⁰⁴⁾

Record of nursing care in the peri-operative. Every intervention and interaction conducted by nursing must be duly documented in the clinical chart and in the different records in accordance with the institution's norms.

Conclusion

Care during the peri-operative is a complex process of relationships, with and for human beings: patients and health staff. Patients transit from the pre-operative to the post-operative, placing them at risk of adverse events; therefore, within this context, patient safety is present in every care provided. Hence, nursing must be aware of details in care so that the passage of patients through this context is as beneficial as possible.

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Principles, Scope, and Limitations of the Methodological Triangulation

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Article on Methodology



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Principles, Scope, and Limitations of the Methodological Triangulation

Abstract

This article sought to collect basic and relevant information about methodological triangulation and make a first approach to the principles underlying its use, potentiality and scope, advances and limitations, and some alternative proposals to surpass them. In that sense, it is an attempt to operationalize concepts and present the procedures to conduct it rigorously. In the first place, conceptual aspects and types of triangulation are presented, and in the second place, the principles, uses and difficulties. But, beyond what must be done, an approach is made to how to do it. The assumption underlying through the article is the complementarity among methods. It is emphasized in the principle through which the nature of objects must guide the selection of the methods and of

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the most effective techniques to approach and account for phenomena that are socially pertinent of being studied.

Descriptors: qualitative research; methodology; observation.

Principios, alcances y limitaciones de la triangulación metodológica

Resumen

El presente artículo pretende levantar información básica y relevante sobre la triangulación metodológica y hacer una primera aproximación a los principios que subyacen en su uso, su potencialidad y alcance, sus avances y limitaciones, y algunas propuestas alternativas para superarlas. En ese sentido, es un intento de operacionalizar los conceptos y presentar los procedimientos para llevarla a cabo en forma rigurosa. En primer lugar, se presentan los aspectos conceptuales y los tipos de triangulación, y en segundo lugar los principios, los usos y las dificultades. Pero, más allá del qué hacer, se hace una aproximación al cómo hacerlo. El supuesto que subyace a través del artículo es la complementariedad entre los métodos. Se enfatiza en el principio mediante el cual, la naturaleza de los objetos debe guiar la escogencia de los métodos y de las técnicas más eficaces para aproximarse y dar cuenta de los fenómenos que son pertinentes socialmente, de ser estudiados.

Descritores: investigación cualitativa; metodología; observación.

Princípios, alcances e limitações da triangulação metodológica

Resumo

Este artigo tem como objetivo coletar informações básicas e relevantes sobre triangulação metodológica e fazer uma primeira aproximação aos princípios que fundamentam sua utilização, seu potencial e alcance, sua avanços e limitações, e algumas propostas alternativas para superá-los. Nesse sentido, é uma tentativa de operacionalizar os conceitos e apresentar os procedimentos para realizá-lo com rigor. Em primeiro lugar, são apresentados os aspectos conceituais e os tipos de triangulação e, em segundo lugar, os princípios, usos e dificuldades. Mas, além do que fazer, é feita uma abordagem de como fazer. A hipótese subjacente ao longo do artigo é a complementaridade entre os métodos. A ênfase é colocada no princípio pelo qual a natureza dos objetos deve orientar a escolha dos métodos e técnicas mais eficazes para abordar e dar conta dos fenômenos socialmente relevantes, se estudados.

Descritores: pesquisa qualitativa; metodologia; observação.

Introduction

According to Boudon,⁽¹⁾ for authors, like Dilthey, Rickert, Jaspers, and Max Weber, research in social sciences follows the path of understanding and the natural sciences through explanation, although for some, especially for Weber, both procedures, although distinct, are not exclusive. The same author found false opposition between the methods of the sciences, given our condition of social beings and the specificities of the human, through the diversity of objects and limitations of the methods, to account for complex phenomena of the social reality. For this author, it is naive to evaluate the methods of the social sciences with the unified parameters of the natural sciences, given that it would not be imaginable, for example, that History could be similar to Physics.

Quantitative research is supported on a set of established logical principles and should not be imposed from the outside for the researcher. *Qualitative research* also obeys an implicit but less unifiable logic.⁽¹⁾ The nature of the object and effectiveness of the methods will guide the researcher's reflection to approach and account for phenomena that are pertinent, socially, of being studied. It must be highlighted that the methods are not the truth, they only constitute tools, procedures, instruments and modes of putting together the theory to investigate a problem and that when used facilitate its understanding; in that sense, the methodological triangulation will be treated as research procedure.

The term triangulation comes from navigation, where, from various angles, an object is situated; in this case, a ship. Thus, triangulation constructs several appendages, namely theoretical or methodological perspectives, several views or several readings, diverse points of view to address the same research problem. As explained by Morse, the discussion among authors has dealt on the appropriations, advantages, and disadvantages of methodological triangulation.⁽²⁾ The issue that has gained greater interest is the combination of qualitative and quantitative methods within the same project. Some authors have published examples of how this is carried out within a specific project, identifying the issues involved in said strategies; others have identified unsolved issues or highlight the guidelines they consider successful and the less developed in the use of methodological triangulation.

This article sought to collect basic and relevant information about methodological triangulation and make a first approach over the principles underlying its use, potentiality and scope, its progress and limitations, as well as solution alternatives.

From triangulation of indicators and variables to theoretical and methodological triangulation: conceptual aspects

What is methodological triangulation? Triangulation is a term originally used in navigation circles by taking multiple reference points to locate an unknown position. Campbell and Fiske are credited in the literature as the first to apply triangulation in research in 1959.⁽³⁾ It is assumed conventionally that triangulation is the use of multiple methods to study the same object. This is the generic definition, but it is only one form of the strategy. It is convenient to conceive triangulation including varieties of data, researchers and theories, as well as methodologies.⁽⁴⁾

Kimchi *et al.*,⁽⁵⁾ assume the definition by Denzin in 1970 on triangulation in research: it is *the combination of two or more theories, sources of data, research methods, in the study of a singular phenomenon*. Close scrutiny reveals that the combination can be interpreted in several manners; for such, the authors start from the classification by Denzin and provide explanations about the most adequate way of performing it.

For Cowman,⁽³⁾ triangulation is defined as the combination of multiple methods in studying the same object or event to better address the phenomenon researched. In turn, Morse⁽²⁾ defines *methodological triangulation* as the use of at least two methods, usually qualitative and quantitative, to guide the same research problem. When a singular research method is inadequate, triangulation can be used for a more comprehensive approach to solve the research problem.

Multiple triangulation strategies

Denzin⁽⁴⁾ describes four basic types of triangulation: 1) data triangulation with three subtypes of time, space and person; the person analysis, in turn, has three levels: aggregate, interactive and collective; 2) researcher triangulation that consists in using multiple observers, more than single observers

of the same object; 3) theoretical triangulation that consists in using multiple perspectives, *more* than single perspectives in relation with the same *set* of objects, and 4) methodological triangulation that can imply triangulation within methods and triangulations among methods.

Data triangulation⁽⁴⁾

Denzin⁽⁴⁾ illustrates this type of triangulation. For the author, observers can triangulate with data sources and researchers make explicit the search for the different sources. For example, analysts can employ, in efficient manner, the same methods for a maximum theoretical advantage. Thus, for example, in studying the social meaning of death in a modern hospital it may be possible to use a standard method (like participant observation, which, in strict manner would be technical) and deliberately follow this method in as many different areas as possible.

Researchers can observe different groups within the hospital and take the family members of the dead people. Death rituals can also be examined with the same process. Other examples are deaths on the road, deaths at home, deaths at work and even deaths at play. Each represents a different area of significance with which the same generic event (death) occurs. Basically, this could be used in a comparison of dissimilar groups as a sampling strategy, but more properly reflects a triangulation strategy. Selecting different collocations systematically, researchers can discover that its concepts (like assignment of reality units) share common issues. Similarly, the constituent unit of those concepts can be discovered in its contextual situation.

Furthermore, all sociological observations report activities of people situated socially —although they are in groups or organizations or distributed in groups in a social *area*—. Focusing time and space as observation units recognizes their relationship with the observations of people. Observers can make a sampling of activities according to time of day, week, month or year. Likewise, they can do it with space and treat it as an analysis unit (for example, ecological analysis), or as a component of external validity. The

most-common analysis unit, the social organization of people can be sampled over time and space. Those three units—time, space and person—are interrelated. Studying one demands studying the others.

Levels of person analysis. Three levels of person analysis can be treated:⁽⁴⁾

1. **Aggregate analysis.** It is the first level; selecting individuals for the study, not groups, or relationships, or organizations. This level of analysis is called aggregate because it does not establish social relationships among that observed. Random samples of house workers, school students, and laborers are examples of aggregate analysis of persons.
2. **Interactive analysis.** It is the second level and is related directly with the symbolic interaction. Regarding the term interactive, a unit exists among people interacting in the laboratory or in the natural field. For example, small groups, families or aviators. Sociologists commonly associate it with participant observation; experiments in small groups and non-obstructive measurements represent this form of analysis. The unit is the interaction more than person or group; for example, face-to-face studies by Goffman, who investigated in insurers, nurses and hospital social structure, only how they interact in the generation of series of interactive episodes.
3. **Collective analysis.** The third level, more commonly associated with the structural-functional analysis, is the collectivity. Here, the observational unit is an organization, group, community or, even, an entire society. People and their interactions are treated only according with how they reflect pressures and demands of the total collectivity.

The three levels of analysis may be illustrated by returning to the example of death in hospital. Research guided in aggregate manner can sample simply the attitudes of the hospital staff during the process. An interactional study can examine how

those attitudes are generated by the encounters of the personnel. Lastly, the researcher aimed towards the collectivity can examine how the hospital's structural units (for example, its organizational charter, job positions) dictate certain attitudes and practices by its members.

In synthesis, any research can combine the three levels and types of data; in effect, those studies commonly recall as classical events these combinations: time, space and person are alternatively analyzed in the aggregate, interactive, and collective levels.

Researcher triangulation⁽⁴⁾

Researcher triangulation means multiple observers are used, rather than a single one. More researchers, in effect, conduct multiple observations, although not all play equally prominent roles in the process. Delegation at work can be established by placing well-prepared individuals in crucial positions. When using multiple observers, the most skilled should be placed near to the data. Upon triangulating observers, potential bias coming from single person is removed and considerable reliability is ensured in the observations.

There are various field workers subjected to the same data. If a colleague reports the same class of observation as another, without prior consultation, trust is increased. If later, listening to the report of an observation, a colleague contributes the same, unquestionably duplicates it; that indicates that our observation techniques have some degree of reliability.

Multiple observers may not agree on what they are observing, given that each observer has unique interactional experiences with the phenomenon observed.⁽⁴⁾ Researcher triangulation is considered present when two or more trained researchers with divergent antecedents explore the same phenomenon. It is considered to take place when; 1) each researcher has a prominent role in the study, 2) the experience of each researcher is different, and 3) the disciplinary bias of each researcher is evident in the

study. This definition, as the previous classifications, was elaborated and extended by Denzin in 1989, who stated that researcher triangulation occurs when two or more skilled researchers examine the data. The concern that stands out from researcher triangulation is that different disciplinary biases are compared or neutralized through the study. Overall, this is not discernible in a research publication. Researcher triangulation is difficult to distinguish, unless the authors describe explicitly how they achieved it.

Theoretical triangulation⁽⁴⁾

Denzin defined theoretical triangulation as an evaluation of the usefulness and being able to test rival theories or hypotheses. This definition includes tests through research, rival theories, rival hypotheses or alternative explanations of the same phenomenon. Denzin placed as example the studies by Campbell of women's responses toward abuse, which provide an example of theoretical triangulation. Two competitive models were tested in the same sample of women. Both were used previously to explain the women's responses. The goal was to pit them against each other in a singular study to determine which one provides the best explanatory model of the phenomenon of abuse. The data collection approached was used to measure specific concepts and variables from each model. The report published placed the objective *a priori*, to the test of two opposing rival theories; this component is necessary to operationalize the theoretical triangulation.

Theoretical triangulation is an element few researchers manage and end up reaching. Overall, a small group of hypotheses guides the study and the data obtained emerge not only in those dimensions, rather they may appear with value, in empirical approach materials with multiple perspectives and interpretations in mind. Data could refute the central hypothesis and various theoretical points of view can take place to determine its power and usefulness. Each strategy can allow the contribution of criticism and controversy from several theoretical perspectives. Confronting theories in the same body of data means

the presence of efficient criticism, more in line with the scientific method. This last issue can be qualified by understanding, for example, that sociologists never have the same body of data; this means that a body of data of empirical materials is always socially constructed and subject to multiple interpretations.

Methodological triangulation

Triangulation of methods using two or more research methods can be made in the design or in the data collection. Two types exist, triangulation within methods and among methods.⁽⁴⁾

Triangulation within methods is the combination of two or more data collections to approach the study of the same object; using two or more quantitative measurements of the same phenomenon in a study is an example. Including two or more qualitative approaches, like the observation and open interview to assess the same phenomenon, is also considered triangulation within methods. Observational data and interview data are coded and analyzed separately, and then compared, as a way of validating the findings.

This form is used more frequently when the observational units are seen as multidimensional. Researchers take a method (from safety) and employ multiple strategies to examine the data. A safe questionnaire can be constructed with different measurement scales for the same empirical unit. For example, in the famous case of the alienation scales, several recent investigations have used five different indices. The obvious difficulty is that only one method is employed. Observers are mistaken if they believe that five different variations on the same method generate five triangulation varieties.

Moreover, each class of data generated —interviews, questionnaires, observation and physical evidence— is potentially biased and its specificity may be threatened. Ideally, data should converge, *i.e.*, they should not contradict, although conserving their multiple variations.

Triangulation among methods is a more sophisticated way of combining triangulation of dissimilar methods

to illuminate the same class of phenomena; it is called among methods or triangulation through methods. The rationale in this strategy is that the weaknesses of a method constitute the strengths of another; and with a combination of methods, observers reach the best of each, overcome its weakness. Triangulation among methods can take several forms, but its basic characteristic can be the combination of two or more research strategies in studying the same empirical unit or several.

With seven research methods on research design – that in a stricter sense, would be techniques, a variety of combinations can be constructed.^(1,2) Completely triangulated research can combine them all. Besides, if the basic strategy was participant observation, researchers can employ safe interviews with field experiments, non-obtrusive methods, filming, and life stories. Most sociological research can be seen to emphasize a dominant method, with combinations of other additional dimensions.

Kimchi *et al.*, state in their article Denzin's classification and add explanations about the most adequate way of conducting the triangulation.⁽⁵⁾ In their opinion, the specificity and the step-by-step procedures to implement the triangulation should be addressed. The purpose of their work was to present operational definitions for the types of triangulation described by Denzin in an effort to clarify the triangulation and attract researchers. Based on the theoretical definitions by Denzin, these show a group of operational definitions of the types of triangulation. The definitions seek to clarify, specify, and provide indicators that research readers can use if they deem there has been triangulation. Operational definitions were made by Kimchi during a review of all the data on which 319 articles were based from six nursing research journals published during 1986 and 1987. The six journals were: *Advances in Nursing Science*, *Image*, *International Journal of Nursing Studies*, *Nursing research*, *Research in Nursing and Health*, *Western Journal of Nursing Research*. The following presents some operational definitions.

- Data triangulation.⁽⁵⁾ Considered as the use of multiple data sources to obtain diverse visions

about a topic for the purpose of validation. Temporal triangulation represents data collection of the same phenomenon during different points over time, as already exposed; in these studies, time is relevant. Longitudinal studies are not considered temporal triangulation because the aim of a longitudinal study is to document changes over time and the purpose of temporal triangulation is to validate the congruence of the same phenomenon through different points over time.

- Spatial triangulation.⁽⁵⁾ It is data collection of the same phenomenon in different sites. Space must be the central variable. Studies in which data are collected in multiple sites, but do not cross, are not considered spatial triangulation. In spatial triangulation, data are collected in two or more scenarios and tests of consistency are analyzed by crossing the sites.
- Person triangulation.⁽⁵⁾ It is data collection from, at least, two of the three levels of person: individuals, couples, families, groups or collectives (communities, organizations or societies). Researchers can collect data from individuals, couples and groups, or each of the three types. Data collection from a source is used to validate data from the other sources or a single one. Kimchi, Polivka and Stevenson set as example the work by Hutchinson who, in 1987, studied the process of dependency on recovery ward nurses on two levels. Data were collected weekly from meetings of groups of recovery nurses over one year (group level) and in selection interviews (individual level). The phenomenon of interest was the recovery process. Each data level was used to validate the findings of the other.
- Multiple triangulation.⁽⁵⁾ This occurs when using more than one type of triangulation in analyzing the same event, contributing more comprehensive and satisfactory sense of the phenomenon⁴; as mentioned, it is the combination of two or more types of triangulation in a study. Using triangulation within methods and researcher triangulation in a study or using triangulation

within methods and among methods in a study are two examples of multiple triangulation. Kimchi *et al.*, give as an example the study by Wallson *et al.*, which combined researcher triangulation and triangulation within methods. The group represents a multidisciplinary mix of researchers and study goals reflected on distinct values from different disciplines. Triangulation within methods was evidenced by the use of three measures of stress, each used to validate the others, a psychological measure and two written tests.

Triangulation in the analysis, a more recent type of development, is the use of two or more approaches in the analysis of the same data group for validation purposes. It is conducted by comparing data analysis results, using different statistical tests or different techniques of qualitative analysis to evaluate similarly the results available. It serves to identify similar patterns and, thus, verify the findings. Use of divergent methods of data analysis for cross-validation purposes constitutes another triangulation potential. For Denzin,⁽⁴⁾ *"the greatest goal of triangulation is to control the personal bias of researchers and cover the intrinsic deficiencies of a single researcher or a unique theory, or the same method of study and, thus, increase the validity of the results"*.

- Combination of results: Morse⁽²⁾ agrees with Mitchell in that the problem of the weight of the results of each component is solved if the findings are interpreted within the context of present knowledge. Each component should fit as a piece in a puzzle. The essential is the process of informed thought, judgment, wisdom, creativity, and reflection, and includes the privilege of modifying the theory, this is the exciting part of each research project and when there is triangulation of different methods, this is particularly exciting. If contradictory results occur from the triangulation of qualitative and quantitative methods, then a group of findings is invalid or the total result of the study is inadequate, incomplete or imprecise or

both. If the study was guided deductively, the theoretical map may be incorrect.

Implementing the methodological triangulation

The methodological triangulation can be classified as simultaneous or sequential.⁽²⁾ The first, when using qualitative and quantitative methods at the same time. In that case, the interaction between both data groups during the collection is limited, but the findings complement each other at the end of the study. Sequential triangulation is used if the results of a method are essential to plan another method. The qualitative method is completed before implementing the quantitative method or vice versa.

Thus, according to Morse,⁽²⁾ in the methodological triangulation, the key issue is if the theory, which guides the research, is developed inductively or is used deductively, as in the quantitative inquiry. From this differentiation, various types of methodological triangulation result. If the research is directed by an inductive process and the theory is developed qualitatively and is complemented through quantitative methods, the *QUAL + quan* notation is used to indicate simultaneous triangulation. If the project is deductive, directed by a conceptual map *a priori*, the quantitative methods take precedence and can be complemented with qualitative methods. In that case, the *QUAN + qual* notation is used. The sequential triangulation is indicated by *QUAL-> quan* with an inductive project, that is, when the theoretical direction is inductive and uses a qualitative foundation. Using the *QUAN-> qual* notation indicates a deductive approach; that is, when we follow the complete quantitative steps and the qualitative method is used to examine or explore unexpected encounters.

Principles

The purpose of the article by Morse² was to explore the principles underlying the use of methodological triangulation when combining qualitative and

quantitative methods. Those principles are related with the consistency among the research purpose, research problem, method used, sample selection, and interpretation of the results. The author coincides with Mitchell who highlights five areas of concern: 1) difficulty to combine text and numerical data; 2) interpretation of divergent results obtained from using qualitative and quantitative methods; 3) success or not in delineating and mixing the concepts; 4) weight of the information from different data sources, and 5) difficulty of guessing the contribution of each method when the results are similar.

The first step in the quantitative-qualitative triangulation is to determine the nature of the research problem, if it is “natural” or “social”, which aims towards a primarily quantitative or qualitative approach. Characteristics of a qualitative research problem: 1) the concept under study is immature due to weak success and conspicuous theory and prior research; 2) a notion that the available theory may be inappropriate, incorrect or biased; 3) a need exists to explore and describe the phenomenon and develop theory, or 4) the nature of the phenomenon is not appropriate for quantitative measurements.

If a research problem is quantitative, the characteristics described are not applicable. Researchers can locate substantial and relevant literature about the topic, create a conceptual map, and identify hypothesis to test. In this case, the research design is comparative or correlational, experimental or quasi-experimental.

The qualitative and quantitative aspects of a research project cannot be weighed equally: besides, a project must be guided theoretically by qualitative methods incorporating a complementary quantitative component, or guided theoretically by a quantitative method incorporating a complementary qualitative component. The important point is that each method must be complete in itself, that is, all the methods used must appropriate rigor criteria. If qualitative interviews are conducted, this must be done as if this method were alone. The interviews must continue while saturation is reached, and the content analysis has

to be carried out inductively, more than forcing the data within a category preconceived for the study.

Further, triangulation may be used with different objectives, among them, the following:

Triangulation is linked by many authors with rigor and quality; in that sense, one of the expectations is to increase research rigor,⁽⁶⁾ thus, Flick⁽⁷⁾ highlights triangulation as “a way to promote quality in research”.

Triangulation as verification: for Patton,⁽⁸⁾ studies using multiple methods that analyze different types of data “provide cross validation”. A less common use of triangulation is to ensure the validity of the instruments. However, this approach should be cautious, testing an instrument before its implementation or establishing its validity during the pilot test.

Triangulation as completeness: for Patton⁽⁸⁾ “(...) qualitative and quantitative data can be combined fruitfully when these elucidate complementary aspects of the same phenomenon”.

Interdisciplinarity: Flick⁽⁹⁾ proposes the possibility of conducting a “systematic triangulation of perspectives”, which may imply “researcher triangulation as collaborative strategy”; this opens the possibility addressing at least the multi- or interdisciplinarity; as proposed by Janesick:⁽¹⁰⁾ I would wish to add a fifth type: “interdisciplinary triangulation”.

In synthesis, following Molina,⁽¹¹⁾ triangulation can “(...) expand the research process to contribute to deeper and broader comprehension of the phenomenon, given that it adds “(...) rigor, amplitude, complexity, richness, and depth to any research”.

Mixed methods in research –perspective under development and emerging since the 1990s– emphasize on integrating different data sets, as highlighted by Creswell.⁽¹²⁾ The author starts from

the labels and notations exposed by Morse who was the precursor of said nomenclature and Creswell proposes it to differentiate design categories or typologies possible to apply in said methods.⁽¹²⁾ Said combined methods “have extended rapidly through social and behavioral sciences”, as stated by Timans, Wouters, and Heilbron⁽¹³⁾ and “have developed linked to the triangulation concept”.⁽¹²⁾ Some authors denominate the singularly as mixed method.

The complementarity of methods

Defining qualitative research as development of theories and generation of hypothesis, and quantitative research as modification of theories and tests of hypothesis, Field and Morse have identified the complementarity of both approaches.

For Morse,⁽²⁾ the biggest threat to validity is the use of inadequate or inappropriate samples. Perhaps due to reasons of convenience, researchers have sought to use the same subjects for both methods, qualitative and quantitative, although it is clearly inappropriate to exchange those samples. For example, quantitative research is based on large representative samples of the population randomly selected; adjustment of the sample is determined statistically, as well as its representativity of the whole population. In qualitative research, appropriation is in relation to how well the sample can represent the phenomenon of interest (for example, how much have the participants experienced the phenomenon and can articulate their experiences); the sample will be adequate when data saturation is enriched. Still, in light of the overall purpose of research, no reason exists (different from convenience) to use the same subjects for both samples.

Clearly, when incorporating quantitative methods within a qualitative study, the qualitative sample may be inadequate for quantitative purposes. Lack of representativity of the qualitative sample selected in purpose is inappropriate and threatens the validity. Selection of the sample through the qualitative and quantitative components of a sequential

(*QUAL* → *quan*) or simultaneous (*QUAL* + *quan*) triangulation must be independent. Because the quantitative sample is inadequate and inappropriate for quantitative purposes, researchers must design a quantitative sample for the population. However, when the quantitative method is used to add more information about the qualitative sample (*QUAL* + *quan*), exceptions can be made if the norms so permit, or if a comparison is available of a normal group, to interpret the results. For example, if dealing with the anxiety of the relatives in the waiting room, the anxiety scales can be interpreted with the norms available for anxiety scales.

A subsample may be used from a large quantitative sample for the qualitative component of the *QUAN* + *qual* or *QUAL* → *quan* triangulation, but those subjects included or the incidental observations in the qualitative part must be selected according with the criterion of good participants than through random selection. Thereby, the subjects selected for the quantitative sample must have greater experience and articulation, and the observations selected must consider the best examples of the situation.

Methodological triangulation is not a term applied to ethnography when the research method includes the use of semi-structured interviews, some levels of participant observation, use of recordings, and administration of questionnaires. It is the combination of said techniques that constitutes the ethnography and what makes ethnography, ethnography. It is not the case of blending or integrating guides from both texts, qualitative and quantitative, rather, it is using appropriate strategies to maintain the validity of each method. The *QUAN* + *qual* triangulation is not only the addition of linguistic and narrative data in an experimental design; at least, the interview data must be collected and analyzed according with the assumptions and principles of the qualitative method. Similarly, incorporating one or two open questions within the quantitative survey does not make study qualitative.

Additionally, using quantitative data in a qualitative study (like frequency data to improve the

description), does not constitute a quantitative study. Methodological triangulation is not a technique to use due to rapidity and convenience in the research. Well done, it will likely lengthen the duration of the project, but the gains reached in the long term are immeasurable.

Methodological triangulation is not a concurrent validation technique. Although the same strategies may be used, these are implemented in a study for different motives. The purpose of the concurrent validation is to find if the results of measuring the same concept through both methods are equivalent. The purpose of simultaneous triangulation is to obtain different but complementary data on the same topic, more than replicating the results.

According to Knafl, methodological triangulation is not merely to maximize the strength and minimize the weakness of each method. If a careful approach is not made, the end result may be to broaden the weakness of each method and invalidate completely the research project. It is more a method to obtain complementary findings and contribute to the theory and development of knowledge.

Some of the controversies of methodological triangulation have emphasized on the issue of qualitative research against quantitative. This controversy advocates for the combination of methods inasmuch as it is consistent with theoretical research. Some researchers forget that research methodologies are only tools, instruments that when used facilitate understanding. Researchers should be versatile and have a repertoire of methods available. To broaden the foregoing, a summary is presented of the discussion by Cowman about the paradigms and the author's proposal regarding triangulation.⁽³⁾

Quantitative approach was the dominant paradigm from 1950 until 1990; the research approach – in turn – has been increasingly localized on the qualitative paradigm. Within the literature there is general support to separate both paradigms. However, accepting the inherent differences between the two, researchers are concerned

that no isolated method can provide understanding of human beings and of their complex needs. Triangulation, as research strategy, represents the integration of two research approaches. The literature that explores its merits in research is incomplete, however, it is reported that triangulation, by reconciling the paradigmatic assumptions of quantitative and qualitative methods, provides richness and productive data. Triangulation offers a bipolar alternative and approaches the quantitative and qualitative. The qualitative-quantitative debate is still in development. It should be noted that each research perspective has several inherent differences. The quantitative approach has been associated exclusively with the dominant empirical-analytical paradigm and sees the causes of human behavior through observations that seek to be objective and collect quantifiable data. More often, research methods are associated with experimental research designs, which examine the causal relations among variables, controlled or removed from their natural scenario and observations are quantified and analyzed through statistically determined probabilities.

Quantitative research holds the methodological assumption that the social world looks at itself through objective forms of measurement. Conversely, Leininger 1985 suggests that people are not reducible to measurable objects and that they do not exist independently of their historical, social, and cultural context. The qualitative paradigm emerges from a tradition in sociology and anthropology, techniques to obtain qualitative data permit observing the world from the perspective of the subject, not the researcher. The qualitative paradigm is concerned for the value of the meaning and for the social world from which this meaning derives; through a variety of theoretical perspectives and research traditions that include phenomenology and ethnography, natural and family data are valued and serve to gain understanding of people. Differences between quantitative and qualitative approaches can be seen, even at the most basic level. The qualitative approach develops theory inductively from the data; in quantitative research, it is done deductively and its methods are encouraged primarily as a theory subjected to statistical tests, that is, falsifiable in Popperian terms.

Knowing the natural difficulties of research quantitative and qualitative methods and having identified the need to integrate the research approaches, the triangulation strategy is proposed. Cowman⁽³⁾ accepts four principles underscored by Mitchell,⁽¹⁴⁾ which, applied carefully, point to maximizing the validity of a particular research, incorporating the methodological triangulation: 1) the research question must be clearly focused, 2) the strengths and weaknesses of each method chosen must complement the other, 3) methods must be selected according with their relevance for the nature of the phenomenon under study, and 4) a continuous evaluation must be performed of the method selected during the course of the research to monitor if the three previous principles are being followed. These consistency elements also apply in mixed methods.

Cowman⁽³⁾ also warns of possible difficulties of triangulation: in first instance, a researcher, accepting the advantages of triangulation, can lose sight of differences between the methods chosen. Danger exists in collecting large volumes of data, which – subsequently – it will not be possible to analyze or are dealt with superficially. Fielding and Fielding emphasized on the danger of taking multiple methods without using simultaneously the bias control procedure.

Moreover, triangulation provides strengths, like animation, creativity, flexibility, and depth in data collection and analysis; as indicated by Cohen and Manion, methodologists often push methods as pets because those are the only methods with which they are familiar or because they believe that their method is superior to all the rest. Reichardt and Cook suggest that it is time to stop constructing walls between methods and start building bridges.

Given that the methods need independence within a single project, the real issue in triangulation can go beyond incompatibility between different assumptions of two paradigms, as argued by several researchers. It also assumes the possible incompatibility of contrasting philosophical issues, of static and dynamic realities, of objective and subjective perspectives, of inductive and deductive approaches or of integral and particular visions. It is not the elusive mix of numerical and text data or of simultaneous considerations of antagonistic approaches of causality and non-causality. Integration of data does not occur in the analysis process, but in the union of the results of each study within a cohesive and coherent product where the confirmation or revision of the existing theory takes place. This can be achieved through adhesion to the rules and assumptions of each method in selecting the sample, purpose, method, and the contribution of the results within the research plan as a whole.

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Application of the Extended Theory of Planned Behavior to Predict Exclusive Breastfeeding Intention, In Pregnant Nulliparous Women. A Cross-Sectional Study

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Application of the Extended Theory of Planned Behavior to Predict Exclusive Breastfeeding Intention, In Pregnant Nulliparous Women. A Cross-Sectional Study

Abstract

Objective. This study investigated the effect of Extended Theory of Planned Behavior (ETPB) extended theory of planned behavior in comparison with the Theory Of Planned Behavior (TPB) in explaining the intention of Exclusive Breastfeeding Intention (EBF) in Pregnant nulliparous women of Kerman (Iran). **Methods.** In this descriptive study, 249 pregnant women in Kerman participated via simple random sampling. The research instruments included Questionnaire related to the structures of the theory of planned behavior, breastfeeding self-efficacy and social support questionnaire for breastfeeding. **Results.** The results of the correlation test showed a significant relationship between all constructs



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of the theory of extended planned behavior and the intention of EBF. The highest correlation belonged to the construct of subjective norms ($r=0.49$). Path regression coefficients in the second model showed that the Self-Efficacy mediator variable is fully capable of meaningful mediation between Social Support and Intention ($p<0.001$; $B=0.383$). The conceptual diagram of Structural equation modeling showed a higher explained variance or R^2 index for the intention variable for the developed model compared to that of the first model, i.e. (the first model: $R^2=0.37$, the second model: $R^2=0.46$). The goodness-of-fit index had a better status for the developed model. **Conclusion.** Extended TPB with social support and breastfeeding self-efficacy constructs can be appropriate model for predicting the intention and behavior of EBF.

Descriptors: pregnant women; breast feeding; self efficacy, social support; health behavior.

Aplicación de la teoría ampliada del comportamiento planificado para predecir la intención de lactancia materna exclusiva en mujeres nulíparas embarazadas. Un estudio transversal

Resumen

Objetivo. Este estudio investigó el efecto de la Teoría Extendida del Comportamiento Planificado (TECP) en comparación con la Teoría del Comportamiento Planificado (TCP) para explicar la intención de la Lactancia Materna Exclusiva (LME) en mujeres nulíparas embarazadas de Kerman. **Métodos.** En este estudio descriptivo participaron 249 mujeres embarazadas de la ciudad de Kerman (Iran), seleccionadas por muestreo aleatorio simple. Los instrumentos de investigación incluían un cuestionario relacionado con las estructuras de la teoría de la conducta planificada, un cuestionario de autoeficacia para la lactancia materna y un cuestionario de apoyo social para la lactancia materna. **Resultados.** La prueba de correlación mostró una relación significativa entre todos los constructos de la TECP y la intención de LME. La correlación más alta correspondió al constructo de normas subjetivas ($r=0.49$). Los coeficientes de la regresión en el segundo modelo mostraron que la variable Autoeficacia mediaba significativamente entre las variables Apoyo Social e Intención ($p<0.001$; $B=0.383$). El diagrama conceptual del Structural equation modeling mostró una mayor varianza explicada o índice R^2 para la variable de intención para

el modelo desarrollado en comparación con el del primer modelo, es decir, (el primer modelo: $R^2=0.37$, el segundo modelo: $R^2=0.46$). El índice de bondad de ajuste fue mejor para el modelo desarrollado. **Conclusión.** La TECP con los constructos de apoyo social y autoeficacia para la lactancia materna puede ser un modelo apropiado para predecir la intención y el comportamiento de la LME.

Descriptor: mujeres embarazadas; lactancia materna; autoeficacia; conductas relacionadas con la salud.

Aplicação da teoria ampliada do comportamento planejado para prever a intenção de amamentação exclusiva em gestantes nulíparas. Um estudo transversal

Resumo

Objetivo. Este estudo investigou o efeito da Teoria Estendida do Comportamento Planejado (TECP) comparada à Teoria do Comportamento Planejado (TCP) na explicação da intenção da Lactância Materna Exclusiva (LME) em gestantes nulíparas de Kerman. **Métodos.** Neste estudo descritivo, participaram 249 gestantes da cidade de Kerman (Irã), selecionadas por amostragem aleatória simples. Os instrumentos de pesquisa incluíram um questionário relacionado às estruturas da teoria do comportamento planejado, um questionário de autoeficácia para amamentar e um questionário de apoio social à amamentação. **Resultados.** O teste de correlação mostrou uma relação significativa entre todos os construtos do TCP e a intenção de LME. A maior correlação correspondeu ao construto das normas subjetivas ($r=0.49$). Os coeficientes de regressão no segundo modelo mostraram que a variável Autoeficácia mediou significativamente entre as variáveis Apoio Social e Intenção ($p < 0.001$; $B=0.383$). O diagrama conceitual da Estrutura equação a modelagem apresentou maior variância explicada ou índice R^2 para a variável intenção para o modelo desenvolvido em relação ao primeiro modelo, ou seja, (o primeiro modelo: $R^2=0.37$, o segundo modelo: $R^2=0.46$). O índice de bondade de ajuste foi melhor para o modelo desenvolvido. **Conclusão.** A TECP com os construtos de apoio social e autoeficácia em amamentar pode ser um modelo adequado para prever a intenção e o comportamento do LME.

Descritores: gestantes; aleitamento materno, autoeficacia; apoio social; comportamentos relacionados com a saúde.

Introduction

The World Health Organization (WHO) defines EBF as “giving no other food or drink –not even water– except breast milk” and the medications, such as oral therapies, vitamins, and supplements.⁽¹⁾ Breast milk plays a vital role in preventing gastrointestinal and respiratory infections.⁽²⁾ It also contributes to maternal health and well-being.⁽³⁾ However, a low rate of EBF has been reported even in developed countries.⁽⁴⁾ At its 65th meeting, the (WHO) decided to increase the rate of EBF to at least 50% by 2025. In developing countries, the concerning rate is 39%, and in Iran, it varies between 13% and 77%.⁽⁵⁾ A study conducted in Riyadh found that although participants had a breastfeeding rate of 72%,⁽⁴⁾ only %20.9 had had EBF for six months.⁽⁶⁾

Early cessation of breastfeeding causes irreparable physical, mental, and socio-economic damages to the child, and ultimately, society.⁽⁷⁾ Subjective norms in lactating and postpartum women, including the views of significant individuals, such as coevals and social networks or important family members, such as partner, parents, or siblings, are important factors in breastfeeding.⁽⁸⁾ One of the effective theories in changing behaviors influenced by social norms is (TPB), which was developed in 1991 by Ajzen and Fishbein and has the following constructs: Behavioral intent, Attitude toward behavior, Subjective norms And Perceived behavioral control.⁽⁹⁾

TPB is a behavioral theory in the field of social psychology, which analyzes the factors affecting behavioral goals and explains the behavior. The theory notes that the main predictor of behavior is a change in the behavioral intention that depends on the attitudes, subjective norms, and the perceived behavioral control of individuals.⁽¹⁰⁾ This theory, which has been used for many health behaviors, explains on average about 40% of the relationships between the intent and health behaviors.⁽¹¹⁾ Some researchers believe that for some behaviors, such as successful breastfeeding, using the concept of self-efficacy is better than the perceived behavioral control variable because it makes it possible to predict the occurrence of the behavior. Breastfeeding self-efficacy is a social cognitive theory adapted from Dennis. Breastfeeding self-efficacy reflects how a mother perceives her breastfeeding ability rather than her true ability to succeed in breastfeeding. Mothers with high self-efficacy can often overcome the barriers that seem exhausting to the mothers with low self-efficacy.⁽¹²⁾ And this is a modifiable factor that can affect breastfeeding success.⁽¹³⁾ One critique of the TPB is neglecting the social factors affecting behavior. Numerous studies have emphasized the role of social support and especially the spouses' attention to the initiation and continuation of EBF. Breastfeeding is a behavior that requires mothers' knowledge, skills, support, and confidence.⁽¹⁴⁾ Social factors, including the support of social groups, affect the mothers' breastfeeding.⁽¹⁵⁾ Therefore, considering the importance and role of EBF in

promoting the health of infants and children, the present study aimed to investigate the predictive power of the TPB constructs in explaining the intention of EBF in pregnant nulliparous women of Kerman and compare it with an extended theory, that in addition to the constructs of the TPB, also includes the self-efficacy constructs of breastfeeding and social support.

Methods

This is a descriptive cross-sectional study in which 249 pregnant nulliparous women referring to comprehensive health service centers in Kerman in November and December 2020 are included in the study. The criteria for inclusion in the study were participants' willingness and being nulliparous, and the exclusion criteria of the study were being infected with breast diseases that prohibit breastfeeding and diseases the treatment of which interferes with breastfeeding. Some statisticians recommend a minimum sample size of 200 in SEM studies.⁽¹⁶⁾ Considering the probable loss data, the final sample size was 249. The samples were also homogenized in terms of participation in childbirth preparation classes and in terms of behavioral intent. Written informed consent was obtained from the participants.

Sampling was conducted through the simple random sampling method. After coordination with the officials of Kerman health center, six public centers of comprehensive health services were randomly selected, and in each center, the samples were included in the study based on the electronic file of the pregnant women and based on inclusion and exclusion criteria. The instrument used in the research was a questionnaire consisting of four sections that included a section to record the demographic characteristics, such as age, education, and occupation, a TPB model structures assessment questionnaire, taken from Alami *et al* study.⁽¹⁷⁾ In the form of 25 five-choice questions, on a Likert scale (attitude in the form

of 11 questions, subjective norms in the form of seven questions, perceived behavioral control in the form of four questions, and behavioral intention in the form of three questions), Benson's breastfeeding behavior self-efficacy questionnaire,⁽¹⁸⁾ and breastfeeding social support questionnaire taken from the Boateng study⁽¹⁹⁾, In the form of 14 tree-choice question.

In the constructs section of the TPB, the questions were assessed using a five-point Likert scale. In case of complete agreement (strongly agree), a score of five, and in the case of disagreement (strongly disagree), a score of one was given to the relevant question. The instrument related to model constructs has acceptable content validity (0.66 to 0.99), and Cronbach's alpha coefficient and intra-class correlation coefficient are 0.79 and 0.81, respectively.⁽¹⁷⁾ The self-efficacy breastfeeding questionnaire consisted of 13 questions. The findings of content and face validity showed almost perfect results. In the reliability study, Cronbach's alpha was also evaluated as favorable (0.91).⁽¹⁸⁾ Also, in the present study, Cronbach's alpha coefficient was recalculated for self-efficacy questions, which was equal to 0.85.

In this study, the breastfeeding social support scale was used, the validity and reliability of which were confirmed.⁽¹⁹⁾ Its validity was re-evaluated qualitatively using the experts' opinions and determining the CVR and CVI indices. In the reliability study, Cronbach's alpha coefficient was calculated as 0.84. Based on the validity indicators, the questionnaire was approved with 13 questions. Finally, the data were entered into SPSS (version 22) (IBM, Armonk, NY, USA). Pearson correlation coefficient was used to determine the correlation between them according to the normal distribution. Independent t-tests and one-way analysis of variance (ANOVA) were used to compare the scores according to demographic characteristics and independent variables of the study. The concept diagram of SEM was used to compare the two models. This research was supported by Rafsanjan University of Medical

Sciences. Conscious consent was obtained from all samples to participate in the study. Ethical approval for this study was approved by Research Ethics Committee with the ethics code of IR.RUMS.REC.1399.102.

Results

A total of 249 mothers were studied in this research. The age range of pregnant mothers was 15-43 years, with an average of 26.98 years. The majority of the women participating in this study (90%) were housewives. Also, the majority of them had a high school diploma or higher (44.2% university education and 35.7% high school diploma). Among the demographic characteristics, the independent t-test statistic showed a significant difference between the mean scores of attitude ($p=0.033$, $t=-2.138$), self-efficacy ($p=0.005$, $t=-2.803$) and behavioral intention ($p=0.021$, $t=-2.323$) by age. The results of the Pearson correlation test showed a statistically significant relationship between all constructs of the extended TPB and the intention of EBF (Table 1).

The conceptual diagram of the SEM of the TPB shows the effect of three variables of subjective norms, perceived behavioral control, and attitude on the variable of intention, as well as the effect of questions related to each factor (Figure 1).

According to the results of this model, the two variables of subjective norms and perceived behavioral control have a direct and significant effect on the variable of intention (with $p<0.001$ and $p=0.015$, respectively). The regression coefficients of the paths in Figure 1 indicate that the path of attitude to intention ($p=0.031$, $B=-0.22$) and the perceived behavioral control ($B=1.18$, $p<0.001$) are significant. In other words, all direct paths to the intent are statistically significant.

To evaluate the goodness of fit of the model, the chi-square to the degree of freedom (DOF) (CMIN / DF) and the RMSEA indices are usually used. In this study, the CMIN / DF index for this model was 2.76, and the RMSEA index was 0.084. Also, the R2 index, or the explained variance for the variable of intention, which represents the percentage of explanation of the changes of the dependent variable (intention) by the independent variables, was calculated as 0.37. In the conceptual diagram of the SEM of the extended TPB, the effect of five variables of self-efficacy, social support, subjective norms, perceived behavioral control, and attitude on the variable of intention as well as the effect of the questions related to each factor are examined and shown (Figure 2).

According to the results of this model, the three variables of self-efficacy, subjective norms, and perceived behavioral control have a direct and significant effect on the variable of intention (with $p<0.001$, $p<0.001$, and $p=0.019$, respectively).

The regression coefficients of the paths in Figure 1 indicate that the path of attitude to intention ($p=0.176$, $B=-1.32$) is not significant, while the path of attitude to perceived behavioral control is significant ($p<0.001$; $B=1.20$). Also, the path of social support to the intention ($p<0.110$, $B=-0.11$) is not significant and the path of social support to self-efficacy is significant ($p<0.001$; $B=-0.383$). Also, the CMIN / DF index for this model was equal to 1.89, and the RMSEA index was equal to 0.060. Also, in this model, the index R2 or the explained variance for the intention variable was calculated as 0.46.

According to the model introduced in the TPB questionnaire, and extended TPB, the coefficients and the effect of each question on different dimensions are examined, and the final results of these coefficients along with the standard error and the significance level of their effect are presented in Table 2.

Table 1. Correlation matrix between the constructs of the ETPB and intention for EBF

	Mean ± SD	Attitude	Subjective Norm	Perceived Control	Self-Efficacy	Social Support	Intention
Attitude	44.77±4.40	1					
Subjective Norm	30.97±3.53	0.49*	1				
Perceived Control	11.46±2.20	0.45*	0.44*	1			
Self-Efficacy	13.11±1.90	0.28*	0.42*	0.19*	1		
Social Support	51.17±8.35	0.25*	0.25*	0.27*	0.25*	1	
Intention	35.93±6.53	0.34*	0.54*	0.28*	0.59*	0.17*	1

* $p < 0.01$

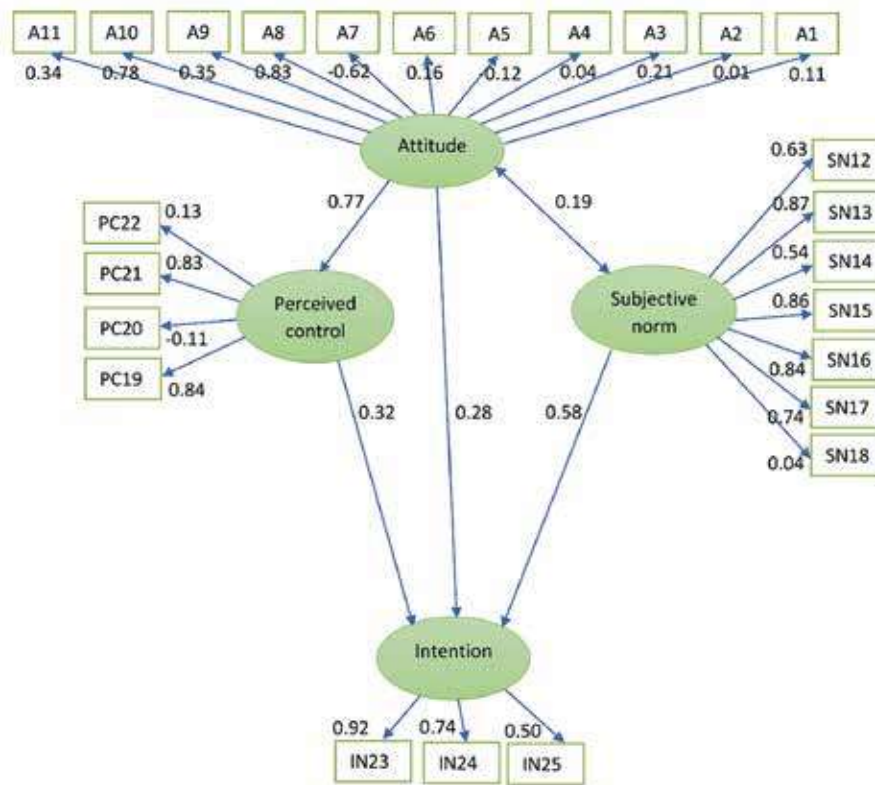


Figure 1. Conceptual diagram of the SEM of the TPB with standard coefficients

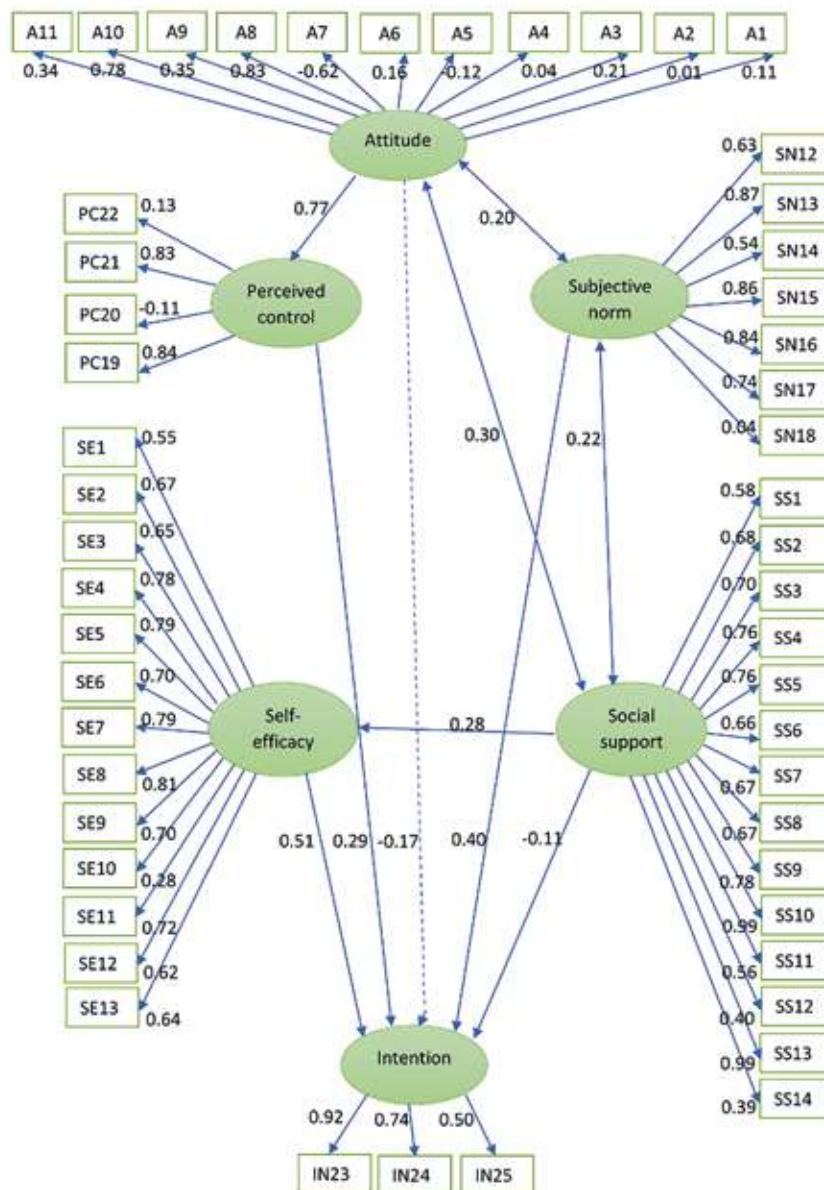


Figure 2. Conceptual diagram of the SEM of the extended TPB along with standard coefficients

Table 2. Coefficients, standard error (SE), and the significance level of constructs in the SEM of the TPB and the SEM of the extended TPB

Scale	Subscale	Matter	Coefficient	SE	p-value
TPB	Intention	Perceived control	0.165	0.068	0.015
		Subjective Norm	0.524	0.102	<0.001
		Attitude	-0.223	0.103	0.031
	Perceived Control	Attitude	1.182	0.163	<0.001
ETPB	Intention	Perceived Control	0.147	0.063	0.019
		Subjective Norm	0.354	0.081	<0.001
		Self-Efficacy	0.385	0.079	<0.001
		Social Support	-0.110	0.069	0.110
		Attitude	-0.132	0.097	0.176
	Perceived Control	Attitude	1.201	0.166	<0.001

Comparison of two models in estimating intention variable

In this study, two models of structural equations were compared. In the first model (theoretical constructs of planned behavior), the effect of three factors of subjective norms, perceived behavioral control, and attitude on the variable of intention is investigated. In the second model (extended TPB), two factors of self-efficacy and social support have been added to the previous

model. According to the goodness of fit indicators reported in Table 3, the extended TPB has a better situation than the TPB in all indicators. Also, the index R² or variance explained for the variable of intention, which indicates that, what percentage of changes in the dependent variable (intention) explained by independent variables, was higher for the second model compared to the first model. This means that the first model explain 37% of the changes in the dependent variable but the second model explains 46% of the changes in the dependent variable.

Table 3. Goodness of fit indicators of the two models

Index	R ²	RMSEA	CFI	IFI	PCFI	PNFI	TLI	CMIN/DF
Acceptable range		<0.08	>0.90	>0.90	>0.80	>0.50	>0.90	1-3
Model 1	0.37	0.084	0.856	0.858	0.721	0.669	0.829	2.756
Model 2	0.46	0.060	0.848	0.850	0.781	0.671	0.835	1.897

Discussion

Various studies have examined the predictive power of TPB constructs for behavioral intention

through some statistical methods, of which some are in line with our study, and some are contrary to our study. In the present study, the extended TPB has been able to explain a higher percentage of changes in the intention variable compared to that in the original model.

In our study, there was no relationship between maternal occupation and the mean scores of EBF, which is consistent with the Haghghi's,⁽²⁰⁾ and Moafi's studies.⁽²¹⁾ However, although some studies, such as Scott's study,⁽²²⁾ consider the occupational conditions of the mother as one of the factors affecting EBF, and the Saffari's study,⁽²³⁾ the conditions of EBF may differ in the occupational environment based on the conditions and facilities available for breastfeeding. In the present study, the Pearson correlation coefficient showed a direct and significant correlation between the constructs of the TPB and the constructs of the extended TPB aimed at EBF. Significant correlations in self-efficacy constructs and EBF have been also shown in other similar studies. The Brockway's study,⁽¹³⁾ showed improved breastfeeding with increased self-efficacy. Brockway⁽²⁴⁾ also showed in another study that for each unit of increasing the mean self-efficacy score, the intention to EBF increased by 10%. Although some studies, such as Newhock *et al.*⁽²⁵⁾ And Senghore *et al.*⁽²⁶⁾. Have considered attitude as the most important predictor of intention, the reason for this difference can be related to differences in the social structural elements that have shaped the mothers' lives.

In terms of the predictive power of constructs, if the value of the CMIN / DF index is less than three and the RMSEA index is less than 0.08, it indicates that the model fits well with the data. In our study, the indices of the goodness of fit in both models were acceptable in predicting the intention of EBF, while all indices had a better status in the extended TPB: in the first model, the effect of the attitude variable on both perceived behavioral control variables and intention is significant. Thus, it can be said that the perceived behavioral control variable plays a significant mediating role for the variables of attitude and intention. Considering that the two predictor variables (perceived behavioral control and attitude) can also directly predict the criterion variable (intention) significantly, it can be said that the mediation variable of perceived behavioral control

can partially mediate the other two variables. In the second model, the attitude predictor variable cannot predict the intention variable directly, so it can be said that the perceived behavioral control mediator variable is fully capable of meaningful mediation between the two attitude and intention variables. Therefore, the perceived behavioral control construct acts both as a mediating factor (in the first model a partial role and in the extended model a complete role) for the attitude variable and as a direct variable to predict the intent of the behavior.

The R2 index or explained variance for the intention variable in the first model was calculated as 0.37. If this index is less than 0.19, the model is weak. If it is between 0.19 and 0.67, it is medium and if it is more than 0.67, the model will be robust. In this study, the value of this index indicates the average power of the first model.

In a cross-sectional study conducted by Bazholvand *et al.*,⁽²⁷⁾ as in the present study, the goodness of fit indicators of the TPB in predicting the intention of EBF were acceptable, and the perceived behavioral control construct could explain the maximum variance predicting the intention (65%) of EBF. Also in a cross-sectional study aimed at investigating the predictive effect of constructs of the TPB in EBF in primiparous mothers conducted by Jameei *et al.*⁽²⁸⁾ Spearman correlation coefficient showed a direct and significant correlation between TPB constructs, and the intention of EBF. Also, the highest correlation was associated with the perceived behavioral control construct. Also, in the extended TPB, the social support predictor variable cannot predict the intention variable directly, but the self-efficacy mediator variable is fully capable of significant mediation between the two variables of social support and intention.

The results of this study and similar studies^(13,26) show that mothers with low levels of self-efficacy are faced with a higher risk of early cessation of breastfeeding. In a study by Dewi Ratnasari

et al. the results showed that adequate family support was significantly associated with a higher likelihood of EBF.⁽²⁹⁾ (OR: 2.89; 95% CI: 1.29–6.44) In a prospective cohort study conducted by Tengku *et al.*⁽³⁰⁾ two hierarchical regression analyzes were performed. The TPB explained 51% of the variance in intention, but adding of the social support construct increased the explained variance by 6%.

The present study is one of the few studies that simultaneously examine the effectiveness of two factors effective on EBF, namely social support and self-efficacy, in addition to the theoretical constructs of planned behavior in the form of SEM. Another strength of the present study is considering the role of the mediating variable, as well as examining the impact of questions related to each factor that has not been considered in the above studies. Therefore, since using the extended model explains a higher percentage of the EBF intention, teaching the skills leading to improved self-efficacy and a sense of empowerment for the intention of EBF and improved family social support, seems necessary in the late pregnancy period.

Our study has some limitations, including that only the intention of EBF has been evaluated. It is suggested that in future studies, EBF behavior will be measured as well to analyze and evaluate the factors affecting the behavior. Given the importance of exclusive breastfeeding

in promoting maternal and infant health, and since encouraging and educating mothers is the duty of nurses and midwives working in maternal and infant wards, The use of the structures of this theory can increase the quality and efficiency of nurses' educational interventions, in order to improve the index of exclusive breastfeeding and promote the health of mother and child.

Conclusion. The results of this study showed that the extension of the TPB and the addition of new constructs to this theory can be appropriate model for predicting the intention of EBF. The present study shows the need for more attention to the implementation of educational programs with optimal impacts on the level of self-efficacy and social support of pregnant mothers, and ultimately the impact on the intention of EBF behavior. It is recommended to conduct several interventional studies to confirm the efficiency of this extended model on promoting the intention and behavior of EBF.

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The Effect of an educational Intervention on Anxiety of Pregnant Women: A Quasi-Experimental Study

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The Effect of an educational Intervention on Anxiety of Pregnant Women: A Quasi-Experimental Study

Abstract

Objective. The aim of study is the effect of educational intervention on anxiety of pregnant women. **Methods.** This quasi-experimental study is done on the pregnant women referring to family physician's offices in Gerash City, Iran. 62 women were selected and divided into 2 groups (control and intervention). In intervention group the anxiety reduction training classes were held as a group discussion in 4 weekly 90-minute sessions. Control group received routine care. The anxiety assessment completed by two groups before and after the educational intervention. The measurement instruments included a demographic information questionnaire and the short form of the Pregnancy Related Anxiety Questionnaire (PRAQ-17). **Results.** Comparison of the mean scores of different dimensions of pregnancy anxiety in the pre-intervention and post-intervention stages in the intervention group



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using paired t-test indicated a statistically significant difference in the dimensions Fear of childbirth, Fear of giving birth to a physically or mentally disabled child, Fear of mood swings and Fear of changes in marital relations ($p < 0.05$) in comparison with control group. **Conclusion.** Holding pregnancy-training classes using group discussion method is a good strategy to reduce anxiety in pregnant women. Therefore, it is recommended that this educational strategy classes be used with mothers from the second trimester of pregnancy in urban family physician centers or those referred to a nearby clinic.

Descriptors: anxiety; pregnant women; family nurse practitioners; pregnancy trimester, second.

El efecto de una intervención educativa sobre la ansiedad de las mujeres embarazadas: Un estudio cuasi experimental

Resumen

Objetivo. Evaluar el efecto de una intervención educativa sobre la ansiedad de las mujeres embarazadas. **Métodos.** Estudio cuasi-experimental realizado con la participación de mujeres embarazadas que acuden a las consultas de los médicos de familia en la ciudad de Gerash, Irán. Se seleccionaron 62 mujeres y se dividieron en 2 grupos (control e intervención). En el grupo de intervención, las clases de entrenamiento para la reducción de la ansiedad se impartieron en forma de debate grupal en 4 sesiones semanales de 90 minutos. El grupo de control recibió atención rutinaria. Los dos grupos completaron la evaluación de la ansiedad antes y después de la intervención educativa. Los instrumentos de medición incluían un cuestionario de información sociodemográfica y la forma corta del Cuestionario de Ansiedad Relacionada con el Embarazo (PRAQ-17). **Resultados.** La comparación de las puntuaciones medias de las distintas dimensiones de la ansiedad durante el embarazo en las etapas previa y posterior a la intervención en el grupo de estudio indicó una diferencia estadísticamente significativa en las dimensiones Miedo al parto, Miedo a dar a luz a un niño discapacitado física o mentalmente, Miedo a los cambios de humor, y Miedo a los cambios en las relaciones conyugales ($p < 0.05$), en comparación con el grupo de control. **Conclusión.** La realización de clases de formación durante el embarazo utilizando el método de discusión en grupo es una

buena estrategia para reducir la ansiedad en las mujeres embarazadas. Por lo tanto, se recomienda que esta estrategia educativa se emplee con las madres desde el segundo trimestre del embarazo en los centros de medicina de familia o a aquellas que sean derivadas a la consulta externa.

Descriptor: ansiedad; mujeres embarazadas; enfermeras de familia; segundo trimestre del embarazo.

O efeito de uma intervenção educativa na ansiedade de gestantes: um estudo quase experimental

Resumo

Objetivo. Avaliar o efeito de uma intervenção educativa sobre a ansiedade em gestantes. **Métodos.** Estudo quase experimental realizado com a participação de gestantes atendidas em consultórios médicos de família na cidade de Gerash, Irã. 62 mulheres foram selecionadas e divididas em 2 grupos (controle e intervenção). No grupo de intervenção, as aulas de treinamento de redução de ansiedade foram ministradas como uma discussão em grupo e em 4 sessões semanais de 90 minutos. O grupo de controle recebeu cuidados de rotina. Ambos os grupos completaram a avaliação da ansiedade antes e após a intervenção educativa. Os instrumentos de medida incluíram um questionário de informações sociodemográficas e a versão curta do Questionário de Ansiedade Relacionada à Gravidez (PRAQ-17). **Resultados.** A comparação das pontuações médias das diferentes dimensões da ansiedade durante a gravidez nas etapas antes e após a intervenção no grupo de estudo indicou diferença estatisticamente significativa nas dimensões; medo do parto, medo de dar à luz um filho com deficiência física ou mental, medo de mudanças de humor e medo de mudanças nas relações conjugais ($p < 0,05$), em comparação com o grupo de controle. **Conclusão.** A realização de aulas de capacitação durante a gravidez utilizando o método de discussão em grupo é uma boa estratégia para reduzir a ansiedade em gestantes. Portanto, recomenda-se que essa estratégia educativa seja utilizada com mães a partir do segundo trimestre de gestação em centros de medicina de família ou com aquelas que são encaminhadas ao ambulatório.

Descritores: ansiedade; gestantes; enfermeiras de saúde da família; segundo trimestre da gravidez.

Introduction

Despite the advancement of care in the field of physical problems during pregnancy and the change in the method of care provision from health centers to comprehensive centers for urban family physician services, anxiety problems with a prevalence of 54.2% in Iranian pregnant women are still an important issue in the area of health of Iranian pregnant women.^(1,2) Anxiety is a very unpleasant feeling commonly experienced that is sometimes left undiagnosed or with one or more physical symptoms such as a feeling of emptiness and shortness of breath^(3, 4). Several factors are directly or indirectly involved in the emergence of anxiety during pregnancy. For every woman, certain aspects of pregnancy are considered stressful.⁽⁵⁾ These factors include women's misunderstanding of pregnancy and labor pains, their low age and education,⁽⁶⁾ hearing scary stories from others, and the unpleasant experience of previous pregnancies and deliveries.⁽⁷⁾ Women's anxiety during pregnancy can be associated with important consequences, such as improper responses of the mother to the fetus during pregnancy and low birth weight of the child, reduced Apgar scores, postpartum depression, increased risk of preterm birth, and increased risk of neurological and mental illness of the child throughout his/her life.⁽⁸⁻¹⁰⁾

One of the best ways of reducing anxiety in pregnant women and sometimes even their families is attending training classes and group counseling and talking about their concerns with peer groups.⁽¹¹⁻¹³⁾ Pregnancy education in Iran, especially in high-risk populations and subgroups of pregnant mothers, is one of the most important factors effective on the prevention of mortality and reduction of the effects of prenatal complications and depression, anxiety, and subsequent problems.⁽¹⁴⁾ Prenatal training classes provide a great opportunity for mothers to correct their misconceptions and misinformation about pregnancy, delivery, and postpartum issues that cause anxiety among them, and decrease mental tension among women by increasing their understanding of the pregnancy process.⁽¹⁵⁾ In fact, these classes help pregnant mothers to meet other mothers in the same conditions to experience less anxiety and more confidence through familiarization with the resources available in their community.⁽¹⁶⁾ Since quality assurance and improvement of health care for pregnant women is a growing issue in the Iranian health system, and the systematic process of pregnancy care must be continuously and effectively implemented by all members of the family physician team,⁽⁵⁾ the health service delivery system has been replaced with comprehensive service centers in Fars and Mazandaran Provinces, Iran, since 2012. In the referral system program, the general practitioner and his team (health care provider such as midwife and nurse) have full responsibility for the health of individuals and families covered by them in accordance with a regular care program and, after referring them to specialists, they are responsible for following their condition.⁽¹⁷⁾

These services include prevention, education, health promotion, and health management services in the population covered.⁽¹⁸⁾ All pregnant women must enter the health care services provision chain through this team to receive health care services and receive the pregnancy care provided by midwives, nurse and other health care provider.⁽¹⁹⁾ In addition, health care supervisors should monitor these services and send the related reports and figures to the health centers on a monthly basis. However, the care services for anxiety in pregnant women are not uniformly available in the Iranian Integrated Health Record System (SIB), and the supplementary care provided for women diagnosed with pregnancy anxiety by the health care provider is in the form of referral to centers with psychiatrists, midwives, or nurse practitioners (NP). However, numerous problems such as overcrowding of health centers, the special condition of pregnant women, and the lack of easy access for women to the centers have prevented them from referring to comprehensive service centers and have limited pregnancy care to addressing physical problems and childbirth awareness. In addition, pregnant and newly delivered women in Iran are often fully supported by their families, and thus, have a greater need for training and counseling than care services from the family physician team.

Therefore, due to the presence of midwives or NPs in the family physician team as family nurses with the important role of caring for and educating family members,⁽²⁰⁾ the researchers decided to use the group training method in the form of family physicians as an important step in reducing women's anxiety problems, to find a way to provide emergency care for pregnant mothers. Pregnant mothers are certainly one of the high-risk groups and were under more care and follow-up during the New Coronavirus pandemics. In this important direction in our study, we tried to take a small step for this group thus; the aim of study is the effect of educational intervention on anxiety of pregnant women.

This was quasi-experimental study. The statistical population consisted of all eligible pregnant women who referred to the selected family physicians' offices in Gerash City, Iran from November 1 to December 1, 2021. The study was carried out with the objective to investigate the effect of group training on reducing pregnancy anxiety. After obtaining the necessary permissions from the research and ethics committee of Gerash University of Medical Sciences, Gerash, Iran, a list of family physicians' offices was prepared, which were randomly divided into 2 groups (intervention and control groups). For this work, the list of all family physicians was written on paper and placed in a box and the paper was randomly removed. Paired numbers were in the control group and odd numbers were in the intervention group. Then, by referring to the family physician's offices and by examining the electronic records, the pregnant women who had the study inclusion criteria were extracted. Adopting the quota sampling method, 70 pregnant women were selected as the participants. Using the Jokar *et al.* study with 95% confidence interval (CI) and 80% power, the sample size was determined as 31 individuals in each of the intervention and control groups, and considering a 15% loss of subjects, this amount was increased to 35 people in each group.⁽²¹⁾ In the final analysis, 4 subjects from the intervention group due to irregular attendance in the training classes and 4 subjects from the control group due to lack of access to the questionnaire were excluded from the study and 62 subjects (31 in each group) were examined. The study inclusion criteria were: being pregnant women, willingness to participate in the study, age <35 years old, being in the first and second trimesters of pregnancy, no history of hypertension, lack of gestational diabetes, lack of smoking, no signs of risk of miscarriage, lack of placenta Previa, ectopic pregnancy, bleeding, and mental illness, and being Iranian, and fluency in Persian. The exclusion criteria included any

problems or illnesses during pregnancy, such as bleeding, multifetal pregnancy, premature rupture of membranes (PROM), diabetes mellitus (DM), and preeclampsia, and failure to attend the training sessions.

Data Collection Tools. The data collection tools used included a demographic information questionnaire and the Pregnancy Related Anxiety Questionnaire (PRAQ-17). The demographic information questionnaire included 9 items related to age, gestational age, height, weight, gravidity, pregnancy type, education level, occupation of the pregnant woman, and average monthly family income. The PRAQ-17 was designed by Wendenburg and includes 17 items. The exploratory factor analysis (EFA) of data from this questionnaire showed 5 factors, with the factors indicating fear of childbirth (3 items), fear of giving birth to a physically or mentally disabled child (4 items), fear of changes in marital relations (4 items), fear of mood swings and its consequences on the child (3 items), and self-centered fears or fear of changes in the mother's personal life (3 items). The total score of this questionnaire is the sum of the scores of all items. The score of each item ranges between 1 and 7, so the total PRAQ-17 score can range from 17 to 119. This questionnaire does not have a cut-off point, but to examine correlations, it has been stated that if an individual has 65-70 percent of the assessed criteria, he/she can be identified as evidently anxious.

Validity and reliability of the questionnaire. The validity and reliability of the questionnaire were measured by Askarizadeh *et al.*⁽²²⁾ The reliability of the questionnaire was confirmed based on a Cronbach's alpha coefficient of 0.78; the Cronbach's alpha of the 5 factors ranged between 0.69 and 0.76. The CI of the questionnaire 1 month later in 40 pregnant women ranged from 0.65 to 0.72 ($p < 0.02$), indicating the reliability of the PRAQ-17 over time.

Intervention method. In addition to receiving routine pregnancy care at the family physician's

office in Gerash, the intervention group participants also took part in pregnancy training classes, but mothers in the control group received only routine pregnancy care. Prior to the intervention, Paper consent containing the information of the study research plan was obtained from pregnant women and the mothers were reassured that continuing to participate in the intervention was optional and the results was confidential. Before the intervention, the pregnant mothers in both groups completed demographic information questionnaire and PRAQ-17. The educational classes were presented in 8-12-person classes in 4 weekly 90-minute sessions. We held meetings with full observance of health protocols, observance of social distance, negative Rapid test for mothers. Classes were also held outdoors. Masks, shields and disinfectants were also given to the mothers. The educational content was based on the guidelines of the Iranian Ministry of Health and Medical Education.⁽²³⁻²⁵⁾ The educational content of the first session included an introduction to physiological changes during pregnancy, weight gain, edema, changes in skin color, and regular monitoring of these changes. The educational content of the second session included familiarization with the advantages and disadvantages of natural childbirth and cesarean section, and explanation on the stages of natural childbirth and methods of reducing pain during childbirth. The educational content of the third session included signs and symptoms of postpartum depression and its prevention and treatment strategies. The educational content of the fourth session included some information on physiological and anatomical changes during pregnancy, training on appropriate situations for sexual activity during pregnancy with the presentation of a chart of these conditions and ways to adapt to them, health education, and explanation on some common misconceptions about sexual activity during pregnancy. The last 30 minutes of each session were devoted to answering the participants' questions. The sessions were held through lectures, question-and-answer, group discussions, and pamphlets. The PRAQ-17 was again distributed among the

both group and completed by them 6 weeks after the end of the training sessions.

Ethical Issues. The present study was derived from research study with the code of ethics IR.GERUMS.RES.1396.018, which has been approved by Gerash University of Medical Sciences, Gerash, Iran. To resolve the ethical issues, we provided the training booklet to the control group after the study if they wished and wanted. Informed consent was obtained from all individual participants included in the study.

Data Analysis. To analyze the collected data, paired t-test, independent t-test, one-way analysis of variance (ANOVA), and the Pearson correlation coefficient were utilized in SPSS software (version 22; IBM Corporation, Armonk, NY, USA). The significance level was $p < 0.05$.

Results

A total of 62 subjects (31 women in each group) participated in the study, and the rate of the clearly anxious women in the whole sample before the intervention was 8.1%. There was no significant

relationship between any of the demographic characteristics and questionnaire subgroups in the whole sample before the intervention. The mean age of the women participating in the intervention and control groups was 27.23 ± 5.20 and 26.06 ± 5.51 years, respectively. The mean gestational age of the women participating in the experimental and control groups was 19.00 ± 4.35 and 20.25 ± 3.15 weeks, respectively. The mean body mass index (BMI) of the women participating in the intervention and control groups was 25.71 ± 3.71 and 23.61 ± 4.21 kg/m², respectively. Among the participants, 13 (41.9%) and 16 (51.6%) women, respectively, in the intervention group and control group were primiparous. The rate of wanted pregnancy in the control and intervention groups was equal (74.2%). Moreover, 22.6% and 29.0% of the pregnant women in the intervention and control groups had a university degree, respectively. In the intervention and control groups 80.6% and 87.1% of the subjects were housewives, respectively. The comparison of mean age and gestational age between the control and intervention groups at the beginning of the study did not show a significant difference ($p > 0.05$), but the mean BMI of the pregnant women in the intervention group was significantly higher than that of women in the control group ($p < 0.05$) (Tables 1 and 2).

Table 1. Comparison of mean scores of demographic information between control and intervention groups

Variable	Control group	Intervention group	<i>p</i> -value
	Mean \pm SD	Mean \pm SD	
Age	26.06 ± 5.51	27.23 ± 5.20	0.410
Gestational age	20.25 ± 3.15	19.00 ± 4.35	0.200
BMI	23.61 ± 4.21	25.71 ± 3.71	0.042

SD: Standard deviation; BMI: Body mass index

Table 2. Frequency distribution of demographic information of control and intervention groups

Variable	Control group		Intervention group		
	Number	Percentage	Number	Percentage	
Gravidity	Primiparous	16	51.6	13	41.9
	Multiparous	15	48.4	18	58.1
Pregnancy type	Intended	23	74.2	23	74.2
	Unintended	8	25.8	8	25.8
Education level	Illiterate	0	0	2	6.5
	Elementary	7	22.6	10	32.3
	Secondary school	3	9.7	7	22.6
	High school	12	38.7	5	16.1
	Academic degree	9	29	7	22.6
Occupation	Housewife	27	87.1	25	80.6
	Employee	3	9.7	6	19.4
	Other	1	3.2	0	0
Average monthly family income	< one million	14	45.2	13	41.9
	1-1.9 million	14	45.2	16	51.6
	2-2.9 million	2	6.5	2	6.5
	≥3 million	1	3.2	0	0

The independent t-test was employed to compare the mean scores of different aspects of pre-intervention pregnancy anxiety between the control and intervention groups. The results suggested that there was no statistically significant difference

between the groups in any of the dimensions (fear of childbirth, fear of giving birth to a physically or mentally disabled child, fear of mood swings, fear of changes in marital relations, self-centered fears, and total pregnancy anxiety) ($p > 0.05$) (Table 3).

Table 3. Comparison of mean scores of pregnancy anxiety dimensions before and after the intervention in the control and intervention groups

Dimensions of pregnancy anxiety	Group	Pre-intervention Mean \pm SD	Post-intervention Mean \pm SD	Independent t-test p -value
Fear of childbirth	Control	9.13 \pm 5.85	7.83 \pm 4.77	0.214
	Intervention	9.09 \pm 5.31	6.00 \pm 2.94	0.004
	p -value*	0.980	0.066	
Fear of giving birth to a physically or mentally disabled child	Control	8.90 \pm 5.83	7.61 \pm 4.73	0.327
	Intervention	8.58 \pm 5.48	5.64 \pm 1.72	0.003
	p -value*	0.823	0.033	
Fear of mood swings	Control	8.80 \pm 4.32	7.70 \pm 4.76	0.219
	Intervention	8.74 \pm 4.06	6.77 \pm 3.74	0.005
	p -value*	0.957	0.331	
Fear of changes in marital relations	Control	9.29 \pm 3.90	8.54 \pm 3.92	0.383
	Intervention	9.85 \pm 3.45	7.93 \pm 3.59	0.023
	p -value*	0.757	0.524	
Self-centered fears	Control	8.78 \pm 4.33	6.90 \pm 3.27	0.259
	Intervention	8.77 \pm 3.95	8.32 \pm 4.26	0.596
	p -value*	0.394	0.167	
Total pregnancy anxiety	Control	43.87 \pm 18.39	38.77 \pm 16.52	0.164
	Intervention	44.77 \pm 15.81	34.77 \pm 13.90	0.001
	p -value*	0.836	0.248	

* Independent t-test

The comparison of the mean scores of different dimensions of post-intervention pregnancy anxiety between the control and intervention groups indicated a decrease in the level of anxiety of pregnant mothers in both groups; however, the level of anxiety in the intervention group showed a greater decrease. The independent t-test showed a statistically significant difference in the mean score of fear of giving birth to a physically or mentally disabled child between the two groups in the post-intervention stage ($p < 0.05$), but there were no significant differences in the other dimensions (fear of childbirth, fear of mood swings, fear of changes in marital relations, self-centered fears, and total pregnancy anxiety) ($p > 0.05$) (Table 3).

Comparison of the mean scores of different dimensions of pregnancy anxiety in the control group before and after the intervention using paired t-test did not show a statistically significant difference ($p > 0.05$) (Table 3). Comparison of the mean scores of different dimensions of pregnancy anxiety in the intervention group before and after the intervention using paired t-test showed a statistically significant difference in all dimensions except self-centered fears ($p < 0.05$) (Table 3). No significant relationship was observed between the different dimensions of pregnancy anxiety and the demographic information ($p > 0.05$).

Discussion

The mean scores of different dimensions of pregnancy anxiety in the intervention group before and after the intervention revealed that the group discussion training method caused a statistically significant difference in all dimensions except self-centered fears. Girija *et al.* also considered group education as one of the main methods to reduce pregnancy anxiety in prim parous women and stated that prenatal group training can significantly reduce women's anxiety.⁽²⁶⁾ This results can be due to the use of the experiences

of the peer group under the supervision of the instructor and reduction of anxiety during training.⁽²⁷⁾ Fear of change in marital relations is one of the issues associated with anxiety in pregnant women on which group education had a positive effect ($p < 0.02$). Kazemi *et al.*⁽²⁸⁾ And Salehi and Shah Hosseini⁽²⁹⁾ declared that most pregnant Iranian women participating in the study had marital problems related to fear of harm to the fetus and physical problems. Akbarinejad *et al.* stated that, despite the cultural and religious limitations of women in expressing their marital problems, group education provided an opportunity for women in Gerash to reduce their fear of change in marital relations by reducing their pregnancy anxiety.⁽³⁰⁾

In urban family physician programs, pregnancy care is provided by a physician and health care provider such as nurses, while training classes are held at comprehensive health centers.⁽¹⁷⁾ According to the most recent statistics announced by the Gerash Health Department, pregnant mothers had the lowest participation rate in educational classes, so that only 8% participated in classes on natural childbirth benefits and 9% in childbirth danger education training class in 2019. Lu *et al.*⁽³¹⁾ stated that there is a gap between the current care provided and high-quality care, and that continuous follow-up and clarification can be effective in reducing this gap. In this regard, it can be claimed that the presence of health care providers (including NPs and midwives) alongside family physicians, as one of the main pillars of the referral system, plays a significant role in reducing pregnancy anxiety through their encouragement of pregnant mothers to participate regularly in pregnancy training classes and follow-up on their presence in these classes. Nurses Practitioner and midwife in the hospital can also use this training program to reduce the anxiety of women referring to labor and gynecology wards and even postpartum care.

Limitation of the study

This was a quasi-experimental study performed on pregnant women under 35 years of age who were

in the first and second trimesters of pregnancy, so it is recommended that subsequent clinical trials be performed on high-risk women (over 35 years of age or lower 18 years of old) with period follow up.

Conclusion. Holding pregnancy training classes using group discussion method is a suitable strategy to reduce anxiety in pregnant women covered by an urban family doctor. Therefore, it is recommended that educational classes be continuously held as group discussion in the second trimester of pregnancy in urban family physician centers or mothers be referred to a nearby clinic. The following up and monitoring of

these classes by health center education liaisons is also recommended. Therefore, group education under the supervision of a family physician can be used as an acceptable way to reduce anxiety and fear among pregnant women.

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Availability of data and materials. The data supporting the findings of the article is available in the <https://research.gerums.ac.ir/> or mail to Corresponding Author for more results.


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Design and Validation of a Self-care Evaluation Instrument to Prevent Diabetic Foot

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Original article



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Diseño y validación de un instrumento para la evaluación del autocuidado para la prevención del pie diabético

Resumen

Objetivo. Diseñar y validar un instrumento de autocuidado para prevenir el pie diabético en adultos colombianos con diabetes. **Métodos.** Estudio psicométrico en el que se diseñó un instrumento para la evaluación del autocuidado para prevención el pie según la Teoría de Mediano Rango del Autocuidado en enfermedades crónicas. Con una muestra de 230 personas con diabetes tipo 2, se determinó la validez de constructo mediante análisis factorial exploratorio y confirmatorio. La consistencia interna se calculó con el coeficiente alfa de Cronbach. **Resultados.** Se obtuvo evidencia favorable de validez de constructo con un modelo formado por tres escalas: mantenimiento del autocuidado con una estructura de tres factores (varianza acumulada 43 %), $\alpha = 0,7$ con buen ajuste ($\chi^2 = 64.698$, $p < 0,001$; RMSEA = 0.066; SRMR = 0.071; CFI = 0.936, NNFI = 0.910); monitoreo del autocuidado

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con la presencia de síntomas halló una estructura bifactorial (varianza acumulada 74.8 %) $\alpha = 0.950$, con buen ajuste ($\chi^2 = 266.83$, $p < 0.0001$; RMSEA = 0.321; SRMR = 0.057; CFI = 0.848; NNFI = 0.789) y sin presencia de síntomas con una estructura unifactorial (varianza acumulada 84 %) $\alpha = 0.9$ con ajuste aceptable ($\chi^2 = 377.327$, $p < 0.01$; RMSEA = 0.355; SRMR = 0.073; CFI = 0.832; NNFI = 0.764) y la tercera escala gestión del autocuidado con una estructura bifactorial (varianza acumulada 53.7%) $\alpha = 0.7$, con buen ajuste ($\chi^2 = 14.317$, $p = 0.014$; RMSEA = 0.144; SRMR = 0.063; CFI = 0.905; NNFI = 0.809). **Conclusión.** El instrumento resultante posee propiedades psicométricas adecuadas, coherente con el modelo teórico del autocuidado en enfermedades crónicas. Se recomienda su uso para la evaluación del autocuidado para la prevención del pie diabético en poblaciones similares a la población de estudio:

Descriptors: diabetic foot, primary prevention, self-care, nursing theory, psychometry.

Design and Validation of a Self-care Evaluation Instrument to Prevent Diabetic Foot

Abstract

Objective. This work sought to design and validate a self-care instrument to prevent diabetic foot in Colombian adults with diabetes. **Methods.** Psychometric study in which an instrument was designed to measure self-care to prevent diabetic foot according to the Medium Range Theory of Self-care in chronic diseases. With a sample of 230 people with type-2 diabetes, construct validity was determined through exploratory and confirmatory factor analysis. Internal consistency was calculated with Cronbach's alpha coefficient. **Results.** Favorable evidence of construct validity was obtained with a model consisting of three scales: self-care maintenance with a three-factor structure (accumulated variance 43%), $\alpha = 0.7$, with good fit ($\chi^2 = 64.698$, $p = 0.001$; RMSEA = 0.066; RMSSR = 0.071; CFI = 0.936, NNFI = 0.910). Monitoring of self-care with presence of symptoms a two-factor structure was found, $\alpha = 0.950$, with good fit ($\chi^2 = 266.837$, $p = 0.000$; RMSEA = 0.321; RMSSR = 0.057; CFI = 0.848; NNFI = 0.789); and without symptoms, a single-factor structure (cumulative variance 84%), $\alpha = 0.9$, acceptable fit ($\chi^2 = 377.327$, $p < 0.001$; RMSEA = 0.355; RMSSR = 0.073; CFI = 0.832; NNFI = 0.764). And self-care management with two-factor structure (cumulative variance 53.7%) $\alpha = 0.7$, with good fit ($\chi^2 = 14.317$, $p = 0.014$; RMSEA = 0.144; RMSSR = 0.063; CFI = 0.905; NNFI = 0.809). **Conclusions.** The resulting instrument has

adequate psychometric properties, consistent with the theoretical model of self-care in chronic diseases. Its use is recommended to evaluate self-care to prevent diabetic foot in populations similar to the study population.

Descritores: pie diabético, prevención primaria, autocuidado, teoría de enfermería, psicometría.

Desenho e validação do instrumento de avaliação de autocuidado para prevenir pé diabético

Resumo

Objetivo. Desenhar e validar o instrumento de autocuidado para prevenir o pé diabético em adultos colombianos com diabetes. **Métodos.** Estudo psicométrico no qual foi elaborado um instrumento para avaliação do autocuidado para prevenção do pé de acordo com a Teoria de Médio Alcance do Autocuidado em doenças crônicas. Com uma amostra de 230 pessoas com diabetes tipo 2, a validade de construto foi determinada por análise fatorial exploratória e confirmatória. A consistência interna foi calculada pelo coeficiente alfa de Cronbach. **Resultados.** Evidência favorável de validade de construto foi obtida com um modelo composto por três escalas: manutenção do autocuidado com estrutura de três fatores (variância cumulativa 43%), $\alpha = 0.7$ com bom ajuste ($\chi^2 = 64.698$, $p < 0,001$; RMSEA = 0.066, SRMR = 0.071, CFI = 0.936, NNFI = 0.910); monitoramento do autocuidado com a presença de sintomas, foi encontrada uma estrutura bifatorial (variância acumulada 74,8%) $\alpha = 0.950$, com bom ajuste ($\chi^2 = 266.83$, $p < 0.0001$; RMSEA = 0.321; SRMR = 0.057; CFI = 0.848; NNFI = 0.789) e sem a presença de sintomas com estrutura unifatorial (variância cumulativa 84%) $\alpha = 0.9$ com ajuste aceitável ($\chi^2 = 377.327$, $p < 0.01$; RMSEA = 0.355; SRMR = 0.073; CFI = 0.832; NNFI = 0.764) e a terceira escala de gestão do autocuidado com estrutura bifatorial (variância cumulativa 53.7%) $\alpha = 0.7$, com bom ajuste ($\chi^2 = 14.317$, $p = 0.14$; RMSEA = 0.144; SRMR = 0.063; CFI = 0.905; NNFI = 0.809). **Conclusão.** O instrumento resultante apresenta propriedades psicométricas adequadas, condizentes com o modelo teórico de autocuidado em doenças crônicas. Seu uso é recomendado para avaliação do autocuidado para prevenção do pé diabético em populações semelhantes à população do estudo.

Descritores: pé diabético, prevenção primária, autocuidado, teoria de enfermagem, psicometria.

Introduction

Diabetes mellitus (DM) is one of the biggest problems for health systems in Latin America. In Colombia, three of every 100 inhabitants has DM and it is one of the main causes of death among people between 30 and 70 years of age.⁽¹⁾ It is estimated that between 15% and 20% of diabetics will have foot ulcers during the course of its evolution and of these 30% will suffer amputation.⁽²⁾ Multiple risk factors are known to contribute to foot ulcers, hence, emphasis is placed on the importance of screening and classifying foot injuries and specific education to prevent diabetic foot.⁽³⁾ Thereby, the person with DM must enter a structured educational program from the moment of diagnosis to learn about the disease and become empowered to achieve and maintain adherence to the treatment and achieve self-care.⁽⁴⁾

It is known that self-care is carried out in both healthy and diseased states; however, self-care could have a different meaning in patients with chronic disease, given that it requires a set of behaviors to control the disease process, diminish the burden of symptoms, and improve survival.⁽⁵⁾ Therefore, health professionals and researchers need valid and reliable instruments that permit evaluating self-care in people with chronic diseases and prove the effectiveness of interventions focused on promoting self-care in this group of people.

Design of valid and reliable instruments to evaluate self-care in people with chronic disease is useful for the nursing discipline because they permit conducting research that provides useful scientific evidence for research and for the professional practice. According with Riegel *et al.*,^(5,6) the design of instruments based on middle range theories constitute empirical indicators that permit testing the practical utility of the theory through research and allows the empirical evidence provided by studies to be used to ratify, modify, or refine theories.

Currently, instruments exist to evaluate self-care in people with chronic diseases in overall manner⁽⁶⁾ and specifically for different chronic diseases, like heart failure,⁽⁷⁾ coronary heart disease,⁽⁸⁾ chronic obstructive pulmonary disease,⁽⁹⁾ arterial hypertension,⁽¹⁰⁾ which are validated in Colombia⁽¹¹⁾ and in DM.⁽¹²⁾ All these instruments were designed with the theoretical bases of the Middle Range Theory (MRT) of Self-care in chronic diseases.⁽¹³⁾

The Self-Care of Diabetes Inventory (SCODI) permits measuring self-care in people with DM. It consists of four scales: maintenance of self-care with three factors that evaluate exercise behaviors that promote health, behaviors of health promotion and disease prevention. The scale of monitoring self-care with two factors: listening to the body and recognizing symptoms. The scale of management of self-care that includes two factors: autonomous behaviors and

consultative behaviors, and the scale of confidence in self-care that reflects the degree of confidence patients have on their capacity to carry out a specific task related with self-care.^(12,13) The SCODI includes only one item related with maintenance of self-care of the feet (Do you take care of your feet (wash them, dries the skin, applies creams, and wears socks or orthopedic stockings?) and a single item related with monitoring self-care (Do you control the state of your feet daily to check for injuries, reddening, or blisters?). It does not include behaviors related with management of self-care to prevent diabetic foot.

Consequently, the study observed lack of information to evaluate specifically behaviors of self-care to prevent diabetic foot. Due to this, the aim of this study was to design and validate an instrument that permits evaluating self-care to prevent diabetic foot in people with DM2.

Methods

A psychometric study was conducted.⁽¹⁴⁾ The study was carried out by following the phases proposed by LoBiondo and Habers⁽¹⁵⁾, which are described hereinafter.

Phase I. Theoretical definition of the construct to be measured

A theoretical, methodological and empirical review of the self-care construct was performed and of the scientific evidence of foot care to prevent diabetic foot. The MRT of self-care in chronic diseases defines the self-care construct as a process to maintain health through health promotion practices and disease management. It has three concepts: maintenance of self-care, monitoring self-care, and management of self-care.⁽¹³⁾ The objective of maintenance is to maintain health and prevent exacerbations of symptoms; the objective of monitoring is the recognition

that bodily change has occurred, monitoring or listening to the body, and the objective of management of self-care is that responding to symptoms implies an evaluation of changes in physical and emotional signs and symptoms to determine if action is necessary. Monitoring of personal care is the link between maintenance of self-care and management of self-care. For example, people with DM2 perform monitoring activities, like measuring blood sugar and early detection of signs and symptoms of changes in blood glucose; likewise, they must understand its severity to take measures before the situation worsens.^(5,13) Within this context, the study reviewed behaviors of self-care to prevent diabetic foot. The Colombian guidelines for the prevention, diagnosis, and treatment of diabetic foot proposes five basic elements to prevent diabetic foot: daily direct observation of the feet; maintaining the skin clean, fresh, and moisturized; wearing with daily change of special prevention stockings: footwear, adapted to the type of feet and immediate direct and trustworthy communication and among patients and their relatives and the management staff.⁽²⁾ These recommendations were kept in mind to formulate the items of the instrument.

Phase II. Formulation of the instrument's items

The Instrument of Self-care for prevention of diabetic foot (ISPDF) was designed with the theoretical bases of the MRT of self-care in chronic diseases.⁽¹³⁾ Self-care behaviors identified in the literature permitted the construction of the items grouped into three scales to reflect the theory's three central concepts: maintenance of self-care, monitoring self-care, and management of self-care. The scale of maintenance of self-care included the common recommendations given by health providers for the prevention of the diabetic foot related with daily care of the feet (maintaining the skin clean, fresh, and moisturized, wearing special stockings and footwear) and behaviors related with the disease (adherence to treatment regimen and monitoring and controlling diabetes).

The self-care monitoring behaviors discussed in the literature were grouped into behaviors related with listening to the body, identifying the first manifestations of foot injuries, and monitoring signs and symptoms. The self-care management behaviors were grouped into autonomous self-care as actions to eliminate risk factors and consultative self-care, like direct and immediate communication upon the presence of symptoms of diabetic foot with the family and health staff.

Phase III. Development of instructions for users and experts

During the design of the first version of the new instrument denominated ISPDF, the different phases of test creation proposed by Muñiz and Fonseca-Pedrero were followed.⁽¹⁶⁾ The purpose of the instrument was determined, assuming that the variable to be observed is self-care. Upon drafting the items, it was taken into account that they were not ambiguous, seeking to express a single idea per statement. The scale was constructed with 29 items, specifying the characteristics of the items and its Likert-type response format, according to the three dimensions to evaluate: maintenance of self-care (10 items) with five response options, where never is equal to 1 and always is equal to 5. Monitoring self-care (without symptoms 9 items, with symptoms 11 items) has five response options, where never is equal to 1 and always is equal to 5 and items 20 and 21 with 6 response options, where *I did not recognize the symptom* is equal to 0 and very quickly is equal to 5. The scale of management of self-care (8 items) with 5 response options, where never is equal to 1 and always is equal to 5.

Phase IV. Validity and reliability tests of the Instrument

The apparent and content validity of the ISPDF was evaluated by six judges (nurses with PhD, clinical and psychometry experience), who evaluated the instrument based on three

qualifying criteria: comprehension, clarity, and precision. Fleiss' kappa index was calculated,⁽¹⁷⁾ which permitted determining agreement between observers correcting for chance. The results were interpreted as satisfactory those items obtaining values comprised between 0.61 and 0.80, recognized as substantial agreement. These same experts evaluated each of the items with the following criteria: "essential", "useful but not essential", and "not necessary". With the data obtained, the content validity ratio and the content validity index of the whole instrument were calculated, following the modified Lawshe model,⁽¹⁸⁾ which establishes a value ≥ 0.58 to consider an item as acceptable, independent of the number of evaluators.

To carry out the construct validity tests, there was a sample of 234 people with DM2 registered in diabetes control programs in four healthcare centers of the network of first level of care in Montería- Colombia, in 2019. To determine the sample size, a number > 200 and a rate > 5 subjects per variable were set, recommended for psychometric analyses, to offer Good guarantees in estimating the parameters, especially with models that include few variables with respect to that proposed by Gorsuch.⁽¹⁹⁾ According to the foregoing, from a population of 614 people registered in diabetes control programs, a sample was chosen of 234 participants calculated with 95% confidence level and 5% margin of error. The sample selection process was through convenience. The inclusion criteria were being older than 18 years, having a medical diagnosis of DM2 according to the criteria of the Clinical Practice Guideline for the diagnosis of DM2 in population over 18 years of age.⁽²⁰⁾ The study excluded patients with high comorbidity, mental and/or sensory deficit.

A sociodemographic characteristics questionnaire developed by the researchers was applied to each of the participants together with the ISPDF instrument designed. To ensure the quality of the data, logistic and operational aspects were taken

into account, such as training for the application of the instrument, providing a place free of interference, giving information to participants before administering the instrument, and adopting the comprehensibility and completeness criteria, seeking to know that the participants understood the indications the instrument contemplates and verifying that all the items were respectively filled out and correctly completing the study database.

The data were analyzed in the SPSS statistical program version 22.0. Initially, an analysis was performed of the descriptors (mean, standard deviation, asymmetry, kurtosis, and item-total corrected correlation coefficient), expecting to obtain calculations of the asymmetry and kurtosis indices, between ± 1.96 in the normality test.⁽²⁰⁾ To assess the adequacy of the sample size and the correlation among variables, the Kaiser-Meyer-Olkin test was used (≥ 0.6 is acceptable) and Bartlett's sphericity test ($p < 0.05$) prior to implementing the factorial analysis. The exploratory factorial analysis (EFA) was performed by using maximum likelihood as extraction method, with Oblimin rotation. An inflection point of 0.32 was taken as the minimum value of factor loading required to maintain each element extracted from the factorial analysis. The criterion to determine what items belong to the factor is the factor loading, which indicates the degree of relation between the item and the factor. The loads of all the elements must be ≥ 0.30 .⁽²¹⁾

For the Confirmatory Factor Analysis (CFA), the data were processed in the IBM SPSS Amos statistical package - version 26.0. The following goodness of fit indices were evaluated: the p value associated with the Chi-squared (χ^2) statistic, which tests the null model against the hypothesized or proposed one. Not resulting statistically significant ($p > 0.05$) can be interpreted as indicator of an adequate fit of the model to the data. The comparative fit index (CFI) was also included, which compares the improvement in the fit of the model in question with a null model to evaluate the degree of loss

produced in the fit when changing from the model proposed to the null model) and the non-normed fit index (NNFI or TLI), which reflects the total proportion of information explained by a model; to accept the model proposed, the value of CFI, TLI must be ≥ 0.9 . Among the indices based on the covariances, the work opted for the root mean square error of approximation (RMSEA) and the root mean square standardized residual (RMSSR), considered optimal when their values are 0.05 or less, and acceptable in the range from 0.05 to 0.08. Akaike's information criterion (AIC) is considered along with the PRATIO parsimony index as measurements of the relative quality of a statistical model because, given a set of candidate models for the data, the model with the best fit is that with the minimum value of these measures.⁽²²⁾

The internal consistency was evaluated by calculating Cronbach's alpha (α) coefficient. The corrected element-total correlation was determined as corrected homogeneity coefficient; if < 0.2 , it is eliminated. A value of $\alpha \geq 0.7$ is expected to consider that the ISPDF is reliable for use in research.⁽²³⁾

The study was conducted according with Resolution 8430 of 1993⁽²⁴⁾ and Legislation 911 of 2004.⁽²⁵⁾ It had the University's ethical endorsement and obtained approval from the healthcare institution where the participants were recruited to carry out the study. All the participants provided their written consent.

Results

Apparent and content validity

The 29 items of the preliminary version of the ISPDF were scored by the panel of experts ($n = 6$) with impact score > 1.5 . Hence, these were adequate and retained. The study obtained Fleiss' kappa index of 0.7 in comprehension, 0.8 in clarity, and 0.8 in precision, which was interpreted as

substantial agreement. All the items were accepted (content validity ratio > 0.79); the content validity index was reported as satisfactory (0.9).

Construct validity

Of the sample of 234 people with DM2, most were women (57%); the mean age was 55 years; the majority reported low educational level (86%) and low income (89%), as shown in Table 1. The average time of being diagnosed with DM2 was four years. The results obtained in the descriptive analysis, based on asymmetry and kurtosis, provides information to detect data normality.

Maintenance of self-care. For the self-care maintenance scale, the internal consistency resulted acceptable with $\alpha = 0.70$. Given the

results of the corrected item-total correlation, there was no need to eliminate any item. The Kaiser-Meyer-Olkin (KMO) sample adequacy index was adequate to apply the EFA, which obtained a three-factor structure that explains 43% of the accumulated variance. The first factor was constituted by items 8, 9, and 10; the second factor by items 4, 5, 6, and 7; and the third factor by items 1, 2, and 3, with item 2 having the lowest communality.

In the CFA, the model suggested by the EFA had better results with respect to the single-factor model of the 10 items that conform the maintenance scale ($\chi^2 = 64.698$, $p = 0.001$; RMSEA = 0.066; RMSSR = 0.071; CFI = 0.936, NNFI = 0.910) being a good fit according to interpretation criteria of the fit indices, as shown in Table 2.

Table 1. Sociodemographic characteristics of the sample (n = 234)

Variable	Frequency	%
Sex		
Female	133	57
Male	101	43
Educational level		
Writes and reads	82	35
Primary	119	50.9
Secondary	18	7.7
Technical	9	3.8
Professional	6	2.6
Income		
< 1 CLMW	210	89.7
≥ 1 CLMW	24	10.3
Has health social security	234	100

CLMW: current legal minimum wage in Colombia, 2019

Table 2. EFA and CFA of the self-care maintenance scale of the ISPDF

EFA (KMO = 0.738; Chi squared: 547.233; df = 45; $p < 0.000$)										
$\alpha = 0.7$ $n = 234$		Factor loading								
10 items		Factor 1	Factor 2	Factor 3						
1.	Do you wash and dry your feet, especially between the toes?			0.577						
2.	Do you moisturize your feet with moisturizing cream to prevent dryness?			0.379						
3.	Do you take care that your feet do not stay wet for a long time?			0.552						
4.	Do you cut your nails straight, avoiding the use of sharp objects?		0.585							
5.	Do you wear thick, seamless, non-pressure stockings without holes or special stockings for people with diabetes?		0.787							
6.	Do you use good shoes, preferably those that when the sole is folded, stay rigid or have a personalized insole adapted to your feet?		0.655							
7.	Do you take care of your feet from the cold and heat?		0.441							
8.	Do you attend your medical and/or nursing check-up appointments?	0.842								
9.	Do you follow the doctor's and/or nurse's recommendations for diabetes control?	0.743								
10.	Do you comply with the treatment to control diabetes?	0.742								
% Variance by factor		21.122	17.886	4.403						
% Accumulated variance		21.122	39.008	43.411						
CFA										
Models	Absolute Fit Measurements						Incremental fit measures		Parsimony fit measures	
	Chi squared	df	p	SRMSR	RMSEA	90%CI	CFI	NNFI	PRATIO	AIC
10-item single-factor model	261.019	35	0.000	0.153	0.166	0.148 – 0.186	0.559	0.433	0.778	301.019
Three-factor model suggested by the EFA	64.698	32	0.001	0.071	0.066	0.043 – 0.089	0.936	0.91	0.711	130.698

Extraction method: principal component analysis. Loads > 0.32 were accepted. Rotation method: Varimax normalization with Kaiser. CI: confidence interval; χ^2 : chi-squared; df: degrees of freedom; *significance $p > 0.05$; AIC: Akaike Index; NNFI: Non-Normed of Fit Index; CFI: Comparative Fit Index; RMSSR: Root Mean Standard Square Residual; RMSEA: Root Mean Square Error of Approximation.

Monitoring self-care. In the self-care monitoring scale conformed by 11 items, observations associated with item 19 (Keep a record of symptoms?) had zero variance, not providing information to the calculation of Cronbach's alpha and the factorial analysis, which is why it was excluded from the analysis. Monitoring self-care can be evaluated in patients with and without symptoms of diabetic foot. The EFA was performed in the sample with symptoms of diabetic foot and in the sample without symptoms of diabetic foot. The results are presented ahead.

With diabetic foot symptoms. The KMO index had an adequate value to apply the factorial analysis. The EFA was conducted with 10 of the 11 items proposed in the scale, item 19 that was eliminated due to zero variance. The EFA results suggested a two-factor structure for which the factor loading of item 20 (How quickly did you recognize you had symptoms in the feet (reddening, blisters, injuries, burns, calluses, ingrown toe nails, fungus, infections, etc.?) did not exceed the minimum established, hence, it was eliminated, leaving a two-factor model that explains 59% of the accumulated variance, factor one conformed by items 11, 12, 13, 15, and 21 and factor two with items 14, 16, 17, and 18. The CFA results indicate a better fit for the two-factor model suggested by the EFA ($\chi^2 = 266.837$; $p = 0.000$; RMSEA = 0.321; RMSSR = 0.057; CFI = 0.848; NNFI = 0.789). Internal consistency was quite good ($\alpha = 0.950$). Table 3 shows the EFA and CFA results.

Without diabetic foot symptoms. The KMO value was Good to apply the EFA. Table 4 shows the EFA and CFA results. A single-factor structure was maintained conformed by eight items that explains 84% of the accumulated variance. The structure of the factor was constituted by items 11, 12, 13, 14, 15, 16, 17, and 18, registering at least a communality of 0.725 for item 17. Note that item 21 should not be included, considering the nature of the question. Although not reaching the optimal values in the CFA for the fit indices, CFI, NNFI and RMSA, the RMSSR was within the acceptable ranges ($\chi^2 = 377.327$; $p = 0.000$; RMSEA = 0.355; RMSSR = 0.073; CFI = 0.832; NNFI = 0.764) with respect to a single-factor structure. The internal consistency was quite good ($\alpha = 0.97$).

Management of self-care. In the self-care management scale, the reliability analysis indicated that the internal consistency increased if item 25 was eliminated (Take medications to control diabetes?), given that it was correlated negatively with the other items, going from having Cronbach's alpha from 0.608 to 0.667. The KMO permitted applying the EFA. A two-factor structure was obtained, which explains 53.7% of the accumulated variance, with acceptable internal consistency ($\alpha = 0.732$) and fit ($\chi^2 = 14.317$, $p = 0.014$; RMSEA = 0.144; RMSSR = 0.063; CFI = 0.905; NNFI = 0.809); the results are shown in Table 5.

Table 3. EFA and CFA of the self-care monitoring scale of the ISPDF in people with diabetic foot symptoms

EFA (KMO = 0.769; Chi squared: 1594; df = 45; p < 0.000)												
$\alpha = 0.95$ n=91											Factor loading	
9 items											Factor 1	Factor 2
11. Monitor injuries or evidence of future foot injuries daily?											0.991	
12. Pay attention to changes observed in feet?											0.985	
13. Observe the feet and spaces between the toes with a mirror or a magnifying glass?											0.955	
14. Watch for evidence of future foot injury (redness, swelling, calluses, etc.)?												0.978
15. Check for foot injuries and infections (wounds, ulcers, ingrown nail infections, fungus, etc.)?											0.778	
16. Inform the health provider if you have a sensation of cutting pain in your feet, burning pain, numbness, sensation of needle-like pricking, pain in your legs that forces you to sit down?												0.941
17. Closely monitor symptoms?												0.895
18. Verify diabetic foot symptoms with the health provider?												0.971
21. How quickly did you know that the symptom was due to diabetic foot?											0.368	
% Variance by factor											59.208	15.895
% Accumulated variance											59.208	74.895
CFA												
Models	Absolute Fit Measurements						Incremental fit measures		Parsimony fit measures			
	Chi squared	df	p	SRMSR	RMSEA	90%CI	CFI	NNFI	PRATIO	AIC		
10-item single-factor model (without item 19)	820.301	35	0.000	0.132	0.499	0.470 – 0.529	0.517	0.379	0.778	865.87		
Two-factor model suggested by the EFA	266.837	26	0.000	0.057	0.321	0.287 – 0.356	0.848	0.789	0.722	304.837		

Source: own authorship. Extraction method: principal component analysis. Loads > 0.32 were accepted. Rotation method: Varimax normalization with Kaiser. CI: confidence interval; (χ^2 : chi-squared; df: degrees of freedom; *significance $p > 0.05$; AIC: Akaike Index; NNFI: Non-Normed of Fit Index; CFI: Comparative Fit Index; RMSSR: Root Mean Standard Square Residual; RMSEA: Root Mean Square Error of Approximation.

Table 4. EFA and CFA of the self-care monitoring scale of the ISPDF in people without diabetic foot symptoms

EFA (KMO = 0.850; Chi squared: 2097.34; <i>df</i> = 28; <i>p</i> < 0.000)										
$\alpha = 0.977$ <i>n</i> =143										Factor loading
8 items										Factor 1
11. Monitor injuries or evidence of future foot injuries daily?										0.994
12. Pay attention to changes observed in the feet?										0.994
13. Observe the feet and spaces between the toes with a mirror or magnifying glass?										0.965
14. Watch for evidence of future foot injury (redness, swelling, calluses, etc.)?										0.885
15. Check for foot injuries and infections (wounds, ulcers, ingrown nail infections, fungus, etc.)?										0.859
16. Inform the health provider if you have a sensation of cutting pain in your feet, burning pain, numbness, sensation of needle-like pricking, pain in your legs that forces you to sit down?										0.790
17. Closely monitor symptoms?										0.852
18. Verify diabetic foot symptoms with the health provider?										0.810
% Variance by factor										84.412
% Accumulated variance										84.412
CFA										
Models	Absolute Fit Measurements						Incremental fit measures		Parsimony fit measures	
	Chi squared	<i>df</i>	<i>p</i>	SRMSR	RMSEA	90%CI	CFI	NNFI	PRATIO	AIC
Single-factor model suggested by the EFA	377.327	20	0.000	0.073	0.355	0.324 – 0.386	0.832	0.764	0.714	409.327

Source: own authorship. Extraction method: principal component analysis. Loads > 0.32 were accepted. Rotation method: Varimax normalization with Kaiser. CI: confidence interval; χ^2 : chi-squared; *df*: degrees of freedom; *significance *p* > 0.05; AIC: Akaike Index; NNFI: Non-Normed of Fit Index; CFI: Comparative Fit Index; RMSSR: Root Mean Standard Square Residual; RMSEA: Root Mean Square Error of Approximation.

Table 5. EFA and CFA of the self-care management scale of the ISPDF

EFA (KMO = 0.610; Chi squared: 260.91; <i>df</i> = 21; <i>p</i> < 0.000)										
$\alpha = 0.73$ <i>n</i> = 234										Factor loading
7 items										Factor 1 Factor 2
22. Eliminate factors that are injuring the feet (dryness, signs of pressure, moisture, etc.)?										0.464
23. Perform cleaning and disinfection of foot injuries?										0.960
24. Perform glycemetic control (Glucometer)?										0.942
26. Consult with health care provider for guidance?										0.742
27. Ask a relative or friend for advice?										0.639
28. Consult with the doctor immediately?										0.774
29. Evaluate if the treatment improved the symptoms?										0.368
% Variance by factor										26.470 27.278
% Accumulated variance										26.470 53.749
CFA										
Models	Absolute Fit Measurements						Incremental fit measures		Parsimony fit measures	
	Chi squared	<i>df</i>	<i>p</i>	SRMSR	RMSEA	90%CI	CFI	NNFI	PRATIO	AIC
7-item single-factor model (without item 25)	177.022	14	0.000	0.185	0.360	0.313 – 0.408	0.346	0.020	0.667	205.022
7-item two-factor model suggested by the EFA	14.317	5	0.014	0.063	0.144	0.059 – 0.234	0.905	0.809	0.500	34.317

Source: own authorship. Extraction method: principal component analysis. Loads > 0.32 were accepted. Rotation method: Varimax normalization with Kaiser. CI: confidence interval; χ^2 : chi-squared; *df*: degrees of freedom; *significance *p* > 0.05; AIC: Akaike Index; NNFI: Non-Normed of Fit Index; CFI: Comparative Fit Index; RMSSR: Root Mean Standard Square Residual; RMSEA: Root Mean Square Error of Approximation.

Bearing in mind the results of reliability, of the EFA and CFA, the ISPDF was finally comprised of 26 items distributed into three scales: maintenance of self-care conformed by 10 items, monitoring of symptoms with 8 or 9 items with or

without diabetic foot symptoms, respectively, and management of self-care with 7 items. The factor structure and the correlations obtained among the variables and the items from each of the scales are shown in Figure 1.

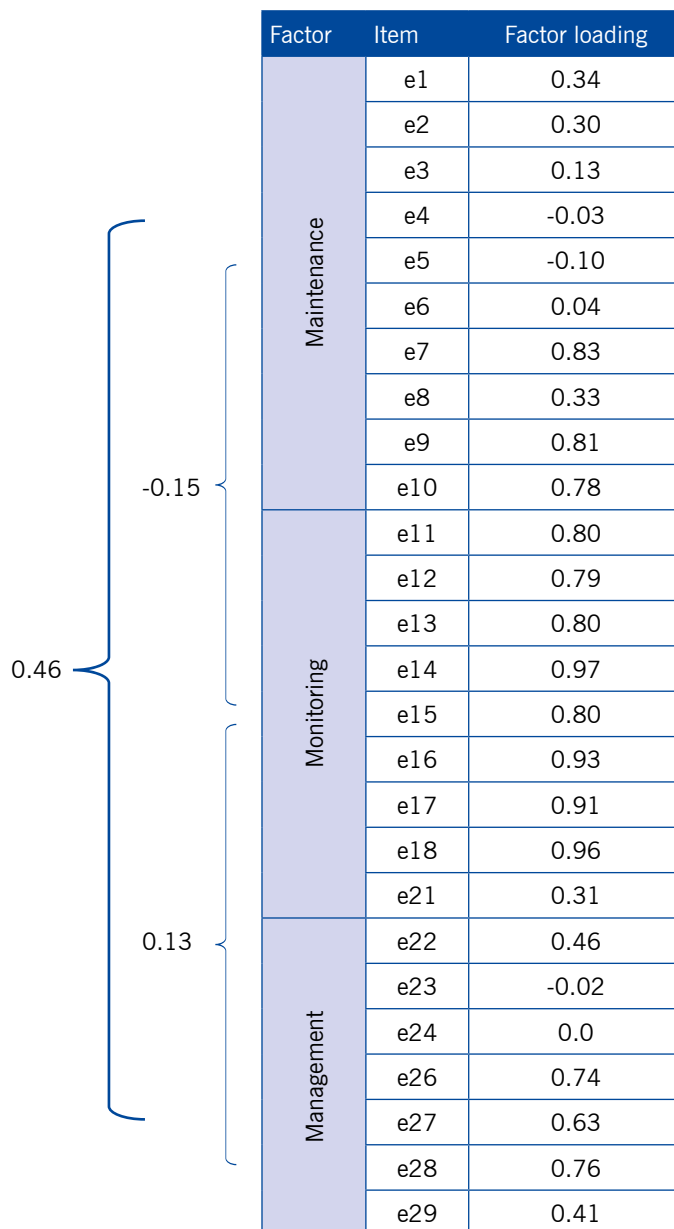


Figure 1. Structural diagram of the confirmed model and the factor loadings

The following presents the scoring algorithm of the ISPDF, which was carried out by bearing in mind the theoretical-conceptual foundations associated with the measurement model that indicates that the instruments developed with the MRT of self-care in chronic diseases must follow a scoring algorithm that can be used to calculate the answers with standardized scores. The three scales have a standardized score range from 0 to 100. A higher score means better self-care. Each of the scales must be calculated separately, never globally. For interpretation, it is necessary to transform the score from each scale into a standardized score ranging between 0 and 100 using the following formula: actual raw score – lowest possible raw score/ possible raw score range by 100.⁽²⁶⁾

To calculate the scores of each of the ISPDF scales, first add the total score to obtain the actual raw score. In the self-care maintenance scale (10 items), the lowest possible raw score is 10 and the highest is 50; the possible raw score range is 40. Monitoring self-care, with 8 or 9 items, depends on the lack or presence of symptoms; the lowest possible raw score is 8 or 9 and the highest possible is 40 or 45, thereby, the possible raw score range is 32 or 36, respectively. In the self-care management scale with 7 items, the lowest possible raw score is 7 and the highest possible is 40 and the possible score range is 33. The final version of the instrument designed is included as annex at the end of this article.

Discussion

The aim of this study was to design a new instrument that permits evaluating self-care to prevent diabetic foot and evaluate its validity and reliability psychometric properties. The ISPDF was designed, ensuring the theoretical base of the instrument in an MRT that describes, explains, and predicts self-care in chronic diseases.

Now, this is not the first study that applies the MRT of self-care in chronic diseases on the design of instruments that permit measuring self-care; this theory has been widely used in the design and validation of instruments with good results.⁽⁷⁻¹²⁾ Studies conducted reflect the empirical adequacy of said theory in the study of the self-care construct that comprises three core concepts, that is, maintenance of self-care, monitoring self-care, and management of self-care that represent the theoretical dimensions of self-care in chronic diseases.

The exploratory factorial analysis for the ISPDF reported a three-factor structure in the variable for maintenance of self-care; the factor loadings ranged between 0.36 and 0.96. The goodness-of-fit indices for this model were statistically significant with acceptable fit. The correlations estimated between the maintenance and monitoring variables were -0.15; between maintenance and management 0.46, and between monitoring and management 0.13. The correlations in the maintenance scale with 10 items ranged between -0.3 and 0.83, indicating low, moderate and high correlations.

In the ISPDF, the scale for maintenance of self-care measures the behaviors destined to daily care of the feet grouped into three factors that promote health, prevent the disease, and help to maintain the disease stable through adherence to DM treatment. This result has been found in other psychometric studies of instruments that assess self-care developed with the theoretical model of the MRT of self-care in chronic diseases, which show that maintenance of self-care is a multifactor scale.⁽²⁷⁾

The EFA for the ISPDF in the variable for self-care monitoring reported a two-factor structure in people with diabetic foot symptoms; the factor loadings ranged between 0.36 and 0.99. The goodness-of-fit indices for this two-factor model were statistically significant with acceptable fit. The correlation estimated among the factors was

0.71 and the correlation with most of the items was ≥ 0.8 , indicating moderate and high correlations. This study identified a two-factor model for the scale of self-care monitoring or perception of symptoms, similar to that proposed in the theoretical model that includes two factors: listening to the body and recognition of symptoms.^(12,13)

For the self-care management scale, the EFA reported a two-factor structure; the factor loadings ranged between 0.36 and 0.96. The goodness-of-fit indices for this two-factor model were all statistically significant with acceptable fit. The correlations estimated among the factors were 0.71 and correlations for the factors with the items ranged between -0.2 and 0.76, indicating low and moderate correlations. The two-factor model is similar to that proposed in the theoretical model that includes two factors: autonomous behaviors and consultative behaviors that characterize the behaviors used by people with DM2 to control their symptoms.^(12,13)

It must be highlighted that the EFA for the ISPDF was guided by the MRT of self-care in chronic diseases. This prior theory permitted proposing hypothesis on the number of factors and of the pattern expected. The validity results obtained confirm the theoretical hypotheses that support the self-care construct in chronic diseases, demonstrating that the three scales of the ISPDF permit measuring self-care. These results are consistent with previous studies conducted in people with diabetes applying the *Self-Care of Diabetes Inventory*,⁽¹²⁾ the *Self-Care of Heart Failure Index*,⁽⁷⁾ the *Self-Care of Coronary Heart Disease Inventory*,⁽⁸⁾ the *Self-Care in Chronic Obstructive Pulmonary Disease Inventory*⁽⁹⁾, and the *self-care of hypertension inventory*⁽¹⁰⁾, which demonstrates the empirical adequacy of the MRT of self-care in chronic diseases in the design of new instruments, like the ISPDF.

The differences found with respect to other studies regarding those found in this study are related with the dimensionality of the scale

of self-care maintenance; prior psychometric studies, like the *Self-Care of Heart Failure Index*,⁽⁷⁾ have demonstrated that behaviors of self-care maintenance comprise two dimensions or factors: consultation behaviors and dietetic behaviors. The *Self-Care of Diabetes Inventory*⁽¹²⁾ comprises four dimensions labeled as: exercise behaviors that promote health (Factor 1), disease prevention behaviors (Factor 2); health promotion behaviors (Factor 3), and behaviors related with the disease (Factor 4).

Reliability measured as internal consistency of the scale of self-care maintenance ($\alpha = 0.7$), monitoring self-care ($\alpha = 0.9$), and management of self-care ($\alpha = 0.7$), was adequate in the sample studied. According with the MRT of self-care of chronic diseases, self-care behaviors reflect a sequence, *i.e.*, most patients first dominate self-care maintenance and then construct experience in monitoring self-care and management of self-care. That is, the three concepts are closely related, illustrating that they are related behaviors from the same general construct; hence, effective performance of self-care encompasses the three behaviors, which must be measured separately and never globally.⁽⁵⁾

This study had some limitations, the sample was recruited in a municipality of the country and, although representing different ages and sexes and the sample size was that suggested for psychometric studies ($n > 200$), it may not be stated that it is representative of the whole Colombian population with DM2. Other psychometric tests of the ISPDF should be performed in different zones of the country and with larger samples. This study did not prove the capacity to detect changes in the construct over time; this requires experimental studies with interventions that promote self-care to permit evaluating the effects of the changes in the self-care behavior and contribute to refining the theory to create sound evidence-based knowledge.

The impact the study could have for the population diagnosed with DM2 and for the nursing discipline

lies mainly on the need to include in the nursing evaluation empirical indicators derived from the MRT of self-care in chronic diseases, which permit identifying where the person is having problems to carry out the self-care behaviors; necessary information to perform specific and adapted interventions centered on improving self-care processes (maintenance, monitoring, and management). Studies reveal that high levels of self-care improve metabolic control,⁽²⁸⁾ reduce hospitalizations,⁽²⁹⁾ complications related with DM2,⁽³⁰⁾ and improve health-related quality of life in people with DM2.⁽³¹⁾

In conclusion, the ISPDF is a valid and reliable instrument that permits measuring self-care to prevent diabetic foot in people with DM2 in population similar to the conditions in this study, based on the MRT of self-care in chronic diseases. The instrument is comprised of 26 items distributed into three independent scales: self-care maintenance, monitoring self-care, and management of self-care that showed good psychometric properties in a Colombian population. Its use is recommended for research.

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Appendix

Instrument to evaluate self-care to prevent diabetic foot

All answers are confidential.

Think of how you have felt during the last month while you fill out this questionnaire.

SECTION A. Listed below are behaviors that people with Type 2 Diabetes Mellitus use to help themselves to maintain foot care. How often or routinely do you do the following?

(Check a number)

Maintenance of self-care	Never		Sometimes		Always
1. Do you wash and dry your feet, especially between the toes?	1	2	3	4	5
2. Do you moisturize your feet with moisturizing cream to prevent dryness?	1	2	3	4	5
3. Do you take care that your feet do not stay wet for a long time?	1	2	3	4	5
4. Do you cut your nails straight, avoiding the use of sharp objects?	1	2	3	4	5
5. Do you wear thick, seamless, non-pressure stockings without holes or special stockings for people with diabetes?	1	2	3	4	5
6. Do you use good shoes, preferably those that when the sole is folded, stay rigid or have a personalized insole adapted to your feet?	1	2	3	4	5
7. Do you take care of your feet from the cold and heat?	1	2	3	4	5
8. Do you attend your medical and/or nursing check-up appointments?	1	2	3	4	5
9. Do you follow the doctor's and/or nurse's recommendations for diabetes control?	1	2	3	4	5
10. Do you comply with the treatment to control diabetes?	1	2	3	4	5

SECTION B. The following lists the changes people with Type 2 Diabetes Mellitus tend to monitor in their feet. How often do you do the following?

(Check a number)

Monitoring of self-care	Never		Sometimes		Always	
11. Monitor injuries or evidence of future foot injuries daily?	1	2	3	4	5	
12. Pay attention to changes observed in the feet?	1	2	3	4	5	
13. Observe the feet and spaces between the toes with a mirror or magnifying glass?	1	2	3	4	5	
14. Watch for evidence of future foot injury (redness, swelling, calluses, etc.)?	1	2	3	4	5	
15. Check for foot injuries and infections (wounds, ulcers, ingrown nail infections, fungus, etc.)?	1	2	3	4	5	
16. Inform the health provider if you have a sensation of cutting pain in your feet, burning pain, numbness, sensation of needle-like pricking, pain in your legs that forces you to sit down?	1	2	3	4	5	
17. Closely monitor symptoms?	1	2	3	4	5	
18. Verify diabetic foot symptoms with the health provider?	1	2	3	4	5	
19. How quickly did you know that the symptom was due to diabetic foot?	I have not had symptoms N/A	I did not recognize the symptom 1	Not quickly 2	Somewhat quickly 3	Quickly 4	Very quickly 5


SECTION C. The following lists the behaviors people with Type 2 Diabetes Mellitus tend to use to control their symptoms of diabetic foot. How likely are you to try the following actions?

(Check a number)

Management of self-care	Unlikely		Somewhat likely		Very likely
20. Eliminate factors that are injuring the feet (dryness, signs of pressure, moisture, etc.)?	1	2	3	4	5
21. Perform cleaning and disinfection of foot injuries?	1	2	3	4	5
22. Perform glycemic control (Glucometer)?	1	2	3	4	5
23. Consult with health care provider for guidance?	1	2	3	4	5
24. Ask a relative or friend for advice?	1	2	3	4	5
25. Consult with the doctor immediately?	1	2	3	4	5
26. Evaluate if the treatment improved the symptoms?	1	2	3	4	5

The importance of applying the statement of assent to children and adolescents: a qualitative study

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The importance of applying the statement of assent to children and adolescents: a qualitative study

Abstract

Objective. To describe the importance of the Statement of Assent for children and adolescents invited to participate in a clinical study and their main reactions to its explanation. **Methods.** This is an exploratory descriptive qualitative study of 17 children and adolescents, who were invited to participate in a clinical study in the field of oncology in a hospital located in Rio de Janeiro (Brazil). Data were analyzed using thematic analysis. **Results.** Two thematic units were generated after data interpretation: signing the statement of assent, in which participants felt their main role when faced with the possibility of expressing their agreement or not to take part in the study; and understanding of the study, when they showed that they understood the steps of the study by asking pertinent questions to clarify their doubts. Children and adolescents understood the steps of the study contained

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in the Statement of Assent, were interested and asked questions to clarify their doubts about the study. **Conclusion.** The Statement of Assent was important for participants understanding the study and having autonomy over their participation. As the statement strengthened the main role of children and adolescents in the research process, the conclusion was that its use in studies involving the pediatric population should be encouraged.

Descriptors: ethics committees, research; consent forms; informed consent by minors; child; adolescent.

La importancia de la aplicación del término de consentimiento para niños y adolescentes: un estudio cualitativo

Resumen

Objetivo. describir la importancia del Formulario de Consentimiento Informado para los niños y adolescentes invitados a participar en un estudio clínico aleatorizado y sus principales reacciones a su explicación. **Métodos.** se trata de una investigación exploratoria descriptiva con abordaje cualitativo, realizada con 17 niños y adolescentes, quienes fueron invitados a participar de un estudio clínico en el área de oncología en un hospital ubicado en Río de Janeiro (Brasil). A los datos se les realizó análisis temático. **Resultados.** Luego de la interpretación de los datos, se generaron 2 unidades temáticas: la firma del formulario de consentimiento y la comprensión del estudio. Los niños y adolescentes entendieron las etapas del estudio contenidas en la firma del Término de Asentimiento y se interesaron, haciendo preguntas para aclarar sus dudas sobre la investigación. **Conclusión.** El consentimiento informado era importante para que los participantes entendieran la investigación y tuvieran autonomía sobre su participación. Al potenciar el protagonismo de los niños y adolescentes en el proceso de investigación, recomendamos que debe fomentarse su uso en los estudios con población pediátrica.

Descritores: comitês de ética em pesquisa; termos de consentimento; consentimento informado por menores; criança; adolescente.

A importância da aplicação do termo de assentimento para crianças e adolescentes: um estudo qualitativo

Resumo

Objetivo. Descrever a importância do Termo de Assentimento para crianças e adolescentes convidados a participar de um estudo clínico e suas principais reações quanto à explicação do mesmo. **Métodos.** Trata-se de uma pesquisa do tipo descritiva exploratória com abordagem qualitativa, realizada com 17 crianças e adolescentes, que foram convidados a participar de um estudo clínico na área da oncologia em um hospital localizado no Rio de Janeiro (Brasil). Os dados foram analisados empregando-se a análise temática. **Resultados.** Após a interpretação dos dados, foram geradas 2 unidades temáticas: a assinatura do termo de assentimento em que os participantes se sentiram protagonistas frente a possibilidade de expressarem a concordância ou não em participar da pesquisa, e a compreensão sobre o estudo quando elas mostraram que entenderam as etapas do estudo fazendo perguntas pertinentes para esclarecer suas dúvidas. As crianças e adolescentes compreenderam as etapas do estudo que constavam no Termo de Assentimento e tiveram interesse, fazendo perguntas para esclarecer suas dúvidas com relação à pesquisa. **Conclusão.** O termo de assentimento foi importante para os participantes compreenderem sobre a pesquisa e para terem autonomia sobre sua participação. Por potencializar o protagonismo de crianças e adolescentes no processo de pesquisar conclui-se que seu uso em estudos que envolvem a população pediátrica deve ser incentivado.

Descriptor: comitês de ética en investigación; formularios de consentimiento; consentimiento informado de menores; niño; adolescente.

Introduction

Research consists of systematic investigation using orderly methods to find answers to certain questions and solve problems. Clinical research is intended to guide professional practice for the improvement of patients' health and quality of life.⁽¹⁾ Studies in the area of nursing usually emerge from problems arising during the daily practice of nurses. In Nursing, research is necessary for the development and achievement of a solid scientific basis to guarantee the quality of care provided, credibility and growth of the profession.⁽²⁾ When research involves human beings, participants are required to sign the Informed Consent (IC) form. In Brazil, according to resolution 466, of December 12, 2012, of the National Health Council, the IC process involves all the steps that must be necessarily observed so that people invited to participate in a study can express themselves autonomously, consciously, freely and in an informed manner.

For children or legally incapable children, the Statement of Assent (SA) is a document in which all steps of the study are explained in accessible and appropriate language for each age group, so that they are duly clarified and can, therefore, agree or not to participate in a particular study.⁽³⁾ In this sense, studies whose participants are children and adolescents require greater attention in order to make the objectives and purposes and possible risks and benefits of the study understood. This attitude of talking to children, explaining that the procedure will only take place if they allow it, even if their responsible person has already authorized it, makes them feel respected in their right and individuality. Obtaining consent of the responsible person and the child or adolescent is fundamental for relationships in the research and a sign of respect for participants' dignity, their ability to express opinions and their right to be heard on issues affecting them.⁽³⁾

Assent, like consent, is an ongoing process that seeks to involve children in decision-making through the disclosure of key information and procedures in appropriate language, and by children's expression of their preferences. Assent is the means by which children exercise their right to participate in the context of clinical research. It is extremely important because it includes the child in the study as a participant and establishes a relationship of trust between the child, researchers and the responsible person, thereby reducing the risks of coercion and exploitation.⁽⁴⁾ However, studies showing the opinion of children and adolescents about their understanding and acceptance of the SA are scarce. Therefore, the aim of this article is to describe the importance of the SA for children and adolescents invited to participate in a specific randomized clinical trial and their main reactions to the explanation of the steps of the study contained in the SA.

Methods

This is a descriptive, exploratory, qualitative study in which facts or phenomena were observed, recorded and analyzed without being manipulated.⁽⁵⁾ The type of design adopted allowed the description and exploration of meanings attributed by children when they were explained about the steps of a clinical study by means of information contained in the SA. This article is part of an excerpt from a data collection performed for a dissertation aimed at evaluating the effects of laser acupuncture for the relief of nausea and vomiting in pediatric patients undergoing chemotherapy.⁽⁶⁾ It was a clinical study in which participants were randomized into two groups: one would receive true acupuncture and the other group would receive placebo acupuncture. The SA was used to explain all steps of the study and to clarify the issue of the groups (randomization) and participants' doubts. In the greater research project of which this excerpt is part, the principles of Resolution n.466 of 2012 were followed, and it was approved by the Research Ethics Committee of the National Cancer Institute, according to opinion n. 978.441, CAAE 33745514.0.0000.5243. The data collection period was between March and November 2015.

Children and adolescents aged 6-17 years of both sexes undergoing chemotherapy for solid tumors were included in this study. The SA was prepared according to two age groups: 6-12 years and 13-17 years. This division was a requirement of the institution's ethics committee, which felt the need for a form prepared according to each age group. Then, the statement was prepared with language and pictures aimed at each age group, for the better understanding of children and adolescents. The chemotherapy outpatient clinic where participants underwent chemotherapy was the setting. A nurse from the sector (an oncology and acupuncture specialist) applied the SA. During

the explanation of the SA and clarification about the study, the behavior, reaction and speech of participants was observed. After that moment, all observations were written in a field diary.

All children and adolescents who agreed to participate in the study were invited to sign the SA. The youngest child was 6 years old, and despite not knowing how to write her name perfectly, she was encouraged and stimulated to do it her own way and within her possibilities. The Informed Consent form was given to the responsible person, who would sign and consent to the minor's participation. For an easier understanding of the study, a language for each age group was used, as well as pictures and images to stimulate interest. Participants' names were omitted from the study and each one was instructed to choose a codename to protect their identities. Each codename presented was chosen by children and/or adolescents themselves. They were explained that even with authorization of their legal guardians, they would need to assent and sign the document, authorizing their participation in the study, and they were not obliged to participate if they did not want to.

Data were analyzed following the steps of thematic analysis.⁽⁷⁾ For the operationalization of this process, after transcribing the dialogues, the material was read for the exploration of contents, and treatment and interpretation of results obtained. Speeches were classified using a colorimetric method, that is, words and expressions with the same meaning were grouped in the same color and codes were generated, giving rise to two thematic units: signing the assent term, and understanding about the study. In order to avoid limiting the analysis to the researcher's view, two more researchers worked independently in the formation of codes and thematic units. Afterwards, there was a meeting between researchers for discussion and consensus in relation to discrepancies.

Results

Seventeen participants were interviewed, including children and adolescents; nine were male, eight participants were aged 6-12 years, and nine were 13-17 years old. (Table 1).

Signing the statement of assent

The approach to participants aged 6-12 years old, as they were younger, occurred through a game, always with the responsible person next to them, so they felt safer. They showed interest and were receptive from the first moment of the approach. They wanted to be sure that their responsible person would be there with them at the time of conversation, as shown in the statements: *Can*

my Mom hear it too? (Elsa); *Mom ... stay here and hear this with me* (Mulher Maravilha).

It was made clear that their permission and signature was essential and that even if their responsible person authorized it, they would not be included in the study if they did not want to. Although indispensable, parental consent alone was not sufficient. Children have guaranteed rights and the right to a voice. Thus, it is essential that the researcher guarantees conditions for the child's choice of participating or not in a certain study. During the dialogue, it becomes clear how crucial the responsible person's consent is for children's participation in the study: *Mom, I'm going to sign now, can I? Have you already signed?* (Menguinho); *Mom, we both have to sign, okay?* (Elsa); *Mom, sign it too, along with me* (Pokemon); *Mom! Sign yours too!* (Batman).

Table 1. Characterization of participants

Codename	Age	Sex
Guerreiro de Jeová	6	M
Ana	9	F
Menguinho	10	M
Pokemon	10	M
Anita	10	F
Elza	11	F
Mulher Maravilha	12	F
Batman	12	M
Bem	13	M
Margarida	13	F
Peter Pan	13	M
Rosinha	14	F
Rapunzel	14	F
Dragon Ball Z	15	M
Cinderela	16	F
Junior	16	M
Neymar	17	M

Only one out of the eight children aged 6-12 years old (Guerreiro de Jeová, 6 years old) took the SA to be signed at home. When he returned with the signature, the mother reported that upon arriving home, the child sat at his little table very happy to sign, demonstrating satisfaction for deciding on the participation in the study. Like him, other children showed satisfaction in signing the term: *See, mom, I'm important... I had to sign it...* (Guerreiro de Jeová); *See mom, I also have to sign. Just like you* (Anita).

At the first moment, when participants aged 13-17 years were asked if they could be approached to talk about the study, they nodded their heads to demonstrate a yes, consenting to the approach. They were usually wearing headphones or lying with their entire bodies covered. They did not ask questions and when asked if they had understood the explanation about the SA, they simply responded with gestures (nodding or shaking the head to deny). Only one out of the nine participants in this age group signed the SA after explanation about the study. Eight took the form home and brought it signed in the next meeting. Adolescents were more reticent in the first contact, and had to take the SA form to be read at home and clarified their doubts in the next meeting. The following speeches demonstrate this attitude: *Can we talk later? It's just that I'm sleepy...* (Ben); *Can you talk later?* (Margarida); *Do I have to sign today? Ah... I'd like to think... Can I answer later?* (Neymar); *I'm not signing today, okay?* (Junior); *I'll take it home...* (Dragon Ball Z).

Understanding about the study

Participants in both age groups asked questions about the study, wanting to understand the research better. However, in the younger age group, these questions were asked on the same day of the explanation about the study. And the most frequent doubts were about pain, especially about pain in laser acupuncture: *Will it be painful and how will I know if the research worked or not?* (Batman); *Does the laser hurt? How long does it take to do the laser?* (Anita); *Will I feel*

pain? (Guerreiro de Jeová); *Will it hurt, nurse?* (Pokémon); *What will I feel?* (Mulher Maravilha).

In the age group of 13-17 years, doubts were clarified in a second meeting, and the issue of pain was not so much questioned. Their most frequent questions were about the steps of the study. Teenagers' speeches demonstrate the desire for clarifications. In the second meeting, an adolescent declared not feeling comfortable participating in the study, understanding that it would be the place of a guinea pig: *I don't want to be a guinea pig... I don't want to be used for testing* (Junior). After this report, it was explained that the laser had already been used with children and adolescents in other studies and the researcher just wanted to see its effect in relieving post-CT nausea and vomiting. After this new conversation, the teenager understood the matter and signed the SA, demonstrating comprehension of this step of the study.

Like Junior, other adolescents also expressed their doubts about the intervention that would be performed. None of them was left without the proper clarification: *Is laser acupuncture as good as needle acupuncture?* (Margarida); *How will I know if it worked or not?* (Cinderela); *Can I leave the study later, if I want to?* (Neymar). The study in question was about the application of laser acupuncture that would always be performed immediately before chemotherapy. On the day of the procedure, when a nurse from the Chemotherapy Center (CT) went to see Anita to administer chemotherapy, the patient said: *No Miss, you have to wait. The research nurse said that the light* (word she used to identify the laser) *has to be done before chemotherapy* (Anita).

The chemotherapy nurse explained that she would wait and reported the child's speech to the researcher. This shows how much Anita understood the procedure and was attentive to the steps of the study protocol. There was a withdrawal from the study. A few days after signing the term, Ana said she no longer wanted to take part in the study: *I don't want to do the laser anymore...*

I want to stop doing it, but my Mom wants me to continue... (Ana). The researcher talked to the mother and explained that the daughter's wish had to be respected. She also asked Ana if that was what she wanted and the child reaffirmed her desire. It was clarified that nothing she did not allow would be done and she was free to withdraw from the study. At that moment, Ana became calmer and thanked her.

In the clinical study for which patients were being invited to participate, there was randomization into two groups: one group with true laser acupuncture and the other with placebo laser acupuncture. A lot of care was necessary to make the understanding of this issue of division of groups easier, and the explanation was repeated as many times as needed. Still, some children did not understand the existence of two groups: *But why do you have to have two groups?* (Dragon Ball Z); *I want to be into the real group, because I feel sick a lot* (Rosinha); *Why can't I know which group I'm in, if in the true or false group?* (Rapunzel).

In view of the above, a new explanation was necessary and very calmly, the researcher explained the randomization process and its importance. She made it clear that she would not be the one to choose; children would do it themselves by picking the envelope in which there would be a letter directing them to one of the groups.

Discussion

In this study, where the importance of applying the statement of assent was evaluated, it was found that participants had doubts to be clarified. Through assent, it is assumed that underage participants should be helped in a way that is appropriate to their level of development, so they understand the nature of the study and have all their doubts clarified.⁽⁸⁾ As in the case of this

article, Lambert and Glacken,⁽⁹⁾ in a study to obtain the signature of children and adolescents for a survey, also formulated statements of assent for two age groups; one for the group of children aged 6-10 years and the other for children aged 11-16 years. The authors reinforce the importance of attention and care with the size of the letter used, the choice for simple words without technical terms, and an attractive and interactive design. They also emphasize the scarcity of studies on the subject and the importance of disseminating experiences of signing statements of assent and informed consent forms by children and the responsible person.⁽⁹⁾

In the present study, it was very important for pediatric patients to decide if they accepted or not to participate in a clinical study. However, for the range of participants aged 6-12 years, the agreement of the responsible person was fundamental and made them more confident and certain of the decision. In a study conducted with children to identify their knowledge about the SA, 47.8% confirmed that someone could influence their decision to participate in the investigation; most cited the mother (69.1%), followed by the father (13.2%), and the others mentioned some other type of person, such as another family member or the health professional.⁽¹⁰⁾ This result is in agreement with what was observed in the present study regarding the age group of 6-12 years. However, for participants aged 13-17 years, at first, the consent of the responsible person did not prove to be decisive for these teenagers' participation in the study. Autonomy and the right to decision-making must be guaranteed to participants. Together with their responsible person, they must be involved in decision-making about their participation or not in research or treatments.^(11,12)

The ability to use information and weigh risks and benefits regarding different options to make a choice was evaluated in a review that demonstrates the emergence of this skill in late childhood and early adolescence, that is, from

the age of 12 or 13 years.⁽¹³⁾ During this period, children begin to reason abstractly about certain situations, alternatives and consequences, to combine multiple variables in a more complex way and examine information in a systematic and exhaustive way. These results converge with those of the present study, where children's doubts were mainly about the issue of pain. The older ones (13-17 years old) had questions about randomization, the effect of laser acupuncture and what would happen if they wanted to withdraw from the study. These questions demonstrate a greater ability to understand information, generating more complex doubts about the procedures.⁽¹³⁾

Participants must be given the right to withdraw from the study whenever they wish, without compromising their treatment and care. The participant Ana had her desire respected when she wanted to leave the study. Participants in a study must be aware they are engaging in a voluntary activity that can be stopped without personal consequences,⁽¹⁴⁾ and their autonomy and decision must be considered, as declared in the SA they signed. Children need to feel comfortable and fearless to talk to the researcher about their wishes regarding participation or not in the study.⁽¹⁴⁾

As for approach strategies for children in research situations, their peculiarities, developmental needs and individual characteristics must be taken into account. Therefore, a SA was designed for each age group taking part in the interview. It is important that the researcher knows the way of thinking, feeling and acting at different ages. Therefore, each stage of contact with the child must be planned, although modifications and adaptations may be necessary during interactions.^(14,15) The adolescents interviewed in the present study (with the exception of one) did not sign the SA on the same day they were approached. They received the document and a recommendation to read it at home and talk with their responsible person or with whom they trusted. In this context, Lind et al.⁽¹⁵⁾ report that an individualized view

of adolescents and their limits brings them closer to the researcher and increases their engagement with the study, providing the necessary tools for their understanding.

Later, when adolescents returned with their doubts, they seemed more receptive to clarifications. In this sense, researchers must show understanding and interest in children/adolescents and above all, make an effort to convey their real intention, clarifying their doubts so that they understand and consequently, can decide whether or not to participate in the study.^(8,12) In a survey that estimated the opinion of parents and children (minors) in studies on informed consent, the general view of adolescents was that they should have control over any decision involving them.⁽¹⁶⁾ Such data corroborate the present article, where adolescents were not concerned with the signature and consent of their responsible persons.

Every participant needs to understand why they are invited to participate and what the study is like. The components included in the statement of assent aimed at the pediatric population must differ and be formulated according to the level of development of each age group.⁽¹⁷⁾ In addition, during the approach to children, researchers must assess their understanding, including the use of other methods and strategies, such as drawing, photography and stories to make themselves understood.⁽¹⁸⁾ Children need to be informed according to their understanding and their participation must be well planned; they are the ones who teach us the path and the way it should be followed.⁽¹⁹⁾ Therefore, with this research it was possible to give voice to pediatric participants. The importance of a SA formulated for each stage of development and explained according to children's ability to understand was observed. This was found by considering that they understood the steps of the study, clarified their doubts and had the option of signing or not, thereby deciding on their participation in the study.

Conclusion. Obtaining the SA signature in studies of children and adolescents requires tools aimed at the age groups of participants. Although the informed consent form must be signed by the responsible person because participants are underage, the authorization of children or adolescents involved must also be obtained, thus considering their ability to understand and make decisions.

In this study, the act of deciding whether or not to sign the SA was important for participants. Children aged 6-12 years signed the SA on the same day, and approval by the responsible person was essential so they could feel safe and agree to participate in the study. On the other hand,

participants aged 13-17 years (with the exception of one) signed the SA in a second meeting and did not show much concern regarding the consent of the responsible person. Both groups understood the steps of the study, expressed their fears and had their doubts answered.

By strengthening the protagonist role of children and adolescents in the research process, we concluded that the use of the SA in studies involving the pediatric population should be encouraged. More studies related to the topic should be conducted, so the participation of the pediatric population in research is done ethically and conscientiously.

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Effect of the Implementation of Interdisciplinary Discharge Planning on Treatment Adherence and Readmission in Patients Undergoing Coronary Artery Angioplasty

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Effect of the Implementation of Interdisciplinary Discharge Planning on Treatment Adherence and Readmission in Patients Undergoing Coronary Artery Angioplasty

Abstract

Objective. To determine the effect of interdisciplinary discharge planning on treatment adherence and readmission in the patients undergoing coronary artery angioplasty in the south of Iran in 2020. **Methods.** This experimental study had an intervention group and a control group with pre-test and post-test. 70 patients participated in the study who were randomly divided into the groups (intervention group ($n=35$) and control group ($n=35$)). In the intervention group, discharge planning was performed based on an interdisciplinary approach. Treatment adherence before, immediately, and one month after the intervention was evaluated with a 10-question survey scored from 1 to 5 (maximum score = 50), as well as readmission three months after the discharge was

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examined in both groups. **Results.** Before the intervention, there was no statistically significant difference between the intervention and the control groups in the treatment adherence score (18.22 versus 17.37; $p=0.84$) but immediately and one month after the intervention statistically significant differences between the groups were showed (21.51 versus 46.14 and 23.28 versus 43.12, respectively; $p<0.001$). Within three months after discharge, the readmission rate was 11.4% in the control group, while no readmission was reported in the intervention group. Within three months after discharge, the readmission rate was 11.4% in the control group, while no readmission was reported in the intervention group. **Conclusion.** The implementation of interdisciplinary discharge planning had positive effects on treatment adherence and readmission rate in patients undergoing coronary artery angioplasty; therefore, it is suggested that health care system managers make the necessary plans to institutionalize this new educational approach for other patients discharge planning.

Descriptors: interprofessional relations; patient discharge; patient readmission; patient compliance; angioplasty.

Efecto de la implementación de la planificación interdisciplinaria del alta en la adherencia al tratamiento y el reingreso en pacientes sometidos a angioplastia de la arteria coronaria

Resumen

Objetivo. Determinar el efecto de la planificación interdisciplinaria del alta en la adherencia al tratamiento y el reingreso en los pacientes sometidos a angioplastia de la arteria coronaria en el sur de Irán en 2020. **Métodos.** Este estudio experimental contó con un grupo de intervención y un grupo de control con evaluación pre-test y post-test. Participaron en el estudio 70 pacientes que se dividieron aleatoriamente en los grupos. En el grupo de intervención, la planificación del alta se realizó sobre la base de un enfoque interdisciplinario. En ambos grupos se examinó la adherencia al tratamiento antes, inmediatamente y un mes después de la intervención con una encuesta de 10 preguntas puntuadas de 1 a 5 (máximo puntaje = 50), así como el reingreso hasta tres meses después del alta. **Resultados.** Antes de la intervención, no hubo diferencias estadísticamente significativas entre el grupo de intervención y el de control en la puntuación de la adherencia al tratamiento (18.22 versus 17.37; $p=0.84$), pero inmediatamente y un mes después de la intervención los grupos mostraron una diferencia estadísticamente significativa (21.51 versus 46.14 y 23.28 versus 43.12, respectivamente; $p<0.001$). A los tres meses del alta, la tasa de reingreso fue del 11.4% en el grupo de control, mientras que no se

registró ningún reingreso en el grupo de intervención. **Conclusión.** La aplicación de la planificación interdisciplinaria del alta tuvo efectos positivos la adherencia del tratamiento y la tasa de reingreso en los pacientes sometidos a angioplastia de las arterias coronarias; por lo tanto, se sugiere que los gestores del sistema sanitario hagan los planes necesarios para institucionalizar este nuevo enfoque educativo para la planificación del alta de otros pacientes

Descritores: relaciones interprofesionales; alta del paciente; readmisión del paciente; cooperación del paciente; angioplastia.

Efeito da implantação do planejamento de alta interdisciplinar na adesão ao tratamento e readmissão em pacientes submetidos à angioplastia coronariana

Resumo

Objetivo. Determinar o efeito do planejamento de alta interdisciplinar na adesão ao tratamento e readmissão em pacientes submetidos à angioplastia de artéria coronária no sul do Irã em 2020. **Métodos.** Este estudo experimental contou com um grupo intervenção e um grupo controle com avaliação pré-teste e pós-teste. Participaram do estudo 70 pacientes que foram divididos aleatoriamente em grupos. No grupo intervenção, o planejamento da alta foi realizado com base na abordagem interdisciplinar. Em ambos os grupos, a adesão ao tratamento foi examinada antes, imediatamente e um mês após a intervenção com um questionário de 10 questões pontuadas de 1 a 5 (pontuação máxima = 50), bem como a readmissão até três meses após a alta. **Resultados.** Antes da intervenção, não houve diferenças estatisticamente significativas entre os grupos intervenção e controle na pontuação de adesão ao tratamento (18.22 vr. 17.37; $p = 0.84$), mas imediatamente e um mês após a intervenção os grupos apresentaram diferença estatisticamente significativa (21.51 vr. 46.14 e 23.28 vr. 43.12, respectivamente; $p < 0.001$). Aos três meses após a alta, a taxa de readmissão foi de 11.4% no grupo de controle, enquanto nenhuma readmissão foi registrada no grupo de intervenção. **Conclusão.** A aplicação do planejamento de alta interdisciplinar teve efeitos positivos na adesão ao tratamento e na taxa de readmissão em pacientes submetidos à angioplastia de artéria coronária; portanto, sugere-se que os gestores do sistema de saúde façam os planos necessários para institucionalizar essa nova abordagem educativa para o planejamento da alta de outros pacientes.

Descritores: relações interprofissionais; alta do paciente; readmissão do paciente; cooperação do paciente; angioplastia.

Introduction

The increasing number of heart diseases and hospitalizations related to them, as well as high health care costs, have presented a serious challenge to the health care system in most countries.⁽¹⁾ According to the American Heart Association, 35% of all deaths worldwide are due to cardiovascular disease.⁽²⁾ World Health Organization estimates that if proper preventive measures are not taken, coronary artery disease (CADs) will have killed 25 million people by 2020.⁽³⁾ In Iran, more than 40% of deaths are caused by cardiovascular diseases.⁽⁴⁾ Angioplasty is one of the treatment methods which is substituted for coronary artery bypass graft (CABG) surgery to treat many patients with coronary artery disease.⁽⁵⁾ Compared to surgery methods, this method is less risky and is also cost-effective in terms of medical expenses.⁽⁶⁾ Some studies show that medication adherence plays a leading role in the success of the treatment of cardiovascular disease.^(7,8) World Health Organization defines medication adherence as the rate of individual behavior including Medicines Consumption, diet adherence, or lifestyle changes based on the recommendations of caregivers.⁽⁹⁾

Some studies indicate that cardiovascular disease patients' adherence to care and treatment recommendations is not very satisfactory, resulting in readmission, the increase in healthcare costs, the deterioration of side effects; finally, the reduction of quality of life and death of patients.^(10,11) Thus, nurses can be helpful in the rate of medication adherence and the reduction of patient readmission rates due to their long and direct contact with the patient and their participation in the discharge planning.⁽¹²⁾ In discharge planning, patient health information is exchanged among the patient, caregivers, and those who are responsible for the patient's health.⁽¹³⁾

Discharge planning can be performed via several methods and one of them is the interdisciplinary approach. It is necessary to adopt the interdisciplinary approach throughout the healthcare chain to have effective discharge planning.⁽¹⁴⁾ In the interdisciplinary approach, employees from two or more professions decided to promote their cooperation with each other to improve the quality of patient care/service delivery.⁽¹⁵⁾ On the other hand, a better understanding of care program in staff and patients can also be provided in this approach via dynamic interaction and effective cooperation between healthcare service providers.⁽¹⁶⁾ An interdisciplinary approach refers to a more integrated level of work by several disciplines to redefine problems outside of normal boundaries and reach solutions based on a new understanding of complex situations.⁽¹⁷⁾

Today, the nurses provide the patients with the necessary training at the time of discharge in Iran, and they arrange the next appointment for the patients to see the doctor in the clinic and follow the medical services; however, other nursing care services end with the patient's discharge. Since no discharge intervention

with an interdisciplinary approach was performed in Iran to follow medication adherence in patients undergoing angioplasty, the present study tries to determine the effect of interdisciplinary discharge planning on treatment adherence and readmission in patients undergoing coronary artery angioplasty in the south of Iran in 2020.

Methods

This quasi-experimental study had an intervention group and a control group with pre-test and post-test. The sample size was calculated based on Negarandeh *et al.* study.⁽¹⁸⁾ Furthermore, it was calculated as 31 for each group by comparing two means of $\alpha = 0.05$ and $\beta = 0.1$ using the following equation, and it is then decided to increase the members of each group to 35 people.

$$n = \frac{(z_{1-\frac{\alpha}{2}} + z_{1-\beta})^2 \sigma^2}{(\mu - \mu_0)^2}$$

This study was conducted using convenience sampling. It means that if the patients, who were referred to the cardiology ward and underwent coronary artery angioplasty, they could meet the inclusion criteria were selected, which were entered into the study when the goals were explained to them and informed written consent was obtained from them. Patients were randomly divided into intervention group ($n=35$) and control group ($n=35$).

Inclusion criteria are admission in the cardiology ward, using coronary artery angioplasty, telephone access, no suffering from a debilitating disease, disability in speech, hearing, and vision, ability to speak and answer the questions, and complete satisfaction in the participation in the study. On the other hand, exclusion criteria are the history of Alzheimer's disease, proven mental or psychological disorders, as well as other advanced diseases other than heart problems such as liver cirrhosis, cancers, rheumatic

diseases, and inability to communicate. Data collection tools consist of the demographic questionnaire including age, sex, marital status, level of education, occupation, risk factors for heart disease, patient diagnosis, duration of heart disease, other co-morbidities, and medical record of heart health indicators such as heart rate and blood pressure. Since there was no specific treatment adherence questionnaire for patients undergoing coronary angioplasty, this study has prepared a researcher-made questionnaire to assess medication adherence. By examining other studies and applying experts' opinions. The treatment adherence questionnaire for patients undergoing angioplasty includes ten items ranged from 1 (never) to 5 (always): 1) I take my medicine on time; 2) I take care of the site of stent insertion in angioplasty as recommended by the medical health care team; 3) I follow my diet regime as recommended by the medical health care team; 4) If there are any side effects of medical drugs, I will go to the medical center as soon as possible; 5) I adjust my activity and rest as recommended by the medical health care team; 6) Refrain from discontinuing or reducing medications arbitrarily without consulting the medical health care team; 7) After discharge from the hospital, I do the follow-up medical procedures such as medical tests, ECGs, and echocardiography as recommended by the medical health care team; 8) I follow the treatment recommendations completely even without the supervision and control of the medical health care team; 9) After discharge from the hospital, if I feel chest pain, shortness of breath, and bleeding from the site, I will go to the medical center as soon as possible; and, 10) I refrain from risky behavior such as smoking, patient immobility, and weight gain.

Therefore, the total score of the questionnaire is 50 divided into three levels: poor, medium, and good. A score between 1 and 25 is considered poor treatment adherence. A score between 26 and 40 is considered medium treatment adherence, and a score between 41 and 50 is considered good treatment adherence. Content validity ratio (CVR)

and content validity index were used to confirm the content validity of the questionnaire. 15 people (i.e., 10 nursing professors and 5 cardiologists) were used to evaluate the content validity ratio (CVR). Based on the Lawshe table, values, which are greater than 0.49, are acceptable for 15 people ⁽¹⁹⁾. In this study, CVR is calculated as 0.84, which is acceptable. 15 people (i.e., 10 nursing professors and 5 cardiologists) were used to evaluate the content validity index (CVI). The score, which is greater than 0.79, is acceptable. In this study, CVR is calculated as 0.87, which is desirable. The test-retest method was used to evaluate the reliability of the questionnaire. Thus, the questionnaire was given to 50 patients in two stages, and then the scores of these two stages were compared with each other. The interval between two stages was two weeks. The correlation coefficient between two scores was obtained as 0.89 which is acceptable.⁽²⁰⁾

Patients' readmission registration form was used to examine readmission rate during three months of follow-up. First, a training workshop was held on interdisciplinary training for the research team working on the discharge planning so that team members get acquainted with the main components of interdisciplinary approach and improve their abilities to use the interdisciplinary discharge planning. The interdisciplinary team members are a cardiologist, a pharmacologist, a nutritionist, a nurse, and a social worker.

Then, interdisciplinary discharge planning was implemented in the intervention group. Therefore, an interdisciplinary round was performed at the time of the patient's admission, the patient's file was discussed, healthcare priorities and objectives were determined; finally, the patient healthcare plan was continued after discharge based on their decisions. Thus, the discharge planning included three face-to-face sessions (one week, one month, and three months after discharge) as well as telephone calls. Sessions were held in the heart clinic and coronary care unit (CCU). In all face-to-face sessions, the amount of patient's

medication was measured. According to the pre-determined schedule, the patients had face-to-face interviews, and their problems of medication adherence were examined, the necessary training was provided; finally, the patient's level of understanding was assessed by asking the question and getting feedback during sessions. The training included the importance of regular medication, proper nutrition, risk factors for heart disease and a healthy lifestyle, regular physical activity, smoking cessation, avoidance of alcohol and drugs, and the method of protection of an angioplasty site. If the patients need company, a member of the patient's family was also present at these sessions. The face-to-face meetings last about 40 or 50 minutes. In addition to face-to-face training, an educational booklet on these subjects was given to patients.

The researcher (i.e., a cardiac care nurse) made some phone calls in the second, sixth and tenth weeks for twelve weeks after discharge to answer patients' questions and encourage them to actively participate in self-care activities and adhere to the medications. Based on the patient's needs, each phone call lasts about 10 minutes which was made between 8 am and 8 pm on a specific date and time based on the agreement between the researcher and the patients. The patients' problems were discussed with members of counseling team after face-to-face meetings or telephone calls, if necessary. In the control group, the usual discharge planning in the hospital including pre-discharge training as well as an educational booklet, was used. Treatment adherence before, immediately, and one month after the intervention, as well as readmission three months after the intervention was examined in both groups.

Kolmogorov-Smirnov test was used for test of normality of quantitative variable. Independent Samples t-tests was used for compare quantitative variable between intervention and control groups, Chi-squared tests was used for compare qualitative variable between two groups, repeated measures

also was used for compare mean of treatment adherence between before, immediately and one month after intervention. SPSS software 22 was used for data analysis. Significance level was set at $P < 0.05$.

All participants gave written informed consent to participate in the study. The present study was conducted according to the principles of the revised Declaration of Helsinki, a statement of ethical principles which directs physicians and other participants in medical research involving human subjects. The participants were assured of their anonymity and confidentiality of their information. Moreover, the local Ethics Committee approved the study of Fasa University of Medical Sciences, Fasa, Iran (IR.FUMS.REC.1397.181).

Results

In the present study, 53(75.7%) of the participants were male and 17 (24.3%) were female. The mean age of patients was 60.58 ± 11.10 years. Independent sample T-test

and chi square test did not show a significant difference between two groups due to age, sex, marriage, level of education, and co-morbidities (Table1). The mean score of adherence treatment in two groups before the intervention showed no significant difference was observed with an independent sample t-test ($p = 0.84$). Further, repeated measurements ANOVA showed that the trend of changes in adherence treatment in the control group ($p < 0.001$) and in the intervention group ($p < 0.001$) was significant and towards increase therapeutic adherence. However, due to the comparison between the two groups according to the Bonferroni post hoc test, the difference in the intervention group immediately after the intervention had a significant increase compared to the control group ($p < 0.001$), which remained one month after the intervention ($p < 0.001$) (Figure 1 and Table 2).

The results indicate that readmission rate within three months after discharge was 11.4% (four patients) in the control group; however, this rate was zero in the intervention group three months after the educational intervention and no patients were readmitted in this period.

Table 1. A comparison of demographic characteristics of subjects in the discharge group with an interdisciplinary approach and control group

Demographic Variable	Grouping	Groups		Test statistics and <i>p</i> - Value
		Intervention	Control	
Age	-	59.08±12.05	62.08±10	t=0.61* P=0.261
Number of previous hospitalizations	-	1.57±1.92	8.77±41.84	t=3.37* P=0.07
Gender	Female	6 (17.1%)	11 (31.4%)	$\chi^2 = 1.94^{**}$ $p = 0.163$
	Male	29 (82.9%)	24 (68.6%)	
Marital status	Single	3 (8.6%)	2 (5.8%)	$\chi^2 = 0.215^{**}$ $p = 0.643$
	Married	32 (91.4%)	33 (94.3%)	
Educational status	Illiterate	11 (31.4%)	13 (37.1%)	$\chi^2 = 0.97^{**}$ $p = 0.80$
	Elementary and guidance school	15 (42.9%)	16 (45.7%)	
	High school	5 (14.3%)	4 (11.6%)	
	University	4 (11.6%)	2 (5.7%)	
Diabetes	Yes	12(34.3%)	12 (34.3%)	$\chi^2 = <0.001^{**}$ $p = 1$
	No	23 (65.7%)	23 (65.7%)	
Hypertension	Yes	15 (42.9%)	15 (42.9%)	$\chi^2 = <0.001^{**}$ $p = 1$
	No	20 (57.1%)	20 (57.1%)	
Obesity	Yes	3 (8.6%)	1 (2.9%)	$\chi^2 = 1.06^{**}$ $p = 0.30$
	No	32 (91.4%)	34 (97.1%)	
Dyslipidemia	Yes	11 (31.4%)	8 (22.9%)	$\chi^2 = 0.65^{**}$ $p = 0.42$
	No	24 (68.6%)	27 (77.1%)	
Smoking	Yes	12 (34.3%)	11 (31.4%)	$\chi^2 = 0.065^{**}$ $p = 0.30$
	No	23 (65.7%)	24 (68.6%)	
Occupation	Unemployed	27 (77.1%)	25 (71.4%)	$\chi^2 = 0.969^{**}$ $p = 0.616$
	Employed	3 (8.6%)	2 (5.7%)	
	Housewife	5 (14.3%)	8 (22.9%)	

*Independent sample t test; **Chi square test

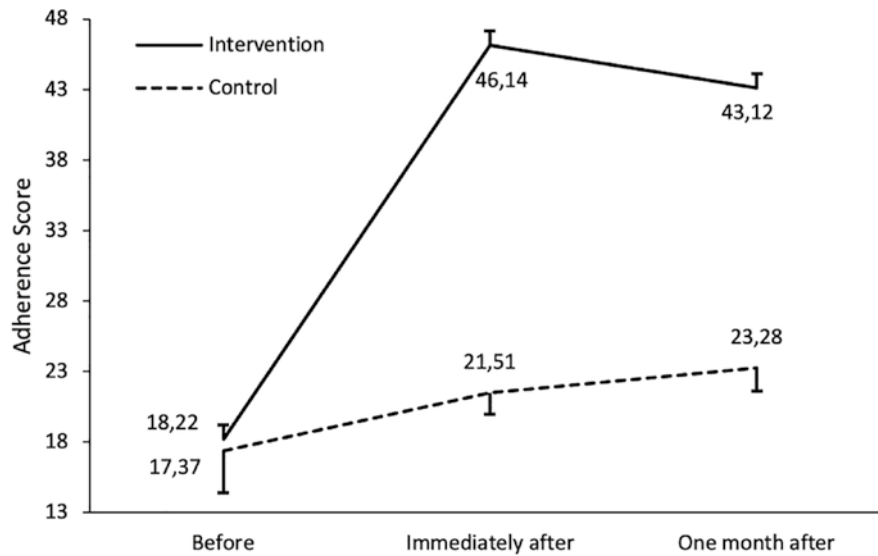


Figure 1. The Mean score of treatment adherence before, immediately after the intervention and one month after intervention in the control group and intervention group

Table 2. Mean score of treatment adherence before, immediately after the intervention and one month after intervention in the control group and intervention group

	Intervention		Control		p-value ¹
	Mean	SD	Mean	SD	
Before	18.22	3.04	17.37	2.95	0.842
Immediately after	46.14	1.49	21.51	1.52	<0.001
One month after	43.12	1.83	23.28	1.69	<0.001
Test Statistics	59.79		12.2		
p-value ²	<0.001		<0.001		
Difference Immediately - Before	27.92	2.93	4.14	2.38	<0.001
p-value ³	<0.001		<0.001		
Difference 1st month - Before	24.90	2.42	5.91	2.49	<0.001
p-value ⁴	<0.001		<0.001		
Difference 1st month - Immediately	-3.02	1.64	1.77	2.62	<0.001
p-value ⁵	<0.001		<0.001		

p-value¹: Comparison between Intervention and control groups (t test)

p-value²: Comparison within group (Repeated Measurements ANOVA)

p-value³: Comparison between immediately after and before (Bonferroni post hock after Repeated Measurements ANOVA)

p-value⁴: Comparison between one month and before (Bonferroni post hock after Repeated Measurements ANOVA)

p-value⁵: Comparison between one month and immediately after (Bonferroni post hock after Repeated Measurements ANOVA)

Discussion

The present research aimed to determine the effect of interdisciplinary discharge planning on treatment adherence and readmission in the patients undergoing coronary artery angioplasty in the south of Iran in 2020. The findings obtained from this study evidenced that treatment adherence scores significantly increased in the intervention group although that was significant in the control group. It indicates that the impact of interdisciplinary discharge planning on adherence to treatment of patients with coronary artery angioplasty is much greater. There have also been studies on interdisciplinary discharge planning on adherence to treatment of patients. Kinugasa *et al.*⁽²¹⁾ examined the Multidisciplinary intensive education on outcomes in hospitalized heart failure patients in a Japanese rural setting. As a result, although improving the risk of the primary outcome, it is possible to use appropriate strategies to interdisciplinary discharge planning such as the optimal medical treatment, comprehensive team education, and pre-discharge diagnostic tests. They showed that using appropriate strategies to plan interdisciplinary discharge such as optimal medical treatment, comprehensive team training, and pre-discharge diagnostic tests reduces the risk of disease outcomes.⁽²⁰⁾ Various studies have confirmed the positive effect of interdisciplinary education on improving treatment adherence in patients with heart failure and vascular disorders. The same results were achieved in the present study.^(21,22) Thus, it can be said that interdisciplinary education is effective to increase the level of knowledge of patients so that the continuation of interdisciplinary education program after discharge can improve the quality of life and reduce side effects in the patients with heart problems.^(23,24) Therefore, interdisciplinary discharge planning in the form of a comprehensive plan can help medication adherence and improve the patients' health.

The results showed that readmission rate of patients in the control group increased relative to

the intervention group, the means this rate was 11.4% in the control group, while it was zero in the intervention group, indicating the interdisciplinary discharge planning was effective in reducing the number of hospitalization of patients undergoing coronary artery angioplasty. Clarkson⁽²⁵⁾ which examined the effect of interdisciplinary education on the number of hospitalization of patients with heart failure, showed that readmission rate of patients after the educational intervention was reduced by 25%. Kinugasa *et al.*⁽²¹⁾ reported that multidisciplinary educational approach is a key strategy for helping prevent re-hospitalization for heart failure in Japanese HF patients in a rural setting. Ching⁽²⁶⁾ showed that the interdisciplinary education approach has been more effective in medication adherence and promotion of quality of life of diabetic patients than other conventional methods of education. Perhaps the improvement in the level of knowledge is the main cause of the decrease in the readmission rate. Kong⁽²⁷⁾ mentioned the lack of knowledge and awareness of patients are the most important factors affecting readmission rate in patients with chronic obstructive pulmonary disease. Other possible factors are healthcare adherence to recommendations and patients' positive behaviors due to the continuation of the educational program. For example, the present study showed that 20% of patients in the intervention group quit smoking, but no change in smoking habit was observed in the control group. It is obvious that insufficient adherence of heart patients to care and treatment programs have negative effects on their clinical outcomes and leads to exacerbation of disease, readmission, and the death of patient in some cases.^(28,29) This study shows that interdisciplinary discharge planning in line with treatment adherence is effectively reduces readmission which is statistically and clinically significant.

In the present study, improvement in treatment adherence was also observed in the control group, although much less than the intervention group. This result can lead to several hypotheses. The

first hypothesis is that completing the adherence therapy questionnaire during several stages, has prepared their minds to accept treatment adherence. Miles et al. in a systematic review show that completing the questionnaire and measurements can lead to a change in the behavior of the subjects.⁽³⁰⁾ The second hypothesis is based on the fact that these patients are trained by CCU nurses at the time of hospitalization and the training provided has been able to improve adherence to treatment in the control group. This hypothesis is consistent with the results of a study by Woo et al. based on the role of CCU nurses in improving adherence treatment and patients' clinical outcomes.⁽³¹⁾ The third hypothesis is that these patients have used the experiences of other heart patients among their friends or relatives because of concerns about heart problems.

The limitations of this study are as follows: First, this study selected subjects from one center in the southern of Iran, so it is necessary to be careful in generalization. Second, the use of a small sample of the limitations of the present study. It is suggested to use a larger sample size in future studies.

The strength of this study are as follows: This study was conducted for the first time in Iran. The one another strength of this study is the use of a researcher-made, specific and comprehensive questionnaire to assess treatment adherence in patients undergoing coronary angioplasty.

Implications for clinical practice: According to the implementation of interdisciplinary discharge planning had positive effects on treatment adherence and the reduction of readmission rates in the patients, It is suggested that this method be institutionalized as one of the new educational methods in the curriculum of nursing education programs. Also, nursing managers should use this educational method as a suitable strategy to increase treatment adherence and the reduction of readmission rate in the patients

Conclusion. The results indicate that the implementation of interdisciplinary discharge planning had positive effects on treatment adherence and the reduction of readmission rate in the patients undergoing coronary artery angioplasty. Therefore, it is recommended that further studies should be conducted on other patients with heart problems in various places.

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Cultural Care Practices Provided at Home by the Zenú Indigenous Mothers to their Premature Children and to Those with Low Birth Weight

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Abstract

Objective. The work's aim was to comprehend the cultural practices of the care by Zenú indigenous mothers to their newborn premature children and those of low birth weight by implementing the Kangaroo-Mother method at home. **Methods.** Qualitative study of particularistic ethnographic approach, with participation from eight mothers and two key informants trained in the Kangaroo-Mother method, who were interviewed and observed in their homes, in the municipalities of San Andrés de Sotavento, Tuchín, Sampués, and San Antonio de Palmitos from the Departments of Córdoba and Sucre (Colombia), respectively. Ethnographic analysis was performed. The criteria of data saturation and methodological rigor, typical of qualitative research, were applied. **Results.** Eight Zenú indigenous mothers and two key informants from the

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family participated in the study. The themes emerging were the context, a different experience, adaptations of the Kangaroo-Mother method at home and care practices, protection and healing based on customs and cultural tradition. **Conclusion.** The indigenous mothers provide holistic care to their newborn premature children and those with low birth weight, by integrating the knowledge and practices of the Kangaroo-Mother method and with the ancestral practices of care, protection, and healing characteristic of the context and culture; thus, transcending the use of resources available in the environment.

Descriptors: infant, premature; kangaroo-mother care method; indigenous culture; qualitative research.

Prácticas de cuidado cultural brindadas en el hogar por las madres indígenas Zenú a sus hijos prematuros y con bajo peso al nacer

Resumen

Objetivo. Comprender las prácticas culturales del cuidado de madres indígenas Zenú a sus hijos recién nacidos de bajo peso al nacer y prematuros al implementar el Método Madre Canguro en el hogar. **Métodos.** Estudio cualitativo de enfoque etnográfico particularista en el cual participaron ocho madres y dos informantes clave entrenadas en el Método Madre Canguro, quienes fueron entrevistadas y observadas en sus domicilios, en los municipios de San Andrés de Sotavento, Tuchín, Sampués y San Antonio de Palmitos de los Departamentos de Córdoba y Sucre (Colombia), respectivamente. Se realizó análisis etnográfico. Se aplicaron los criterios de saturación de los datos y del rigor metodológico, propios de la investigación cualitativa. **Resultados.** Participaron ocho madres indígenas Zenú y dos familiares informantes claves. Emergieron temas: el contexto, una experiencia diferente, las adaptaciones del método madre canguro en el hogar y las prácticas de cuidado, protección y curación basada en las costumbres y la tradición cultural. **Conclusión.** Las madres indígenas brindan cuidado holístico a sus hijos recién

nacidos con bajo peso al nacer y prematuros, al integrar el conocimiento y prácticas del Método Madre Canguro y con las prácticas ancestrales de cuidado, protección y curación propias del contexto y la cultura; trascendiendo así el uso de recursos disponibles en el medio.

Descriptor: recién nacido prematuro; método madre-canguro; cultura indígena; investigación cualitativa.

Práticas culturais de cuidado no domicílio por mães indígenas Zenú a seus filhos prematuros e de baixo peso

Resumo

Objetivo. Compreender as práticas culturais de cuidado de mães indígenas Zenú para o baixo peso ao nascer e recém-nascidos prematuros na implantação do Método Mãe Canguru no domicílio. **Métodos.** Estudo qualitativo com abordagem etnográfica particularista, no qual participaram oito mães e dois informantes-chave treinados no Método Mãe Canguru, que foram entrevistados e observados em suas residências, nos municípios de San Andrés de Sotavento, Tuchín, Sampués e San Antonio de Palmitos de los Departamentos de Córdoba e Sucre (Colômbia), respectivamente. Foi realizada análise etnográfica. Foram aplicados os critérios de saturação de dados e rigor metodológico, típicos da pesquisa qualitativa. **Resultados.** Participaram oito mães indígenas Zenú e dois familiares informantes-chave. Emergiram temas: o contexto, uma experiência diferente, as adaptações do método mãe canguru em casa e as práticas de cuidado, proteção e cura baseadas em costumes e tradição cultural. **Conclusão.** As mães indígenas prestam cuidados holísticos aos seus recém-nascidos de baixo peso e prematuros, integrando os saberes e práticas do Método Mãe Canguru e com as práticas ancestrais de cuidado, proteção e cura típicas do contexto e da cultura; transcendendo assim o uso dos recursos disponíveis no ambiente

Descriptor: recém-nascido prematuro; método canguru; mães; pesquisa qualitativa.

Introduction

Globally, each year there are 15-million pre-term births⁽¹⁾ and nearly 20-million newborns with low birth weight.⁽²⁾ In both cases, a direct relation exists with neonatal mortality, either as the main cause, or as a predictive factor for the suffering of chronic noncommunicable diseases during later stages of life. In addition to the foregoing, low weight occurs with a higher proportion in low- and middle-income countries and in vulnerable populations,⁽²⁾ which is why, the 2030 Sustainable Development Goals seek to reduce neonatal mortality by at least 12 neonates for every 1,000 live births.⁽³⁾

In Colombia, during the first period of 2021, registered a rate of low birth weight of 98.4 per 1,000 live births; in the departments of Córdoba and Sucre, this indicator reached 91.2, and 101.7 per live births, respectively.⁽⁴⁾ In addition, the rate of pre-term births per every 1,000 live births in the departments of Córdoba and Sucre was 115 and 126 per live births, respectively.⁽⁴⁾ The specific statistical analysis of the ethnic groups, self-recognized as indigenous, evidences a proportion of pre-term newborns of 9.3%.⁽⁴⁾ In this sense, given the importance of ancestral peoples and the behavior of the indicators, it is significant to focus knowledge on the context and circumstances surrounding the experience of caring for premature newborns and newborns with low weight in these populations.

Regarding the problem of low birth weight and prematurity, implementing the Kangaroo-Mother method (KMM) has permitted saving the lives of nearly 450,000 premature babies each year,⁽⁵⁾ given the multiple benefits that impact positively on the humanization and quality of care, on the health of the newborns and those with low birth weight, and on mortality indicators.⁽⁶⁻⁷⁾ Under this panorama, it is relevant to specify that, the success of its implementation at home depends on the training in the KMM carried out in the hospital,⁽⁸⁾ more so in the indigenous communities, in whom language becomes a barrier to implement the method; hence, as proposed by Raffray *et al.*,⁽⁸⁾ and Siedman,⁽⁹⁾ knowledge of the cultural context of implementing the KMM should be expanded in indigenous communities through ethnographic research that account for these two aspects, especially when no studies exist to unveil the way the experience of applying the KMM takes place in indigenous communities. Thereby, the objective of this research was to comprehend the care practices of a group of Zenú indigenous mothers from Córdoba and Sucre, by describing the experiences in implementing the KMM at home, taking the cultural traits as starting point.

Methods

A qualitative study was conducted with particularistic ethnographic approach,⁽¹¹⁾ From the database of the Kangaroo Mother Program in a private hospital in the city of Sincelejo, Colombia, the study selected eight indigenous mothers, members of the Zenú community from the municipalities of San Andrés de Sotavento, Tuchín, Sampués, and San Antonio de Palmitos, who were trained in the KMM between 2018 and 2019 and whose newborn children left the institution alive. Access to the field was through two gatekeepers, the coordinating nurse of the neonatal intensive care unit, who made the first contact with the participants and introduced the researcher, and a motorcycle-taxi driver from the zone, who knew the territory and its inhabitants. A preliminary study was carried out, which served to refine the techniques and guide questions. The study employed semi-structured interview and observation techniques, using a guide. Prior to the visits, the dates to meet with the researcher were arranged by telephone.

Once at home, each participant was explained the aim of the research, addressing doubts about such, the informed consent process was conducted, and the study proceeded with interviews and observations. The observations began from the researcher's travel route to the participants' home. The work used 40 h of observation, both in the territory and in the homes of the participants and key informants. The observations were consigned in the field diary. The time employed for the interviews was 11 h, with an average between 45 and 50 min per interview. Each interview began as an informal conversation, formulating open questions to inquire on general aspects and then questions were made about the experiences regarding the care of the newborns at home, such as: Tell me, how has your experience been caring for your premature newborn and/or low birth weight child at home? Each participant was interviewed, with the need to have an additional

interview with some participants. The interviews were audio recorded and transcribed by the researcher as soon as possible, to avoid losing relevant information about them and the context in which they were made.

Analysis of the interviews and of the observations was performed in parallel to the collection process, through exhaustive reading of the texts in search for codes that were grouped into categories and themes. To apply the criteria of rigor of qualitative research,⁽¹²⁾ upon finishing each interview, a recount of the conversation was made to each participant; as well as the return and validation of the final findings. Complementarily, researcher triangulation was conducted (principal researcher, the research tutor, and a nurse researcher expert on ethnography). This view broadened the analytic perspective and comprehension of the experience and context of the phenomenon. For the theoretical linking process, the topics were contrasted with the theoretical aspects of the Health Traditions Model, proposed by Rachel Spector,⁽¹³⁾ to describe and comprehend care practices and beliefs around the maintenance, protection and restoration of the health of newborns. The data saturation criterion was used, once sufficient, relevant, and redundant information was obtained on each theme analyzed. To safeguard the identities of the participants, these were assigned a pseudonym, preserving the ethical principles of respect, justice and confidentiality. Additionally, the study was authorized by the healthcare institution and was supported by the research committee in the Faculty of Nursing at Universidad de Cartagena (Colombia).

Results

Eight Zenú indigenous mothers and two key informants participated. The mean age of the eight participating mothers was 25 years, with high-school studies and dedicated mainly to household chores alternated with the elaboration

of handcrafted weaving in “caña flecha”. With respect to the premature newborns, the gestational age was between 29 and 36 weeks and hospital stay in the neonatal intensive care unit was 25 days. Participation was also secured from key informants, the grandmother and father of one of the newborns, who were active in the training process and carried out the kangaroo mother strategy at home.

In the KMM implementation and practices at home, four main themes emerged: the context; a different experience; KMM adaptations at home; and care practices, protection and healing based on the customs and cultural tradition. In their reports, the participants describe how to care for premature newborns at home, making the necessary adjustments from the resources available within the context and in accordance with the cultural and ancestral care practices learned within their families.

Theme 1. The Context

The study context was located in disperse rural areas of the municipalities of San Andrés de Sotavento, Tuchín, Sampués, and San Antonio de Palmitos characterized by difficulties of roadway access and deficient transport means. The physical characteristics of the homes keep common features, like the construction materials “bahareque” (wall of interwoven sticks with reeds and mud), basic spatial distribution, and poor basic sanitation conditions, which together represent a framework of difficulty for the caring for premature newborns, added to the economic difficulties of the participating mothers, who derive their livelihood from economic activities, like small-scale crops, raising domesticated animals, and handicrafts, which represent low income, compared with the requirements for caring for premature newborns.

In relation with the economic conditions of the participating mothers, demarcated between the small-scale domestic economy of cultivating corn, cassava and yams; raising domesticated animals,

principally for consumption; and elaboration of handmade weaving to manufacture hats and bracelets; and motorcycle taxi activities or the various trades of their companions.

Theme 2. A Different Experience

Unlike the experience in the hospital, the mothers manifest feeling freedom, tranquility and confidence of caring for their children at home, as a “different” and positive experience: *It was a totally different experience, but at the same time beautiful, because, well, you are already living here out in the open, you are not there locked up [...] how should I say, I had her here at home, I could hold her, lay down with her; it was something quite beautiful (E1P7Orquidea).*

Theme 3. KMM Adaptations at Home

During the adaptation process of the KMM at home, the participants put into practice the teachings received in the clinic about issues, like feeding the child and the mother, hygiene, and protection measures to care for the newborns: *One of the things I put into practice the most was feeding, that is, primarily on his hygiene, on the part of hygiene and on the medications, and well on hygiene, bathing him, that is, when he was discharged because he was tiny, they told me there that I could not bathe him until he weighed two-thousand five-hundred grams (E10P17Violeta).*

The bath activity as care and hygiene underwent location adaptations at home. Also, inclusion of plants known for their medicinal use plays a protective function complementary to the cultural care actions focused on preventing and healing diseases acquired from the environment, like “cold”: *Because in the clinics there is a lot of air, a lot of air conditioning, they say that babies get cold [...] So if, if baths are applied, one comes and makes a guava leaf bath with orange and those things [...] Guava leaf works according to them to relax them, to make them drowsy, if they have a cold, the cold goes down (E1P16Orquidea).*

Hand washing with liquid soap, as a hygiene measure learned by the mothers in the hospital, continued being performed at home, as a protection measure against risks of infection, added to the use of masks for people in contact with newborns: *So I said, no!, everyone who is coming over, well there is the liquid soap, they have to wash their arms to here (pointing to the elbow) and to go in there, I bought some facemasks for them to wear, yes, well and that's how it was done, based on care too (E12P17Crisantemo).*

When the mothers recognized the fragility of their children, they implemented protection isolation measures, like environmental control and limitation of visits against potential diseases; such is the case of contact with smoke from the kitchen and exposure to insects and mosquitos: *My mother always told me when she was cooking, the smoke, she always kept me with her (the baby) in the bedroom, locked the door and always sent me in there with her (the baby) in the room, that way to protect her from the smoke and all that [...] Mom always told me that, given that there are mosquitos around here, one always has to use the insect canopy [...] I always had to place a cap on the baby's head, because, always... that they have the... The winds enter the baby through the head (E5P4, 5, 8 Girasol).*

Controlling visits means for the mothers avoiding contact of the children with women who are pregnant, menstruating, or who recently had engaged in sexual intercourse, given that the children can contract traditional diseases recognized by the indigenous culture, as is the case of “pujo” or the “evil eye”: *So these are customs we still have, so everyone would tell me to not let everybody inside because the child will get “pujo”, so they are customs we have here as indigenous (laughter) [...] As we Indians commonly call it here (laughter), we have customs, that we say if so and so comes over with the menstrual period or had sexual relations so they will get the baby sick (E1P15,16Orquidea).*

The mother's consuming foods considered stimulants of breast milk and avoiding consumption of others that affect the health of the newborn, constitute adaptations of the context and a form of their indirect care of the child: *The indigenous, just like me, have beliefs and that, they said, we here said to eat salted meat, that sesame seed, milk with panela, all that I took to get breast milk (E3P9Amapola); Avoiding heavy meals, like too much fat, drinking lots of liquids, soup every day and natural juice to help her and so the girls [...] Both your food that you have to take too, also has to be controlled so that you can't affect the girls (E12P12,15 Crisantemo).*

Likewise, the particularities and feeding needs of each child, suppose necessary adjustments to meet this need, which implies even using traditional knowledge and putting them to practice: *So my mom would say, let's make rice chicha, corn chicha, little things like that, well for one, well, for the eldest, because the other was very difficult because everything she made for him, that is, made him have loose stools, his stomach never tolerated it, then we prepared for one, yes and we gave him (E3P22Amapola).*

Theme 4. Care Practices, Protection and Healing Based on the Customs and Cultural Tradition

In their narratives, the mothers describe “pujo” in the child with symptoms, like abdominal pain and overall discomfort, associated occasionally with fever episodes and which they prevent by limiting visits, as already narrated. They describe the “evil eye” as general discomfort, head fever, cold extremities, and constant crying of the child and which is acquired by strong stares from other people toward the child: *The evil eye, they say comes from other people and who have a bad eye (E3P15Amapola); Because his head is hot and the other parts of his body are cool, only his head gets hot and the eyes, sort of as in tears, that is, from the very headache he has, so well,*

that is when you realize that is “eye” what he has and that at night does not let you sleep, because he gets startled so suddenly and starts crying (E10P21Violeta).

As healing measure, the mothers describe curative actions to counteract “the bad energy” of the person causing the condition in the newborn, as illustrated in the following account: *That when a person gives you the evil eye, well, there is the custom that you go to that person and take a piece of clothing, that is, that the person has worn... you rinse with that... you place it, let's say, on the trail or on the royal road and make a cross, the cross is for when people pass by there, they take away that bad energy, they take it until it is pushed away* (E12P16Crisantemo).

For its part, “the vision” or “sorcerer’s vision” is described by the participants as a disease caused by taking the child out of the home without an amulet, without having been baptized or taking them at night through solitary paths in which sorcerers or spirits could potentially appear. Given this, the mothers take actions to protect the newborns or counteract the condition, as shown by the following testimony: *When at night I would dress the baby with red garments, but inside out [...] Because when they are small there are many visions they see and that is very dangerous; as they say, those sorcerers come out, when the*

children are just born, they like to play with the babies (E5P5,6Girasol).

In the testimonies by the mothers complementary actions emerged of protective and curative nature and to counteract the “bad energies” or “bad spirits” that cause the aforementioned diseases, evoking ancestral practices and rituals typical of the culture, like the use of “amulets” and the “prayers”: *We had to tie one on, this one, there is a little animal that is like a little cricket and it has some pebbles, some little things, so they tie them to their hand, that is done, it has to be done in odd number...then you make the bracelet and tie it to the baby's left hand so that they don't even have vision...evil eye or they get vision on the path and that is done* (E3P15Amapola).

As a theoretical linking strategy and to advance in comprehending the cultural practices, the study used the holistic conception of Spector’s Health Traditions Model,⁽¹⁴⁾ according to which balance is required in body, mind and spirit, family, community and natural forces; reached through maintaining and defending the traditional beliefs and practices that persist in people who know and live according to the traditions of their ethnocultural or religious heritage.⁽¹⁵⁾ Table 1 gathers the data derived from the observations and interviews, within the framework proposed by the author.

Table 1. Personal perspective in Health Traditions and implementation of the KMM in Zenú indigenous people from Córdoba and Sucre

	Physical	Mental	Spiritual
Maintenance of Health	Use of red-colored garments to avoid sorcerers and caps to keep the cold from entering the child. Consume food to improve the production of maternal milk. Suspend routine household and artisanal activities.	Support from family members in implementing the KMM that provides security, tranquility and confidence to the mothers at home.	Spirituality seen in prayers to improve the mother's and child's health, asking for help to cope with the experience and seeing the child as a miracle.

Table 1. Personal perspective in Health Traditions and implementation of the KMM in Zenú indigenous people from Córdoba and Sucre. (Cont.)

	Physical	Mental	Spiritual
Protection of Health	Use of red-colored garments in children. Avoid foods that cause illnesses to the mothers.	Prevention from visits by women who are menstruating, who have had intercourse and avoid taking the children out to dark and solitary places, such as dams and wells that cause “Evil eye” “Pujo” and Visions Family activities: protection baths.	Use of amulets and other symbolic objects, red-colored garments to prevent the “evil eye” or to defray other types of damage; “Mate” in hands and/or feet to cross children and avoid endemic diseases.
Health restoration	Baths with medicinal plants to heal the children from illnesses like the flu.	Use of medicinal baths for cleansing and healing with traditional medicinal plants from the region, others such as azulene water, water product of the rinsing of clothes, cow’s milk.	Sanctify the children with traditional healers of the culture, bathe the children with the garments of the person who caused them the “evil eye”, bathe them and throw away the water making the sign of the cross.

Discussion

The experience of caring for newborns at home is frame-worked by learning and knowledge acquired during the KMM training and the adequate practice, which agrees with the proposal by Abanto *et al.*,⁽¹⁶⁾ inasmuch as certain confidence is generated when applying what has been learned at home, and guides the adequacy of care with the resources available in the context. Although the mothers indicate that the experience of homecare is different by virtue of these adaptations, no negative feelings or inability to care for newborns are generated, which can be determined by accompaniment from other members of the family group; an aspect described by other authors as a positive factor in caring for the premature child at home.⁽¹⁷⁻¹⁸⁾ Additionally, there is the satisfaction of having their children at home, as identified by Osorio *et al.*⁽¹⁹⁾ These practices agree with the knowledge the mothers

acquire during the KMM training KMM indicated by Abanto *et al.*,⁽¹⁶⁾ in which – with a higher level of knowledge of homecare in the dimensions of security, protection, comfort, and feeding – said mothers will conduct better practices on their newborns, also contrasting with that reported by others, like Castiblanco,⁽²⁰⁾ with respect to basic care of premature newborns, recognizing warning signs, administration of medications, vaccine applications, and follow up of medical and nursing indications, as a distinctive feature of maternal basic care and as measures to provide comfort and protection to premature children,⁽²¹⁾ reflecting among the participants on the conservation and control of the environment, maintenance of body heat, application of hygiene measures, baths, and their adjustments for the protection of the newborns. Further, it accounts for other experiences of the indigenous in hospital to satisfy their basic needs and overcome their limitations through adaptation and learning⁽²²⁾ This synergy between knowledge acquired during KMM training and traditional knowledge, such as

adjustments in feeding the mother to stimulate maternal breastfeeding and prevent diseases in the newborn, guides the care of the dyad and tributes positively on the child's and mother's health.⁽²³⁾

Comprehending the experience and applying some elements from the Health Traditions model by Rachel Spector,⁽¹³⁾ guided by the logical and comprehensive analysis of the ethnographic approach of the research, grant relevance to the context and to cultural aspects, emerging in a flourishing way the care of the premature newborn and with low birth weight based on the beliefs, ancestral practices and myths that promote the protection, treatment and healing of the newborn, also described by Banda *et al.*,⁽²⁴⁾ and the adaptations conducted on the care environment from the knowledge gained and experiences of the KMM training. Besides the basic care aimed at satisfying the basic needs of the children, care by the mothers seeks to protect and heal the child from diseases known culturally among the Zenú as “pujo”, the “evil eye”, and the “visions” and some studied by authors⁽²⁵⁻²⁶⁾ in other cultures that describe them with similar causes, manifestations and forms of healing guided by own resources of ancestral knowledge, such as the use of amulets or the use of garments, baths with of medicinal use, traditional healing prayers, and use of amulets, like protection collars or bracelets.⁽²⁷⁾ It is important to highlight that the study observed no unfavorable cultural practices or practices that endangered the newborn.

The principal limitations of this study had to do with the difficulties of geographic accessibility in disperse rural zones, place of residence of some of the participants, as well as the telephone communication with the participants due to poor coverage by mobile operators in the zone or no access to their own telephone number.

In conclusion, this study has it that comprehending the KMM practice at home is conditioned with the context of the environment, geographic and socio-economic conditions, cultural heritage, and family support of each participant, which have a strong cultural component. Applying the KMM at home for the group of participants is holistic and congruent care, which incorporate new knowledge from the learning acquired during the KMM training and el traditional care based on el ancestral knowledge learned within the indigenous culture. Thus, the KMM dialogues with the traditional knowledge and permeates culture through the nursing professional's teaching role in the neonatal intensive care units. This cultural approach is a starting point to promote cultural competence and adaptation of care to the conditions of the people, taking culture as referent, particularly in a multicultural country, like Colombia, where – according with the results – intense work must be done in the incorporation of substantial changes in formation scenarios and in professional practice scenarios to improve cultural care by nurses. Moreover, it constitutes the input for the construction and consolidation of public policies of intercultural and ethnic care with territorial approach.

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A reusable learning object for assessment cardiovascular and respiratory responses


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A reusable learning object for assessment cardiovascular and respiratory responses

Abstract

Objective. Produce and determine the validity of a reusable learning object for assessment cardiovascular and respiratory responses from the taxonomy of the North American Association of Nursing Diagnosis Domain 4. Activity/Rest, Class 4. Cardiovascular/Pulmonary Responses. **Methods.** A descriptive methodological study was developed that included three phases (1) construction of the reusable learning object incorporating Gagné's nine instructional events, (2) content validation was carried out with 24 nurses who served as experts, and (3) and Usability was evaluated by 22 nursing students from a Public University in Colombia. **Results.** The reusable learning object was organized into three modules: introduction, assessment of cardiovascular responses,

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and assessment of pulmonary responses. The learning object obtained a content validation index of 0.86; the usability indicators had proportions of agreement greater than 85%. **Conclusion.** The reusable learning object is valid and can be used for teaching the assessment of cardiovascular and respiratory responses in nursing students.

Descriptors: Nursing; Distance Education; Educational Technology.

Un objeto de aprendizaje reutilizable para la valoración de las respuestas cardiovasculares y respiratorias

Resumen

Objetivo. Producir y determinar la validez de un objeto de aprendizaje reutilizable para la evaluación de las respuestas cardiovasculares y respiratorias de la taxonomía de la Asociación Norteamericana de Diagnóstico de Enfermería Dominio 4. Actividad/Descanso, Clase 4. Respuestas Cardiovasculares/Pulmonares. **Métodos.** Fue desarrollado un estudio metodológico descriptivo que incluyó tres fases (1) construcción del objeto de aprendizaje reutilizable incorporando los nueve eventos de instrucción de Gagné, (2) validación de contenido con 24 enfermeras que fungieron como expertas, y (3) evaluación de la usabilidad por 22 estudiantes de enfermería de una Universidad Pública en Colombia. **Resultados.** El objeto de aprendizaje reutilizable se organizó en tres módulos: introducción, valoración de las respuestas cardiovasculares y valoración de las respuestas pulmonares. El objeto de aprendizaje obtuvo un índice de validación de contenido de 0.86; además, los indicadores de usabilidad tuvieron proporciones de acuerdo superiores al 85%. **Conclusión.** El objeto de aprendizaje reutilizable desarrollado es válido y puede ser

empleado para la enseñanza de la valoración de las respuestas cardiovasculares y respiratorias en estudiantes de enfermería.

Descriptor: Enfermería; Educación a Distancia; Tecnología Educativa.

Um objeto de aprendizagem reutilizável para avaliar as respostas cardiovasculares e respiratórias

Resumo

Objetivo. Produzir e determinar a validade de um objeto de aprendizagem reutilizável para avaliar respostas cardiovasculares e respiratórias a partir da taxonomia da Associação Norte-Americana de Diagnósticos de Enfermagem Domínio 4. Atividade/Repouso, Classe 4. Respostas Cardiovasculares/Pulmonares. **Métodos.** Foi desenvolvido um estudo metodológico descritivo que incluiu três fases (1) construção do objeto de aprendizagem reutilizável incorporando os nove eventos instrucionais de Gagné, (2) validação de conteúdo realizada com 24 enfermeiros que atuaram como especialistas e (3) avaliação da usabilidade por 22 estudantes de enfermagem de uma universidade pública da Colômbia. **Resultados.** O objeto de aprendizagem reutilizável foi organizado em três módulos: introdução, avaliação das respostas cardiovasculares e avaliação das respostas pulmonares. O objeto de aprendizagem obteve índice de validação de conteúdo de 0,86; os indicadores de usabilidade tiveram proporções de concordância superiores a 85%. **Conclusão.** O objeto de aprendizagem reutilizável é válido e pode ser utilizado para o ensino da avaliação das respostas cardiovasculares e respiratórias em estudantes de enfermagem.

Descriptor: Enfermagem; Educação a Distância; Tecnologia Educacional

Introduction

Assessment is the first step in the application of the nursing process and involves critical thinking skills for data collection.⁽¹⁾ The ability to assess the state of health is a competence of great importance for nursing students and nurses alike. The obtained information allows for the correct identification of care needs for healthy or sick people. In the Nursing program at the Industrial University of Santander (UIS), Colombia, the health status assessment is carried out within the framework of the taxonomy II of the North American Nursing Diagnosis Association (NANDA-I);⁽²⁾ for the implementation of this framework, an assessment form was created in 2008, which included the thirteen domains or categories of nursing practice. In the NANDA Domain 4. Activity/Rest, Cardiovascular and Pulmonary Responses are addressed as class 4.

In our teaching experience, we observed that nursing students have difficulties in learning and assessing these responses. Although scarce, some studies available in the scientific literature show that teachers have problems in the teaching pulmonary and cardiovascular assessment-mainly in what has to do with auscultation;⁽³⁾ as well as, nursing students have difficulties in cardiac auscultation and the identification of the sounds.⁽⁴⁾ To address these difficulties, it is necessary to generate conditions so that the nursing student can develop the ability to perform accurate assessments. Subsequently, as professionals, this will result in the improvement of health outcomes and quality of patient care. It is important to notice that nurses with higher levels of assessment skills have a greater capacity to monitor the changes in the health of the people they care for.⁽⁵⁾

The results from a cohort study that aimed to investigate the risk of mortality associated with nurses' assessments of patients by physiological systems, including respiratory and cardiovascular systems, showed that patients whose nursing assessments at admission did not meet the minimum standards had significantly higher hospital mortality than those patients who had assessments that met the minimum.⁽⁶⁾ The authors concluded that the results show evidence of the clinical validity of nursing assessments as well as the fact that they can help with medical care and possibly reduce the mortality of hospitalized patients;⁽⁶⁾ also, we recognized that the deterioration of the physiological state is often unappreciated or acted upon in a timely manner.^(7,8) Evidence suggests that health personnel may lack the knowledge and skills necessary to perform a respiratory and cardiovascular assessment; this ultimately has a detrimental effect on the potential to minimize adverse patient events;^(9,10) therefore, encouraging nursing students to develop skills for assessing health status is a matter of interest to the discipline.

In recent years, educational technologies to mediate nursing teaching have transformed the way students learn since they went from passive receivers of information to protagonists of their learning. With its implementation, a greater dynamism is generated in the traditional classroom method, and the students' interest is favored.⁽¹¹⁾ However, incorporating these technologies requires a change in the educational paradigm,⁽¹²⁾ teacher training, and investment in technological infrastructure.

Educational technologies such as reusable learning objects (RLOs) have been introduced to assist in the learning process in nursing education.⁽¹³⁾ The RLO is an interactive, multimedia web-based resource focused on a single learning objective that can be used in multiple contexts; it focuses on a specific topic and is highly visual with an auditory component and high-quality graphics.^(14,15) This resource encourages active and meaningful learning in students and changes the relationship between the student and the content objective for study.⁽¹³⁾ The use of RLOs has proven to be an innovative, constructive, and interactive educational experience for nursing students, similar to real situations faced in a healthcare setting, appealing for their significant learning.⁽¹⁶⁾

Some studies have produced and validated RLO for teaching medication administration,⁽¹⁷⁾ vital signs,⁽¹⁷⁾ the systematization of nursing care,⁽¹⁷⁾ semiotics and neonatal semiology,^(17,18) anatomy,⁽¹⁷⁾ pain assessment⁽¹⁵⁾ and nursing care of intestinal elimination stoma.⁽¹⁹⁾ Of these, two studies^(15,18) report positive results for student learning when exposed to an educational intervention based on the RLO. We emphasize that, to date, there are no published studies that report the construction and evaluation of any virtual object for teaching the assessment of the NANDA Domain 4. Activity/Rest, class 4 Cardiovascular and Pulmonary Response.

Because of the need for new resources in teaching nursing students to quickly and easily master the

content related to pulmonary and cardiovascular responses assessment, this study aimed to produce and determine the validity of an RLO for assessment of the NANDA Domain 4. Activity/Rest, class 4 Cardiovascular and Pulmonary Responses. The following research question was formulated: What is the validity of an RLO for assessing the NANDA Domain 4. Activity/Rest, class 4 Cardiovascular and Pulmonary Responses?

Methods

A descriptive methodological study was conducted between December 2017 and December 2018, with sequential phases that included: (I) construction of the reusable learning object, (II) content validation by nurses, and (III) evaluation of usability by students of the nursing program of the UIS; It is a non-profit public higher education institution located in the urban setting of the medium-sized city of Bucaramanga, Colombia.

In phase I, we adopted the first three steps of the methodology proposed by Mendoza-Galvis⁽²⁰⁾ to create virtual learning environments; these were analysis, design, and development. In the analysis step, we characterized the target audience and defined the learning objectives, modules, and content of the RLO by examining relevant literature in databases, virtual libraries, and books about assessing health status. In the design step, we produced the theoretical content in the Word processor and developed support resources for approaching the subject in this stage, such as drawings, videos, and photographs. Also, we incorporated Gagné's nine events of instruction; the way it was done will be presented in the results section. This instructional design model was applied because it provides a formal template that gives structure to the lesson to achieve learning objectives.⁽²¹⁾ Finally, in the development step, a graphic designer built the RLO and integrated the content and resources produced in the previous step using a standard

programming language (HTML5) with Java Scripts and CSS3. The illustration was created with Adobe Illustrator.

In phase II, 22 nurses who served as experts carried out the content validation; the number of experts was calculated by Equation (1) which was proposed by Lopes and collaborators⁽²²⁾ in the context of content validation of nursing diagnosis to get the proportion of experts who agree upon the inclusion of a given component (for example, clinical indicator) for a specific diagnosis.

$$n = Z_{\alpha}^2 \frac{P(1-P)}{e^2} \quad (1)$$

In Equation (1), " Z_{α}^2 " refers to the confidence level adopted, P corresponds to the expected proportion of the nurses reporting the suitability of each component evaluated (objectives, content, relevance, and environment) for the RLO, and e^2 represents the acceptable proportional difference about what would be expected.⁽²²⁾ For this study, we adopted a confidence level 95%, a coefficient Z of 1.96 according to the standard normal distribution, and an expected expert proportion of 85% with a 15% margin of error, indicating that at least 70% of nurses who participated in the content validation would have to rate the component evaluated as suitable.⁽²²⁾

The inclusion criteria were (I) to be a nursing professional, (II) to have at least two years of experience in teaching the assessment of health status, and (III) to have at least 2 years of clinical experience in cardiorespiratory care; the search for specialists was through social contact; there were no exclusion criteria.

In phase 3, the nursing students evaluated the usability RLO; the usability was defined as the capability of understanding, learning, using, and being attractive to the user, when used under specified conditions.⁽²³⁾ The aspects contemplated in this evaluation were language, design, content, interaction, and stimulus; the sample size was

calculated applying the same criteria used for the calculation of the nurses; therefore, the sample size was 22 nursing students. Inclusion criteria adopted for students were (I) to be enrolled in the Nursing program and (II) having taken and passed the subject nursing process II; there were no exclusion criteria. The students evaluated the usability RLO. Usability was defined as the capability of understanding, learning, using, and being attractive to the user, when used under specified conditions,⁽¹⁶⁾ the aspects contemplated in this evaluation were language, design, content, interaction, and stimulus.

According to the above, two instruments were used to collect the data; one was applied to nurses in phase 2, and the other was applied to nursing students in phase 3. Both were adapted from other published studies on validation.⁽²⁴⁻²⁶⁾ The instrument of nurses was divided into two parts: the first contained the characterization question, and the second contained the content validation questionnaire (33 questions). The instrument of nursing students was also divided into two parts: the first with the sociodemographic question, and the second, the usability questionnaire (21 questions). For both questionnaires, a Likert scale with five response options was used, being: (1) totally inadequate, (2) considerably inadequate, (3) somewhat adequate, (4) considerably adequate, and (5) totally adequate.

Besides, nurses and nursing students were invited to participate in the study in person and by email; they responded to the self-applied instruments after signing the informed consent. The instruments were filled after navigating freely (for approximately 3 hours) through the RLO in a computer classroom of the university. The data were processed in Microsoft Office Excel and analyzed using the Statistical Package for the Social Sciences (SPSS), version 25; the characterization variables of the nurses and nursing students were analyzed using descriptive statistics. The content validation process by nurses used two methods.

First, the Fehring method,⁽²⁷⁾ which has been used to validate the content of diagnosis nursing of the NANDA-I and outcomes of The Nursing Outcomes Classification (NOC), allowed to verify how suitable were the components evaluated in regard to LO; for this, the experts' rating received a weight: (1) totally inadequate = 0, (2) considerably inadequate = 0.25, (3) somewhat adequate = 0.50, (4) considerably adequate = 0.75, (5) totally adequate = 1. Then, the weighted averages for each component evaluated were calculated. To calculate content validity index of the RLO (IVC) we added the weighted averages and divided them by the total number of components evaluated; components with weighted average equal to or higher than 0.78 were considered valid.⁽²⁸⁾

Second, the proportion of experts who agreed with the relevance of the components evaluated was verified using an analysis of proportions by means of the binomial test; for this analysis, the responses were grouped dichotomously. The frequencies of responses concerning options (1), (2), and (3) of the Likert scale were classified as not relevant; (4) and (5) as relevant. The level of significance adopted was <0.05 , so values above 0.05 indicated that the proportion that considered the appropriate item was statistically not less than 70%; in the case of usability, we also performed an analysis of proportions with the same criteria. After receiving the validation instruments completed by the nurses and students, the need to adjust the RLO was verified; this made it possible to obtain a final version of the RLO.

This study was developed in accordance with resolution 008430 of October 4/1993, which establishes the scientific, technical, and administrative standards for health research in Colombia. The *Comité de Ética en Investigación*

Científica (CEINCI) of the UIS, Colombia, approved this study. All participants in this study signed the informed consent form.

Results

The results obtained in this research work are shown below.

Construction of the reusable learning object

We determined that the population of the RLO would be nursing students from a public university in Colombia. We also proposed, as learning objectives, that once the student interacted with the RLO, he/she would be able to a) integrate theoretical concepts of anatomy and physiology with the practice of assessing cardiovascular and pulmonary responses, b) correctly execute the techniques of assessment applied to Domain 4. Activity/Rest, cardiovascular and pulmonary responses.

The RLO was organized into three modules: introduction, assessment of cardiovascular responses, and assessment of pulmonary responses (Figure 1). The last two modules were subdivided, respectively, into three sections: a review of anatomy and physiology, assessment (interview, inspection, palpation, percussion, and auscultation), and tasks; the RLO offered interactive resources, including the possibility of listening to the chest with a stethoscope for learning to identify normal and abnormal heart and lung sounds, and a self-assessment questionnaire. Its exercises provided immediate feedback to the student as, at the end of the activities, correct answers can be verified (Figure 2). Gagné's nine events of instruction were incorporated in the RLO as follows (Table 1).

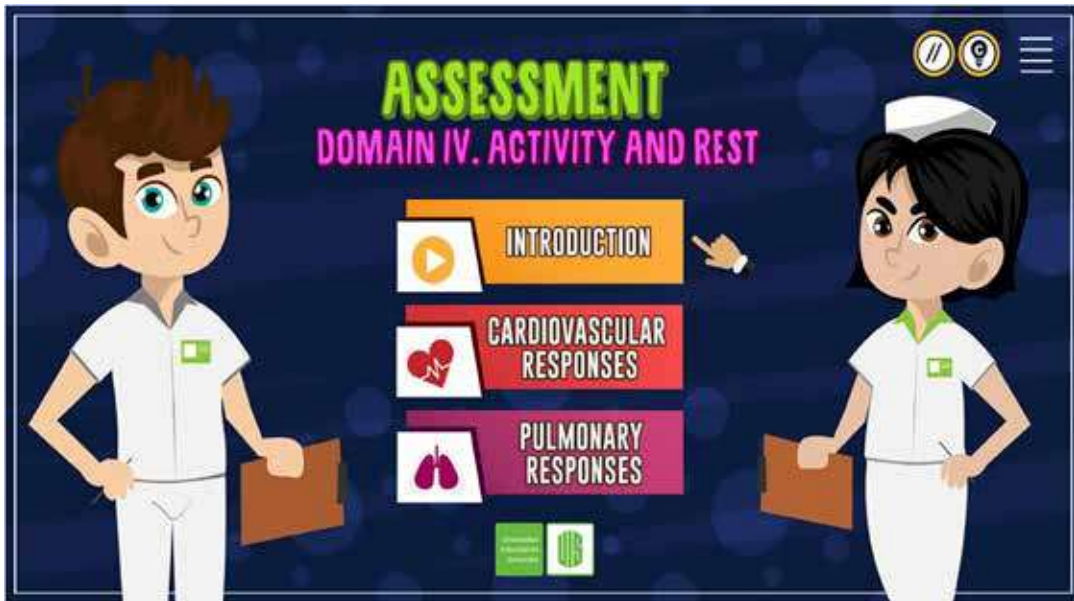


Figure 1. Starting screen.

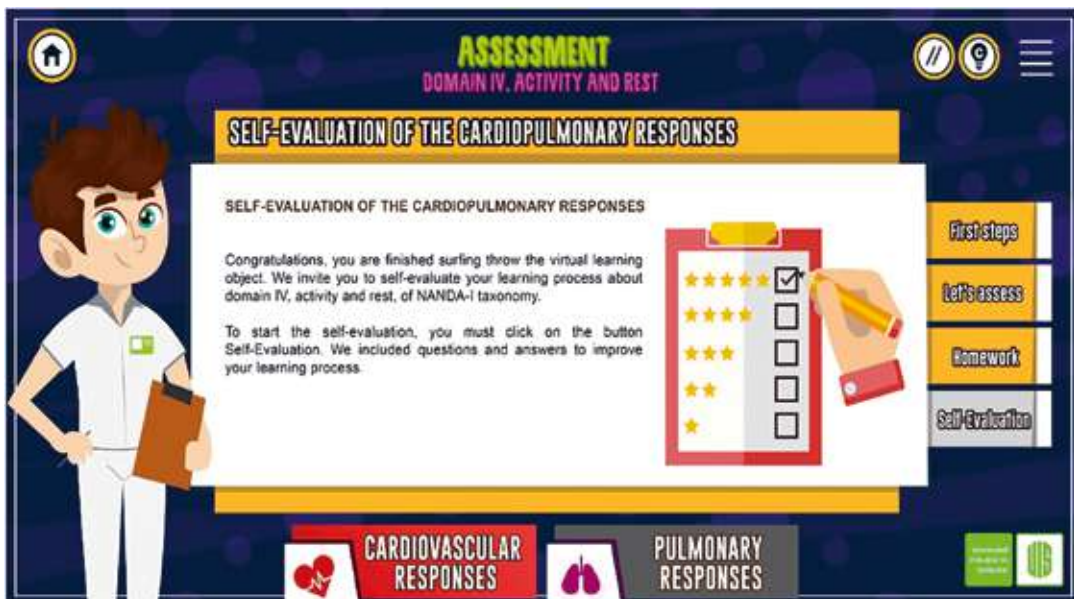


Figure 2. Section assessment.

Table 1. Operationalization of instruction events proposed by Robert Gagné

Events of instruction	Operationalization
Inform students of the objectives	The learning objectives were specified in the introduction.
Gain attention of the students	Images of the respiratory and cardiovascular system, and audios of normal <i>and abnormal</i> breath/heart sounds were recorded and implemented in the LO. In the texts drafted, the main elements that should be learned by the students were highlighted.
Stimulate recall of prior learning	A chart called “Key Points” was created to remind students of the relevant aspects addressed in the LO.
Present the content	An introduction was drafted. It explained the contents and resources of the LO as well as how to use it.
Provide learning guidance	Videos demonstrating the procedures that students must perform to assess pulmonary and cardiovascular responses were developed. The videos were supported by texts.
Elicit performance (practice)	Simulation exercises were proposed in the section “Task” for the student to practice at home.
Provide feedback	In the self-assessment section, when the questions are not answered correctly, messages are displayed explaining the correct option or answer.
Assess performance	A section of self-assessment exercises was created where ‘true or false’ and multiple-choice questions should be answered. At the end of answering the self-evaluations, a report of the qualification obtained is presented.
Enhance retention and transfer to the job	The development of tasks and evaluation by the students also stimulates retention.

Content validation by nurses

26 Nurses were identified and invited to participate, 24 of whom agreed to participate. Then, the sample was composed of 24 nurses; the majority were female (75%), with a specialization in critical care nursing (46%) and/or a master’s degree in nursing (54%). The time of teaching experience in assessing health status and clinical experience in cardiorespiratory care were, on average nine years (SD=5 years) and 13 years (SD=6 years), respectively. The results of content validation are shown in Table 2.

The IVC was 0.86, and all the components of the RLO obtained a weighted average equal to or higher than 0.78, together with a minimum proportion of 85% of agreement on the relevance of each component evaluated ($p>0.05$); therefore, the RLO was considered valid in its content. In this phase, the experts recommended the replacement of the image about palpation of the femoral pulse, standardization of typing and repeating expression, and revision of the redaction of the self-assessment exercises. The authors accepted all these recommendations.

Table 2. Validation content by Nursing experts (n=24)

Evaluated aspects	WA*	% Agree	p-value**
Objectives			
Consistent with nursing practice	0.91	88	0.50
Objectives can be achieved	0.93	96	0.10
Content			
The content is consistent with the proposed objectives	0.85	88	0.50
The content is consistent with nursing practice	0.93	96	0.11
The content is presented in a logical sequence	0.90	92	0.28
The content addresses precisely the assessment	0.80	83	0.49
The information presented is correct and updated	0.89	88	0.51
The images illustrate correctly what was mentioned in the text	0.80	83	0.49
The videos are compatible with the reality	0.89	100	1.00
The audios are compatible with the reality	0.84	83	0.49
The content is adequate for students	0.88	92	0.28
The language used is understandable	0.89	83	0.49
The RLO has a sufficient number of topics, properly divided	0.86	83	0.49
The content has all the necessary resources to demonstrate the assessment	0.79	75	0.14
The content has all the necessary steps to carry out the assessment	0.84	83	0.49
Relevance			
The RLO is relevant for nursing practice	0.97	100	1.00
The homework is relevant so that the student can complement their knowledge	0.80	75	0.14
The images illustrate important aspects for the assessment	0.83	83	0.49
The videos illustrate important aspects for the assessment	0.87	91	0.31
The audios reproduce important sounds for assessment	0.82	83	0.49
The images are relevant for students can make the assessment	0.82	83	0.49
The videos are relevant for students can make the assessment	0.85	83	0.49
The audios are relevant for students can make the assessment	0.83	79	0.29
Environment			
The virtual object is adequate for content presentation	0.89	88	0.51
The images used are adequate for learning	0.80	79	0.29
The videos used are adequate for learning	0.86	83	0.49
The homework provides learning situations	0.81	71	0.06
The evaluation favors learning	0.81	75	0.14
Content validity index	0.86		

*Weighted averages

**Binomial test

Evaluation of usability by nursing students

Twenty-two students participated in this phase, with a predominance of women (91%), with a mean age of 22 years (SD = 1.7); the majority of the students were studying in their seventh semester of Nursing (55%). The results of the usability evaluation by the students are shown in Table 3. All the evaluated components obtained a

minimum proportion of 85% agreement among the nursing students on the relevance of each evaluated component ($p > 0.05$), it is inferred that the RLO can be understood and engaging for the students who use it. As with the nurses, the nursing student suggested reviewing the redaction of the self-assessment exercises as well as the veracity of the answers to these exercises. The authors accepted the recommendations resulting from phase 3.

Table 3. Evaluation of the usability of the virtual object by Nursing students (n=22)

Aspects evaluated	n	% Agree	p-value*
Language			
The language is appropriate for the students	22	100	1.000
The language is easy to understand	22	100	1.000
Design			
The amount of information on each page is appropriate	17	77	0.226
The colors are appropriate	20	91	0.338
The font size is appropriate	21	95	0.137
The sections divide appropriately the content	20	92	0.280
The modules divide appropriately the content	22	100	1.000
Content			
The objectives are clearly defined	21	95	0.137
The information is presented in a logical and consistent way	21	95	0.137
There is correlation between images and content	22	100	1.000
There is correlation between videos and content	22	100	1.000
There is correlation between audios and content	22	100	1.000
The proposed homework is relevant	21	95	0.137
The evaluation is relevant	20	91	0.338
Interaction and stimulus			
The RLO generates interest	22	100	1.000
The RLO is easy to use	22	100	1.000
The RLO proposes learning situations	22	100	1.000
The RLO invites to reading	22	100	1.000
The RLO stimulates learning	22	100	1.000
The RLO facilitates the retention of content in memory	21	95	0.137
Recommends using the RLO to other nursing students	22	100	1.000

*Binomial test

Discussion

This study produced and evaluated the validity of a reusable learning object for teaching the assessment of NANDA Domain 4. Activity/Rest, cardiovascular and pulmonary responses for use in virtual learning environments; we also assessed nursing students' perceptions about the usability of this RLO. Participants, nurses who served as experts and nursing students, positively evaluated the RLO. Although the RLOs offer new opportunities for the teaching and learning process, previous studies in Spanish-speaking countries about the construction and validation of such technologies in the area of nursing were not found, let alone, in the teaching of the assessment of the human responses according to the domains of the NANDA-I Taxonomy.

The construction and validation of educational technologies, such as in the case of the RLOs, require an adequate pedagogical and technical approach; without them, there is a risk of producing technological material free of educational objectives effective.⁽²⁹⁾ Hence, the elaboration of the RLO was based on the instructional theory of Robert Gagné, specifically in the Nine Events of instruction.⁽³⁰⁾ Gagné's instructional theory seeks to describe the conditions that favor the learning of a particular ability;⁽³¹⁾ it places the student as the focus of the learning process since the student is mainly responsible for the acquisition of knowledge or skills.⁽³¹⁾ In this study, Gagne's events of the instruction provided a sound structure for developing the content of the RLO, which we believe can promote effective learning for the assessment of the cardiovascular and respiratory responses without requiring the constant presence of a teacher.

We highlight that the construction phase of the RLO was the most complex phase of this study; it required the participation of a professional with certified experience in creating RLOs, and another expert in video development. Regarding the

content validation phase, it is emphasized that the criterion "aspects addressed by the RLO are important for nursing practice in terms of nursing assessment" obtained the highest score (weighted average 0.97; 100% concordance), see Table 2. In addition, the global Total-VC was satisfactory for the validation process (0.86); however, the specialists made necessary suggestions to improve the RLO.

The content validation of educational technologies allowed us to verify the relevance of the components of the teaching material to the construct they represent; due to the findings in content validation, as in other studies,^(25,32) in this study, adjustments to the RLO had to be made before obtaining the final version of it. The content validation demonstrates the importance of this stage in obtaining quality educational resources. On the other hand, the results related to the usability of the RLO from the evaluation carried out by the nursing students were satisfactory, given that all the proportions were greater than 85% ($p > 0.05$). We noted that all students assessed aspects related to interaction and stimulation as appropriate, except for the "Facilitates retention of content in memory" criteria, evidenced by the proportions of 100% concordance.

Current nursing students regularly use the Internet, are digitally fluent, and prefer alternative methodologies to traditional classes; they are a generation that evidence knowledge, skill, and interest in using virtual objects.⁽³³⁾ Also, as maintained by Windle et al.,⁽³⁴⁾ the RLOs can be an effective and popular educational intervention within an aspect of the curriculum that students traditionally find difficult. They are more effective in terms of students' attainment than the traditional lecture format. Such popularity and effectiveness can be explained by la flexibility and accessibility that they provide for study.⁽³⁴⁾ In this regard, and as well as exposed by other researchers,⁽³³⁾ the RLO construed and validated in this study can encourage nursing students to learn autonomously about cardiovascular

and pulmonary responses assessment. In the light of the above, we recommend using and making the RLO available to nursing students for assessment of the NANDA Domain 4. Activity/Rest, cardiovascular and pulmonary responses. However, teachers who wish to integrate the RLO in their classrooms must receive preparation based on a fundamental pedagogical approach.⁽²⁹⁾

On the other hand, with the advent of the COVID-19 pandemic, advances in technology-mediated teaching became necessary to cover the qualified training needs of nursing students; consequently, the current perspective is the development of new technologies that mediate learning.⁽³⁵⁾ In that sense, studies on the development and validation of educational technologies, as is the case in this study, acquire particular relevance because they allow the production of educational resources that make it possible to address content remotely within a friendly learning environment.

It is essential to highlight that one of the strengths of this study was the participation of experts and nursing students who represent the audience for which the RLO was intended. Such participation is crucial because it increases the acceptance and credibility of this educational technology.⁽³⁶⁾ Although a rigorous procedure was implemented to develop and validate the proposed RLO, this methodological study has limitations; first, the fragility of the inclusion criteria for experts. In this

study, postgraduate training, or publications in the thematic area of the study were not considered, as some authors propose, due to the difficulty of finding nurses in our environment with these characteristics; second, this study having been carried out with nursing students from only one educational institution.

Finally, the authors used only the methodological research approach; therefore, objective measures of improvement in knowledge of assessment of cardiopulmonary responses were not collected; future research should evaluate the effectiveness of the RLO to increase knowledge and improve the performance of nursing students concerning the assessment of the NANDA Domain 4. Activity/Rest, cardiovascular and pulmonary responses.

Conclusion. The reusable learning object developed in this study is a new resource for teaching the assessment of the NANDA Domain 4. Activity/Rest, cardiovascular and pulmonary responses. It can be considered a valid RLO based on the above results. The validation process included nursing professionals with experience teaching and assessing the health status and nursing students. The suggestions of the nursing specialists and students were considered for the adjustment and final version of the RLO, which can be used for teaching the assessment of cardiovascular and respiratory responses in nursing students.

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Knowledge of teachers about suicidal behavior in adolescents

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Original article



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Knowledge of teachers about suicidal behavior in adolescents

Abstract

Objective. To identify the knowledge of teachers about suicidal behavior in adolescents. **Methods.** Qualitative exploratory-descriptive study conducted in a state school in the municipality of Porto Alegre, RS, Brazil. Twelve teachers participated in the study. Data were collected through semi-structured interviews analyzed using Bardin's Content Analysis. **Results.** Three categories were built: "Warning signs of suicide", related to the signs identified by the professionals; "Risk factors for suicide", which indicate the reasons that may lead adolescents to present this type of behavior; and "Difficulties in dealing with the behaviors", referring to the behaviors adopted by adolescents and the difficulties of teachers before the theme. **Conclusion.** It was possible to identify that teachers recognize some signs of suicidal behavior, as well as some risk factors. Nonetheless, it is necessary to

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qualify them to approach the subject, since they feel insecure to act in more critical moments, thus generating mainly feelings of sadness, guilt and powerlessness.

Descriptors: alert; behavior; knowledge; guilt; education; risk factors; mental health; adolescent health; suicide; sadness.

Conocimiento de los profesores sobre el comportamiento suicida en los adolescentes

Resumen

Objetivo. Identificar el conocimiento de los profesores sobre el comportamiento suicida en adolescentes. **Métodos.** Estudio exploratorio-descriptivo y cualitativo realizado en una escuela pública del municipio de Porto Alegre, RS, Brasil. Doce profesores participaron en el estudio. Los datos se recogieron mediante entrevistas semiestructuradas, que fueron analizadas utilizando el Análisis de Contenido de Bardin. **Resultados.** Se construyeron tres categorías: “Señales de alerta de suicidio”, relacionada con las señales identificadas por los profesionales; “Factores de riesgo de suicidio”, que indican las razones que pueden llevar a los adolescentes a presentar este tipo de comportamiento; y “Dificultades para lidiar con los comportamientos”, relativa a las conductas adoptadas por los adolescentes y a las dificultades de los profesionales frente al tema. **Conclusión.** Se pudo identificar que los profesores reconocen algunas señales de comportamiento suicida, así como algunos factores de riesgo. Sin embargo, es necesario cualificarlas para el abordaje del problema, pues se sienten inseguros para actuar en los momentos más críticos, generando principalmente sentimientos de tristeza, culpa e impotencia.

Descritores: alertas; conducta; conocimiento; culpa; educación; factores de riesgo; salud mental; salud del adolescente; suicidio; tristeza.

Conhecimento de professores sobre comportamento suicida em adolescentes

Resumo

Objetivo. Identificar o conhecimento de professores sobre comportamento suicida em adolescentes. **Métodos.** Estudo exploratório-descritivo, qualitativo, realizado em uma escola estadual no município de Porto Alegre, RS, Brasil. Participaram no estudo 12 professores. Os dados foram coletados mediante entrevistas semiestruturadas analisadas por meio da Análise de Conteúdo de Bardin. **Resultados.** Foram construídas três categorias: “Sinais de alerta para o suicídio”, relacionada com os sinais identificados pelos profissionais; “Fatores de risco para o suicídio”, que apontam os motivos que podem levar os adolescentes a apresentarem este tipo de comportamento; e, “Dificuldades em lidar com os comportamentos” referentes às condutas adotadas pelos adolescentes e as dificuldades dos professores frente ao tema. **Conclusão.** Foi possível identificar que os professores reconhecem alguns sinais de comportamento suicida assim como alguns fatores de risco. Porém, é preciso qualificá-los para a abordagem ao assunto, visto que se sentem inseguros para agir em momentos mais críticos, gerando principalmente sentimentos de tristeza, culpa e impotência.

Descritores: alerta; comportamento; conhecimento; culpa; educação; fatores de risco; saúde mental; saúde do adolescente; suicídio; tristeza.

Introduction

Globally, one in seven young people between 10 and 19 years old has some type of mental disorder, representing 13% of the global burden of disease in this age group. Diseases such as depression and anxiety, as well as behavioral disorders (attention deficit hyperactivity disorder and conduct disorder), are the main causes of comorbidities among adolescents. In turn, suicide is the fourth leading cause of death among young people aged 15 to 19 years.⁽¹⁾ Suicidal behavior comprises suicide ideation, suicide attempt and suicide itself.⁽²⁾ The increased incidence of suicidal behaviors in adolescence can be explained due to the process experienced by these individuals. Conflicts, changes, physical and sociocultural transformations, which amplify levels of anxiety and depression, are considered risk factors for this type of behavior.⁽³⁾ Teachers, because they spend a considerable amount of time with their adolescent students, can be sources of information about signs that indicate their mental health. When qualified, they can help in the identification of risk signs of suicidal behavior occurring at school, being part of the support network in crisis situations.⁽⁴⁾

Given this, the school plays an important role in promoting and protecting the health of students, having a great impact on all aspects of their lives. In this environment, patterns of behavior and relationships that can endanger the health of young people are reproduced.⁽²⁾ Therefore, the school environment can be a privileged place for early identification of problematic situations and implementation of preventive and protective measures. The nurse who participate in education actions facing intersectoral programs of the public health and education networks must participate in interdisciplinary activities, contributing to the development of skills through training, with the professionals who are closest to the adolescents. In view of this, the objective of the study was to identify the knowledge of teachers about suicidal behavior in adolescents.

Methods

This is a qualitative exploratory-descriptive study, carried out in a state school in the city of Porto Alegre, RS, Brazil, which serves about 150 children and adolescents between 6 and 17 years old, from the 1st to the 9th grade of elementary school. The choice of the place for the study was by convenience. Twelve teachers who worked in the morning and afternoon shifts were interviewed. The inclusion criteria were: being an active elementary school teacher and being available to participate in the interview. Teachers on Health or Special Leave at the time of data collection were excluded. The collection

occurred in the period from July to August 2019, through semi-structured interviews, with open questions, respecting the following themes: perceptions of suicidal behaviors, warning signs of suicide, motivations for suicidal behaviors in adolescents and possible actions in the face of these behaviors and, finally, difficulties before this theme. The interest in the research topic was due to the verification of cases of suicide attempts among adolescents.

The participants were approached face to face and informed that the research would be conducted by an undergraduate nursing student and that the results of this research would be presented in the academic and scientific environment. They were aware of the interview script. As proposed by Gaskell,⁽⁵⁾ the steps for conducting individual interviews were followed. The interviews were carried out by an undergraduate nursing student under the supervision of the person in charge of the research, a PhD in nursing. The researcher developed skills and competencies to conduct interviews during her academic training.

The individual interview was held in a reserved space, with date and time previously arranged, at the workplace of the teacher, during the opposite shift, so as not to interfere with his or her work activities and with a maximum duration of one hour. Only the interviewer and the participant stayed at the interview site, ensuring the accuracy and anonymity of the contained information, omitting the names of the participants and replacing them with numbers. There was no refusal among the educators invited to participate in the research. Similarly, there were no dropouts during the study. Audio recordings were used for data collection, which will be kept for five years under the responsibility of the researchers, and after this period they will be destroyed. There was no need to repeat any interview. Notes were made after reading the interview transcripts thoroughly. The transcripts were not returned to the participants. For data analysis, the Content Analysis method proposed by Bardin was used. It consists of three

steps: pre-analysis, exploration of the material and treatment of results, inference, and interpretation.⁽⁶⁾ Data saturation was discussed among the research team members. The researchers transcribed the interviews in Word documents and then coded the data in an Excel spreadsheet, providing a description of the categories that emerged after coding. The categories presented in the research were derived from the obtained data, with quotes from the participants being presented to illustrate the findings according to them. There was consistency between the presented data and the main findings, being clearly presented in the findings, and with discussion of minor themes throughout the research. Due to the onset of the COVID-19 pandemic, the aforementioned institution closed, and then it was not possible to conduct a presentation of the data found in the research to the participants.

The research was approved by the Research Committee of the School of Nursing (COMPESQ/EENF) of the Federal University of Rio Grande do Sul (project number 36425) and by the Research Ethics Committee of the Federal University of Rio Grande do Sul (opinion number 3.416.739), in June 2019. There was also prior authorization from the educational institution in which this research was conducted, with the project being presented and personal objectives and reasons for doing the research clarified. The study participants signed the Free and Informed Consent Form in two copies, one for the interviewee and the other for the researcher.

Results

The analysis of the interviews allowed the grouping of data into three categories: (1) warning signs, (2) risk factors and (3) actions and difficulties.

Warning signs

When asked, based on their professional experience, about *“what are the warning signs*

of suicide?”, isolation is pointed out as one of the main changes observed in the behavior of adolescents at school, and most of the research participants affirm that they are aware of this change. Likewise, changes in activity or mood levels are reported: *I think that not only isolation, but also too much euphoria. This is also a worrisome thing (E4); She had a very unstable behavior, sometimes she was very depressed and sometimes she was very happy (E8).*

Self-injury is also mentioned as a warning sign, along with a change in the way the adolescent dresses: *Then I asked her: did you do that? She told me: teacher, I feel such a great pain inside me, that I'd prefer to feel physical pain than this pain that I carry inside my chest (E5); [...] she came to talk to me a lot, I noticed that, even in the heat, she was wearing long sleeves and always saying that one day she would end her life. [...] (E11).* The decrease in school performance is mentioned as a fact that draws the attention of the teacher, believing that something is not right with the student: *He starts getting low grades [...] (E12).*

Finally, another important sign reported is suicidal ideation. Adolescents sometimes express suicidal intentions at school, in moments when they are questioned or simply verbalize the desire to commit the act: *I've already had cases of students who came to me and verbalized: "I don't want to live anymore" (E12), They say: "I'm going to kill myself," and we think it's a child and it won't happen ... (E11).*

Risk factors

When asked about possible risk factors for the development of suicidal behaviors, some interviewees bring up statements that relate them to the issue of body acceptance and low self-esteem: *I think that acceptance, that standard thing, I'm too fat, I can't have my group of friends because no one will accept me or I'm too thin (E1); There's another boy who was fat, he's still fat, but he got breasts, so he really wants*

to have that fat removed. Then, the question of acceptance arises (E6); The bullying that can occur in the school environment appears in the reports as a reason for concern for professionals; There are students who are so terrified of this type of aggression from their peers (bullying) that they end up thinking that they are not part of society because they are not equal to the standards they have set in their heads. (E5).

The use of the internet is mentioned as an important element that requires attention, because there is too easy access to social and digital media, which can generate negative influences on the adolescent: *Not to mention the internet. And since they are vulnerable, they are ashamed of everything, "what do people think of me?", exposure is one thing ... (E8); People, our own students, see a lot of things on social networks. Remember there was a program on social networks that said "do it", or "if you don't do it, kill, you have to do it and kill". Blue whale (E7); Some teachers point out the occurrence of psychiatric disorders, especially depression, in the development of suicidal behaviors. I understand that this suicidal behavior starts with a depression [...] (E1); Because of a depression, I attempted suicide all the time (E12).*

The lack of family structure, often associated with the occurrence of domestic violence, alcohol and drug use, as well as being in a situation of social vulnerability, has already alerted the professionals who live with these adolescents: *First of all it is the family, the family disorganization can be a risk factor (E8); They have these social issues we can say so that are quite aggravating, the lack of resources, family, the environment where they are, their social vulnerability situation (E12); One factor that can lead to suicide is domestic violence (E12); A student told me the other day that his mother drinks, his father drinks, his grandfather drinks and he drank too. He told me that his stepfather allows him to drink beer. I told him that it is wrong. Then you understand children; usually they are innocent and are*

portraying what they see inside the home. It is complicated (I1).

Actions and difficulties

For teachers, when there is a suspicion of suicidal behavior, the most common approach is to seek guidance from the Administration or Educational Guidance Service (SOE, as per its Portuguese acronym) of the school, according to the statements below: *Well, first place I would seek help at the school, at the SOE, with the Administration, seek support in what I have within the school [...] We are a team and we have to help each other. Accordingly, with them, we have to look for what we can do, look for our rights (E2); I would talk to the manager, with the SOE [...] it's hard (E7).*

Some reports talk about the importance of communicating with the family: *Look, as I told you; it is important to call the parents urgently, report the fact (E5); After (passing the case to the administration) we call the family member to be able to talk (E9).* According to the statements, it is necessary to follow-up the outcome of the case, because if family negligence is identified, other directions can be taken: *And then there is that, pass it on to the Administration, to the Guardianship Council; these are the means we have (E10); If the Guardianship Council can't solve it, then we go to the Public Prosecutor's Office. That's the way (E11).*

In turn, the reported lack of preparation leads to difficulties in dealing with the situation, thus generating feelings of guilt, for not having been able to identify something before; and of sadness, for believing that they cannot help enough: *We do much more than we should, not because we don't want to, but we are not prepared. I was very afraid, even when I wrote a letter to a student who was hospitalized for self-injury. I was afraid of what I could or couldn't say, we don't have guidance, we don't have preparation on the subject (E8).*

The speeches show the internal conflict on the part of teachers when faced with a student presenting suicidal behavior. Conducts adopted with insecurity lead them to worry that they are doing something wrong or that may worsen the situation of an adolescent. In the attempt to help, they also end up suffering: *Gosh! Something happens in class, tomorrow the guy doesn't come. Two days later you find out that he tried to commit suicide. Therefore, you feel guilty because a word you could have said! (E1); When I got his essay I burst into tears, I started to cry, cry, cry. Then the manager got worried, "this kid is going to kill himself, we have to do something. I was very shaken psychologically (E9); I did what I thought was right at the time, but today I think I was a little negligent, I think I should have called before, should have sent for the father before, because I tried to talk to her(manager), you know, not to expose this to the father because we do not know the depth of the thing (E8).*

The overload of work and the concern of the teacher with literacy were also cited as difficulties related to the perception of signs consistent with suicidal behavior. Together with the lack of information to adapt them to the subject, these factors can lead teachers to not notice situations that are happening with the student in the classroom. The narrated experiences are below: *But they signal, we, due to the rush of day to day, don't stay so attentive. (E11) With children, sometimes we are worried about teaching literacy, discipline and behavior, and sometimes it goes unnoticed. If it's a larger group, it goes unnoticed; if they are fighting, one at the other's desk, sometimes this can go unnoticed (E3).*

Even with the qualification of the teachers, it is still necessary to improve sensitivity and empathy to act when faced with a critical situation. The statements corroborate these as important strategies in what concerns suicide prevention: *I'm always taking care, I'm attentive to my students, I always try to know more, how they act outside school, how they are treated, I get into these*

conversations to understand a little better what is going on (E5); I'm doing some dynamics with them. I enter the room to work on issues of emotion, but I feel that there is a lack of theoretical basis to better understand the drawings, the meanings, and here we have openness to do so (E4). The participants emphasize the importance of being alert to disrespectful behaviors among adolescents and willing to talk openly about respect and individuality: [...] when the student comes from another school and calls our attention, many are not educated to deal with differences and start joking when they should not. I said "no, everyone has to respect each other, no one is programmed to have a standard, they will seek that throughout life and we, as human beings, have to respect it", this is the message I pass on to them (E5).

As the following statement shows, the participants understand the need to address the issue in the school environment, so that young people can feel safe to share their feelings. *I always try to talk to them in class, I'm very honest with them, I tell them that I've had depression, serious problems, that I still take medicines, that they have to be honest about it, for them to talk to their parents, talk to us, to an older friend, always something for them to seek help, pay attention to their friends (E8).*

Discussion

This study sought to identify what teachers know about suicidal behavior in adolescents and how they face this situation at school. Isolation, along with mood swings, were indicated as the main changes observed by teachers. The literature describes isolation and mood swings as warning signs of suicidal behavior, along with the practice of self-injury.^(2,7) Corroborating with these findings, Gijzen et al, using a large community sample of adolescents aged 11 to 16, found that loneliness was a central factor for depression networks and also the factor that contributed most to suicidal

ideation.⁽⁸⁾ Regarding mood swings, one study demonstrated that transient impulsive choice abnormalities are found in a subset of those who attempt suicide. Both suicidal ideation and behavior were associated with impulsivity of choice and intense psychological pain.⁽⁹⁾ Regarding emotional dysregulation, a study conducted with adolescent girls with borderline personality disorder identified that participants who had greater difficulty in regulating their emotional experiences were at greater risk for making a suicide attempt.⁽¹⁰⁾

Self-injuries in adolescents were also identified by teachers in the school environment. Data from the Brazilian Ministry of Health point out that, nationally, the age group between 10 and 19 years old appears in second place in the occurrences of self-injury, and this practice is considered a predictive factor for future suicide attempts.^(11,12) According to this result, studies show that the main risk factors for self-injury include bullying, concomitant mental illness and a history of childhood abuse and neglect.^(12,13) Decreased school performance also appears as a major change in attitudes among adolescents.^(2,14) This event may be associated with depression, characterized by a series of signs and symptoms that go beyond a decline in performance at school, such as irritability/instability, difficulty concentrating, feelings of hopelessness and/or guilt, sleep alterations, suicidal ideation and suicide attempts. Suicidal ideation is directly related to most symptoms of depression in adolescents.^(8,15) Results from one study show that anxiety and suicide are strongly linked, since anxiety amplifies the stress response, thus increasing suicidal tendencies.⁽¹⁶⁾

Regarding the risk factors cited by the participants, they bring issues related to body acceptance and low self-esteem. Adolescents dissatisfied with their image are, in fact, more susceptible to suicidal ideation, as shown in the literature.^(2,3) Bullying also appears as a risk factor, since suicidal behavior in the studied age group is several times related to these acts of violence.

⁽²⁾When talking about bullying, it is important to think not only about the victims, but also about the perpetrators, because both suffer emotional and social consequences. Nonetheless, the anguish generated in this process is responsible for the development of depressive symptoms, especially in the victims.⁽¹⁷⁾

According to UNICEF data, cyberbullying also affects young people. In Brazil, 37% of them say they have already been victims of the practice, and 36% report that they have stopped going to school after online violence. Because of this, social and digital media can also influence the development of suicidal behaviors.^(2,18) The results of one study showed that bullying, cyberbullying and peer problems are related, thus indicating a direct and positive relationship with suicidal behavior.⁽¹⁹⁾ As far as family relationships are concerned, they can assume the role of risk or protective factors. Difficulties in relationships, communication, lack of affection and support, fights, physical and verbal violence are present in dysfunctional family relationships. Being exposed to an environment in which young people experience displacement and a sense of not belonging contributes to the occurrence of suicidal behavior in adolescents.^(14,20)

On the other hand, there are studies that show that satisfaction in interpersonal relationships, especially with the family, is a very important protective factor for suicide attempts, since the offered family support has the potential to decrease the psychological impact of difficult situations faced by the individual.⁽²⁰⁾ A review study identified that the most common protective factors for both suicide and bullying were being female, having good mental health, belonging to a two-parent family, safe school environment, good family relationships and having an involved teacher.⁽²¹⁾ The use of alcohol and drugs also presents itself as a risk factor, as shown by Neto and Pelizzari, who, after researching the medical records of young people followed-up in a Psychosocial Care Center for Alcohol and Other Drugs (CAPS AD, as per its Portuguese acronym), with ages between 12 and

18 years, found that 97% of the records analyzed with complaints of suicide attempts were related to alcoholic ingestion. The use of drugs such as marijuana and cocaine, practice of self-injury and being female are also cited as risk factors by the authors.⁽²²⁾ In this sense, evidence identifies that social vulnerability in adolescents is related to negative aspects, especially those associated with involvement with drugs, loss of guaranteed rights and opportunities in the areas of education, health and social protection, with situations of violence, whether domestic or communal, and child labor.⁽¹⁹⁾

Despite still being treated as taboo, issues related to psychological suffering and mental disorders, especially in the adolescent phase, have been taking place in the school environment and require rapid and early interventions, in order to prevent these young people from developing risk behaviors that culminate in suicide. For example, a multicenter European study, which conducted an intervention entitled Young Mental Health Aware Program, which aimed to prevent suicide at school for students at risk. The program was effective in reducing the number of suicide attempts and severe suicidal ideation in school adolescents in the long term (12 months).⁽²³⁾ Thus, considering the role of the school in the lives of children and adolescents, it is evident that this is a privileged environment for the promotion of mental health and suicide prevention. The insertion of suicide prevention strategies in schools is necessary.

During the study, it is evident that educators lack contact with the theme during their training and while working in schools, a fact that can be observed through the reports about the difficulty in acting when faced with a case of suicidal behavior. Concomitantly with this research, another similar study shows that teachers are unaware of the warning signs of suicidal behavior among students. They also report that they do not know how to support students in case of an attempt or completed suicide of another student. Reinforcing the data found in the current research,

it was also pointed out that the school curriculum is perceived as lacking information about suicide and suicidal behavior.⁽²⁴⁾

The action taken by the teacher shows the concern of this professional for the theme and, in particular, the concern for his or her student as a human being who, sometimes, needs to feel safe to be heard, truly heard. Considered a public health problem,⁽¹⁾ suicide requires that nurses inserted in the context of health education and through the School Health Program⁽²⁵⁾ promote the strengthening of bonds between family, students and teachers, thus creating spaces for discussion to systematize, reflect and organize intersectoral work, in order to overcome the difficulties related to the subject under discussion. The lack of understanding about the subject generates emotional discomfort for all involved, and it is up to the health professional to welcome this demand, whether by the adolescents or teachers, and assist in the prevention and promotion of health.

The limitations of the study were due to the number of participants and the fact that the

research was carried out in a single center, which does not allow the results to be generalized. There is a need to expand the studies on the work of nurses in school contexts, in order to be able to assist professionals in the field of education in the early identification of potential cases of suicide. However, this study can serve as a basis for new studies, and the results can be used to improve health care in school, prevent suicide in adolescents, and/or support policies aimed at achieving these goals.

Conclusion

It was possible to identify that teachers recognize some signs of suicidal behavior, as well as some risk factors. Nonetheless, it is necessary to qualify them to approach the subject, since they feel insecure to act in more critical moments, thus generating mainly feelings of sadness, guilt and powerlessness.

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Experiences and Perceptions in Dyads about Ostomy Care. Meta-synthesis of Qualitative Studies

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Original article



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Experiences and Perceptions in Dyads about Ostomy Care. Meta-synthesis of Qualitative Studies

Abstract

Objective. To understand the experiences and perceptions of care dyads (person and caregiver) when having a permanent discharge ostomy. **Methods.** Meta-synthesis that followed the ENTREQ standards and was registered in PROSPERO CRD42020221755; It was developed in three phases: (i). Search for studies in academic search engines, with MeSH terms: [(Patients) AND (Ostomy)] AND (Caregivers)], including qualitative primary studies published between 2000 and 2020; (ii). Assessment of the methodological quality with the CORE-Q instrument and the credibility of qualitative findings under the guidelines of the Johanna Briggs Institute; and (iii). Comparative analysis according to the guidelines by Sandelowski and Barroso. **Results.** The work identified 664 studies; in screening, 35 passed to full-text analysis; 22 to methodological quality evaluation; and 10 to meta-

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synthesis. The study found 43 qualitative findings that constituted four categories: dyads perform instrumental and emotional care; ambivalent family caregiving feelings and actions; assertive and effective family care; and rejection of bodily changes and sexual dysfunction. These categories constitute the central meta-theme: “The dyads experience a life rupture, which is restored in a sea of ambivalent emotions and learning; at the same time, affective, instrumental and assertive care is constructed”. **Conclusions.** People who experience having a permanent discharge ostomy express their rejection to the change in bodily image, alterations in sexual life and as a couple. Caregivers and families are the main source of support by being facilitators in self-care, through relationships of mutuality and reciprocity.

Descriptors: nursing; perceptions; patients; ostomy; caregivers.

Experiencias y percepciones en díadas sobre el cuidado con ostomías. Meta-síntesis de estudios cualitativos

Resumen

Objetivo. Comprender las experiencias y percepciones de las díadas del cuidado (persona y cuidador) al tener una ostomía de eliminación. **Métodos.** Meta-síntesis que siguió los estándares ENTREQ y contó con registro en PROSPERO CRD42020221755. Se desarrolló en tres fases: (i) Búsqueda de estudios en buscadores académicos, con términos MeSH: [(Patients) AND (Ostomy)) AND (Caregivers)], incluyendo estudios primarios cualitativos publicados entre los años 2000 al 2020; (ii) Valoración de la calidad metodológica con instrumento CORE-Q y de credibilidad de hallazgos cualitativos bajo lineamientos del JBI; y (iii) Análisis comparativo según los lineamientos los autores Sandelowski y Barroso. **Resultados.** Se identificaron 664 estudios; en el cribado 35 pasaron a análisis de texto completo, 22 a evaluación de calidad metodológica y 10 a meta-síntesis. Se identificaron 43 hallazgos cualitativos que constituyeron 4 categorías: las díadas desarrollan el cuidado instrumental y emocional; sentimientos y acciones de cuidado familiar ambivalentes; cuidado familiar asertivo y eficaz; y rechazo a los cambios corporales y disfunción sexual. Estas categorías constituyen el meta-tema central: “Las díadas viven una ruptura de vida, la cual se restaura en un mar de emociones y aprendizajes ambivalentes; a la vez, se construye un cuidado afectivo, instrumental y asertivo”.

Conclusión. Las personas que vivencian el tener una ostomía permanente de eliminación, expresan el rechazo al cambio en la imagen corporal, alteraciones en la vida sexual y de pareja. Los cuidadores y las familias se constituyen como la fuente principal de apoyo al ser facilitadores en el autocuidado, por medio de relaciones de mutualidad y reciprocidad.

Palabras clave: enfermería; percepciones; pacientes; ostomía; cuidadores.

Experiências e percepções em díades sobre os cuidados com a ostomia. Metassíntese de estudos qualitativos

Resumo

Objetivo. Compreender as vivências e percepções das díades de cuidado (pessoa e cuidador) ao ter uma estomia de descarte. **Métodos.** Meta-síntese que seguiu os padrões do ENTREQ e foi registrada no PROSPERO CRD42020221755. Foi desenvolvido em três fases: (i) Busca de estudos em buscadores acadêmicos, com termos MeSH: [(Pacientes) AND (Ostomia)) AND (Cuidadores)], incluindo estudos qualitativos primários publicados entre 2000 e 2020; (ii) Avaliação da qualidade metodológica com o instrumento CORE-Q e credibilidade dos achados qualitativos sob as diretrizes do JBI; e (iii) Análise comparativa segundo as orientações dos autores Sandelowski e Barroso. **Resultados.** 664 estudos foram identificados; na triagem, 35 passaram para análise de texto completo, 22 para avaliação da qualidade metodológica e 10 para metassíntese. Foram identificados 43 achados qualitativos que constituíram 4 categorias: as díades desenvolvem o cuidado instrumental e emocional; sentimentos e ações ambivalentes de cuidado familiar; cuidado familiar assertivo e eficaz; e rejeição de alterações corporais e disfunção sexual. Essas categorias constituem o meta-tema central: “As díades vivem uma pausa na vida, que se restabelece em um mar de emoções e aprendizados ambivalentes; Ao mesmo tempo, constrói-se o cuidado afetivo, instrumental e assertivo”. **Conclusão.** As pessoas que vivenciam uma estomia de remoção permanente expressam rejeição à mudança na imagem corporal, alterações na vida sexual e com o parceiro. Os cuidadores e as famílias constituem-se como principal fonte de apoio por serem facilitadores no autocuidado, por meio de relações de mutualidade e reciprocidade.

Descritores: enfermagem; percepções; pacientes; ostomia; cuidadores.

Introduction

People who need a discharge ostomy as part of their therapy face bodily changes that impact the roles they represent, also affecting their families and main caregivers, who support them by assuming care activities upon this highly demanding condition; being required to learn to use and access devices for ostomy care and to health services,⁽¹⁾ which generates economic overload. A long-term adaptation becomes necessary, given that this condition impacts the psychological, social, and sexual dimensions,⁽²⁾ along with integral wellness. These characteristics demand additional services from specialized professionals⁽³⁾ to promote adaptation and develop self-care because high levels of quality of life are strictly related with high levels of skills for self-care.⁽⁴⁾

Within this context, the informal caregiver is understood as the person with or without a family bond, in charge of making decisions and supporting in daily life activities;⁽⁵⁾ they play a key role in developing the capacity for self-care in patients with ostomy by providing time and effort to offer tangible and emotional care, which is associated with better self-control behavior, better control of the disease, and lower risk of mortality.⁽⁶⁾ People person with permanent discharge ostomy and their informal caregivers develop dyadic affective and care relationships characterized by permanence over time, mutuality, and reciprocity through interpersonal relations.⁽⁷⁾ It is important to understand how these dyadic relationships take place around a challenging health phenomenon, like having a permanent discharge ostomy, given that informal caregivers provide emotional support, support in comprehending the information and in the instrumental care of the ostomy, besides economic support, in food preparation, dressing, in daily life activities, and on reincorporation to the new role; likewise, in the case of older adults or people with limitations to perform their self-care, even more demanding support is required from their informal caregivers. If these relationships are assertive, processes of adaptation to this new health situation are facilitated; however, if there is little or no support, the person with ostomy faces greater difficulties.

Overall, according with the Federation Association of Incontinence and Ostomy (FAIS), the number of people who currently live with an ostomy in the world is estimated in two-million.⁽⁶⁾ In Colombia, a 2018 study conducted in a health center in Bucaramanga reports the epidemiological profile of the population with ostomies, describing that 57% were men, 51% > 63 years of age, colostomy predominated (71%), and 59.8% of the discharge stomas were temporary.⁽⁸⁾ In turn, these require in their care frequent hygiene and observation of the normal characteristics of the stoma, besides changing their devices.⁽¹⁾ These care procedures must be learnt by the patient and the caregiver prior to leaving the hospital, but on occasion the patient has upon discharge multiple doubts regarding the instrumental cares and how to confront this new health situation; hence, the dyad faces its situation by diminishing the

emotional burden and seeking family support. Due to this, this meta-synthesis seeks to comprehend the experiences and perceptions of the care dyads (person and caregiver) when having a permanent discharge ostomy.

Methods

Qualitative meta-synthesis with constant comparative analysis approach by Sandelowski and Barroso specific for meta-synthesis,⁽⁹⁾ under the methodological approach adapted by Arias Murcia (2015),⁽¹⁰⁾ besides following the standards given by the Enhancing Transparency in Reporting the Synthesis of Qualitative Research (ENTREQ)⁽¹¹⁾ with registry in PROSPERO CRD42020221755.⁽¹²⁾ This study was conducted from the qualitative research question: 'How do care dyads deal with having a permanent discharge ostomy', which has the following components under the SPIDER structure: **Sample:** Care dyads conformed by adults 18 years of age and older with permanent ostomy and their informal caregivers; **Phenomenon of interest:** Carrying a permanent discharge ostomy; **Design:** Primary qualitative studies (phenomenology, ethnography, grounded theory, among others); **Evaluation:** Perceptions and experiences of the care dyads; and **Research type:** Meta-synthesis of qualitative studies.

Three methodological phases were conducted by five researchers (nurses with master's degree, experienced in qualitative research and in caring for people with ostomies). Phase 1 included the search for studies in the databases WOS - Web of Science, PubMed, ProQuest, Academic Search Complete, Clinical Key, Sage, Ovid, Scopus, Google Scholar, and Lilacs, in the Nacional, Sao Paulo, and La Sabana university repositories; in addition to a manual search; using MeSH-validated terms and their equivalents in Spanish and Portuguese ((*Patients*) AND (*Ostomy*) AND (*Caregivers*)). The foregoing, by selecting studies that complied with the inclusion criteria

of approaching a population constituted by adults 18 years of age and older with permanent ostomy and their informal caregivers, which did not deal with studies in children (this exclusion was contemplated because the relationships of pediatric dyads imply differential characteristics, like increased dependency on care). The work included studies published during the last 20 years (between 2000 and 2020) of qualitative primary designs; the search was carried out from September to December 2020. The identification and selection of the studies was plotted in flow diagram under the PRISMA structure.

Phase 2 performed the assessment of the methodological quality through the COREQ checklist "Consolidated criteria for reporting qualitative research"⁽¹³⁾ with 32 items organized into three domains: research team and reflexivity, study design and analysis-findings. Each manuscript was evaluated in its full text by two independent reviewers and then in committee to agree on the inclusion of the manuscripts. This process was conducted in Excel spreadsheet when recording the characteristics of the article and the evaluation of the COREQ items (complies, partially complies, or does not comply); 12 studies were discarded due to reporting insufficiently information about the participants, data collection and analysis, and not providing significant findings to the research question. The 10 studies selected complied with at least 50% of the 32 COREQ criteria and passed to the data-analysis phase.

Phase 3, according with Sandelowski and Barroso,⁽⁹⁾ performed the following methodological steps: 1) characterization de studies; 2) extraction of findings, identifying *in-vivo* concepts from each manuscript; 3) grouping of these concepts *in vivo* into common codes defined since their conceptualization and evaluating their level of credibility according to the JBI; for each finding, the following criteria were applied of the different levels of credibility: unequivocal (includes evidence that does not generate doubts, like informed conclusions by the participants and

directly observable), credible (includes analyses that are logically inferred in light of the data and the theoretical framework) and not too credible (results not compatible with the data), taking for the study only findings with credible and unequivocal levels.⁽¹⁴⁾ 4) Identification of similarities and differences of the codes; 5) grouping of codes into thematic categories and definition of their conceptualization; 6) construction of the study's thematic categories and meta-theme with the definition of their conceptualization. These steps were worked

on during weekly meetings for six months with participation by the five researchers, constantly comparing through reading and re-reading of the findings, thus, achieving data maturity. Table 1 displays an example of the analysis process performed for the first category generated, which merges subcategories, identifies their concepts, and highlight their similarities and differences, in such a way that the central categories of analysis generated are structured forcefully.

Table 1. Example of construction of the thematic categories for Category 1 “The dyads develop the instrumental and emotional care of ostomies through a relationship of trust”

Subcategories	Concept	Concept	Similarities	Differences
H4. Learning intention / couple / physical and emotional care	H4. Positive care relationship between couples , which evidences the learning intention to provide physical and emotional support.	Need to learn the instrumental skills of ostomy care to support the partner or person with ostomy, through trust and bonding they strengthen	Talk about the specific care of the ostomy and the need to learn to carry it out, to retake daily activities. It manifests the need for support. Identifies positive dynamics in the learning intention.	The role of the person providing support, sometimes it is the partner, other times it is another family member
H9. Need for support	H9. Need for instrumental support (physical) related with the ostomy upon hospital discharge.			
H46. Adaptation to the new role / instrumental support / acceptance of the changes / independence	H46. Positive care relationship between couples , related with el support in the instrumental care of the person with ostomies; besides, evidences that the person develops independence in self-care			
H47. Trust and bonding / adaptation / family affective support / need for companionship	H47. Positive care relationship between couples , related with support in the instrumental care of the person with ostomies; besides, evidences that the person prefers the partner's company in the self-care			
H48. Trust and bonding / adaptation / family affective support / need for companionship	H48. Positive care relationship between couples , related with support in the instrumental care of the person with ostomies; besides, evidences that the person prefers the partner's company in the self-care			
H27. Trust and bonding / adaptation / family affective support	H27. Positive family care relationship , with family instrumental support in caring for the person with ostomy.			

Results

The identification and selection of studies is shown in Figure 1; initially, the different databases and search engines identified 664 studies, of these, the work excluded 13 duplicate studies and 616 studies due to not complying with selection criteria upon reviewing titles and abstracts; 35 studies were recovered and reviewed in full text. When applying the selection criteria, 22 passed to the

evaluation phase of methodological quality with the COREQ checklist; 12 studies were discarded in this phase, given that these did not comply with 50% of the 32 items proposed in this instrument, with the greatest shortcomings related to the information on personal characteristics and the relation with the participants, data collection and analysis; the studies included had scores ranging between 16 and 29 (Table 2); finally, 10 studies were included in this review and were subjected to qualitative meta-synthesis analysis.

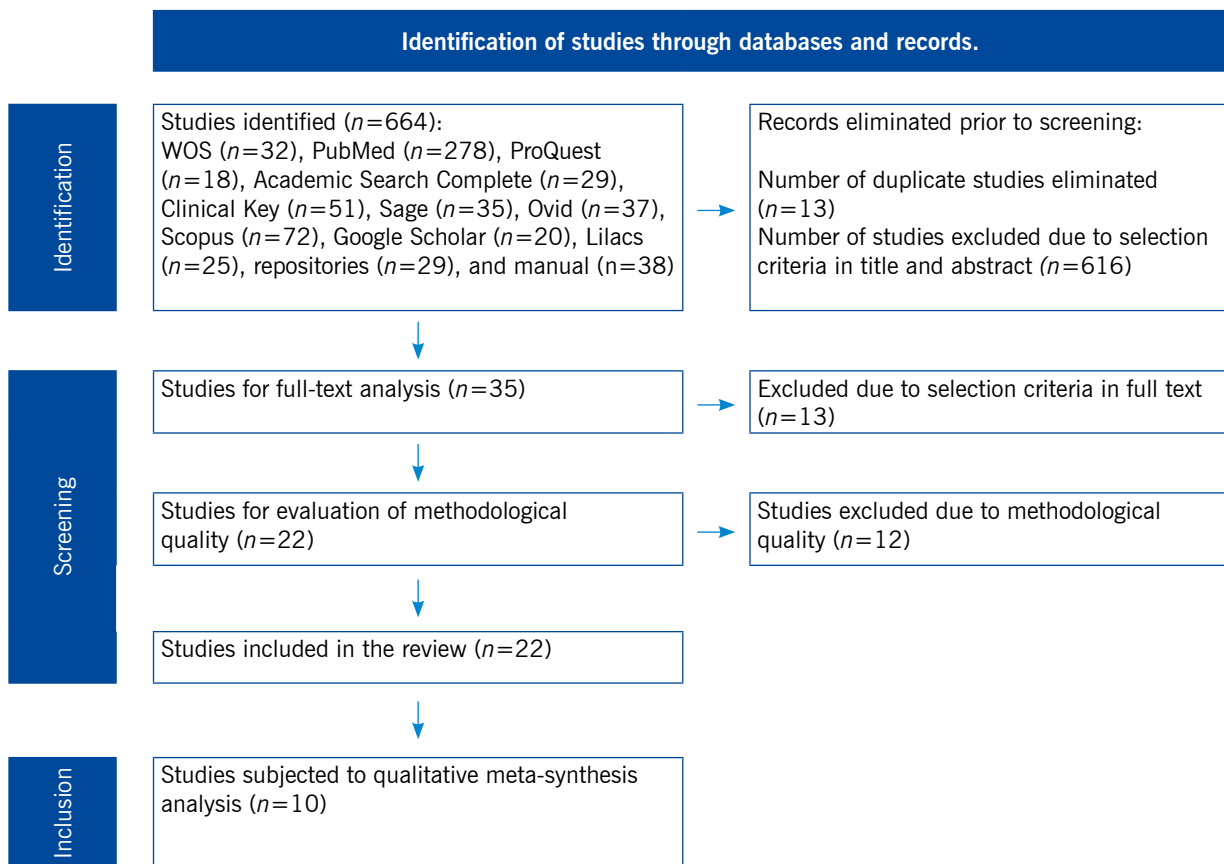


Figure 1. Flow diagram of article selection

The studies selected for qualitative meta-synthesis after passing the filters of identification, screening, and selection were published between 2004 and 2020, from six countries, reporting eight in English and two in Portuguese; only three studies used NVivo qualitative data analysis software;

most used individual qualitative interviews in their different variables (in depth, semi-structured, telephone, among others) and only one study applied focal groups as part of its methodology; these studies integrated participation from 206 individuals with ostomies and 90 primary caregivers and other relatives (Table 2).

Table 2. Characterization of studies selected

Author, year, country and language	Design	Population	Methodological aspects	Methodological quality score	In-vivo codes and credibility
Altschuler <i>et al.</i> , ⁽¹⁵⁾ 2018 - USA, English	Qualitative inductive	31 cancer survivors colorectal ostomized and their caregivers. Most of the survivors were 71 years of age or older (67%), women (55%). Two thirds lived with their spouses and received care from them.	In-person interview – semi-structured and demographic questionnaire. Analysis with the NVivo 8 software with inductive analysis techniques.	24.5 / 32	3 <i>in-vivo</i> codes; Credibility: 3 credible.
Poletto and Silva, ⁽¹⁶⁾ 2013 - Brazil, English	Qualitative - Amplified and Shared Clinical Perspective	10 ostomized people and their relatives. No demographic data specified.	Semi-structured interviews. The analysis was through stages according with Trentini and Paim.	21/ 32	2 <i>in-vivo</i> codes; Credibility: 2 credible.
Halliday <i>et al.</i> , ⁽¹⁷⁾ 2017 – The United Kingdom, English	Qualitative - thematic research	15 ostomized people and 8 caregivers. Median age of patients was 67 years. Most caregivers were spouses or sons/daughters of the patients.	Semi-structured interviews were audio recorded, transcribed textually and anonymized. An inductive thematic analysis was used with the NVivo 10 software.	29 / 32	6 <i>in-vivo</i> codes; Credibility: 6 credible.
M ^o Mullen <i>et al.</i> , ⁽¹⁸⁾ 2011 - USA, English	Qualitative - ethnographic	31 cancer survivors ostomized and their relatives. Age of patients: 45-70 (32.3%) 71-84 (46.9%), and >85 (19.4%). Relationship with caregiver: spouse (67.7%), son/daughter (6.5%), other relative (19.4%), and not related (6.5%).	In-depth interviews. The inductive theme analysis technique by Strauss was used and qualitative data analysis through the NVIVO8 software	20 / 32	3 <i>in-vivo</i> codes; Credibility: 2 credible and 1 unequivocal

Table 2. Characterization of studies selected. (Cont.)

Author, year, country and language	Design	Population	Methodological aspects	Methodological quality score	In-vivo codes and credibility
M ^o Mullen <i>et al.</i> , ⁽¹⁹⁾ 2019 - USA, English	Qualitative – modified grounded theory	57 people with cystectomy and 5 caregivers. Mean age of participating patients was 68 years (range: 38 to 93 years).	Focal groups and in-depth interviews. Analysis performed with focus of modified grounded theory.	20 / 32	2 <i>in-vivo</i> codes; Credibility: credible.
Tao-Maruyama, ⁽²⁰⁾ 2004 - Brazil, Portuguese	Qualitative – ethnographic	12 ostomized people and 5 relatives. Ages of patients range between 45 and 72 years; 7 are women. Caregivers' ages range between 19 and 71 years, four are women.	Semi-structured interviews in form of narratives and observations of the participants. Interpretation through the interpretive anthropology by Clifford Geertz and by Arthur Kleinman.	25 / 32	14 <i>in-vivo</i> codes; Credibility: credible.
Silva and Shimizu, ⁽²¹⁾ 2007 - Brazil, Portuguese	Qualitative – life history	10 ostomized people. No demographic data specified.	Semi-structured interviews. The content analysis technique was used	18 / 32	5; Credibility: credible.
Swenne <i>et al.</i> , ⁽²²⁾ 2015 - Sweden, English	Qualitative - systematic condensation	19 people in postoperative cytoreductive surgery. Mean age was 56 years (range 32 -79 years).	Individual in-depth telephone interviews. Data were analyzed with systematic text condensation according to the Malterud method.	16 / 32	2 <i>in-vivo</i> codes; Credibility: credible.
Sujianto <i>et al.</i> , ⁽²³⁾ 2020 - Indonesia, English	Qualitative - phenomenological	10 relatives of people with colostomy. Most were < 40 years of age (60%).	In-depth interviews. Analysis of data in this study used a method created by Colaizz.	16 / 32	1 <i>in-vivo</i> code; Credibility: credible.
Villa <i>et al.</i> , ⁽²⁴⁾ 2018 - Italy, English	Qualitative - Interpretative phenomenology	11 people with urostomy. 69 years of age, with age range between 59 and 83. Types of caregivers: family caregiver (8): wife (7) and relative (1), caregiver formal (3).	Semi-structured interviews. Interpretative phenomenological analysis	17.5 / 32	5 <i>in-vivo</i> codes; Credibility: credible.
Total	10 studies	206 ostomized people 90 caregivers and relatives			43 <i>in-vivo</i> codes: 42 with credible and 1 un-equivocal.

The work identified 43 findings / *in-vivo* codes, of which upon evaluating their level of credibility – according to the JBI,⁽¹³⁾ 42 were credible and one unequivocal (Table 2), which validated their inclusion in this analysis. As shown in Figure 2, four principal thematic categories were structured that constitute the meta-theme that answers the study’s research question: the dyads with ostomies experience a life rupture, restored in a sea of ambivalent emotions and learning; at the same time, affective, instrumental, and assertive care is constructed. The categories emerging from the analysis centered around four principal ones, which mention performance of instrumental activities in direct care of the ostomy and progressive acquisition of trust when overcoming the fear of making mistakes.

Another fundamental aspect is the ambivalence in the feelings and care actions experienced by the dyad, where they go through moments of fulfillment, acceptance, and trust; but also, through moments of crisis, feeling of abandonment, grief or loss of identity and quality of life. Moreover, it is perceived that assertive care and companionship from the dyads generate satisfaction, feelings of appreciation and a bond of security. Lastly, as indicated in the fourth category, rejection of the new bodily image, loss of their self-esteem and negative self-perception, after the creation of the discharge stoma, as well as loss of sexual functionality sexual when establishing relationships secondary to the perception of rejection or of having accidents with the collection devices.

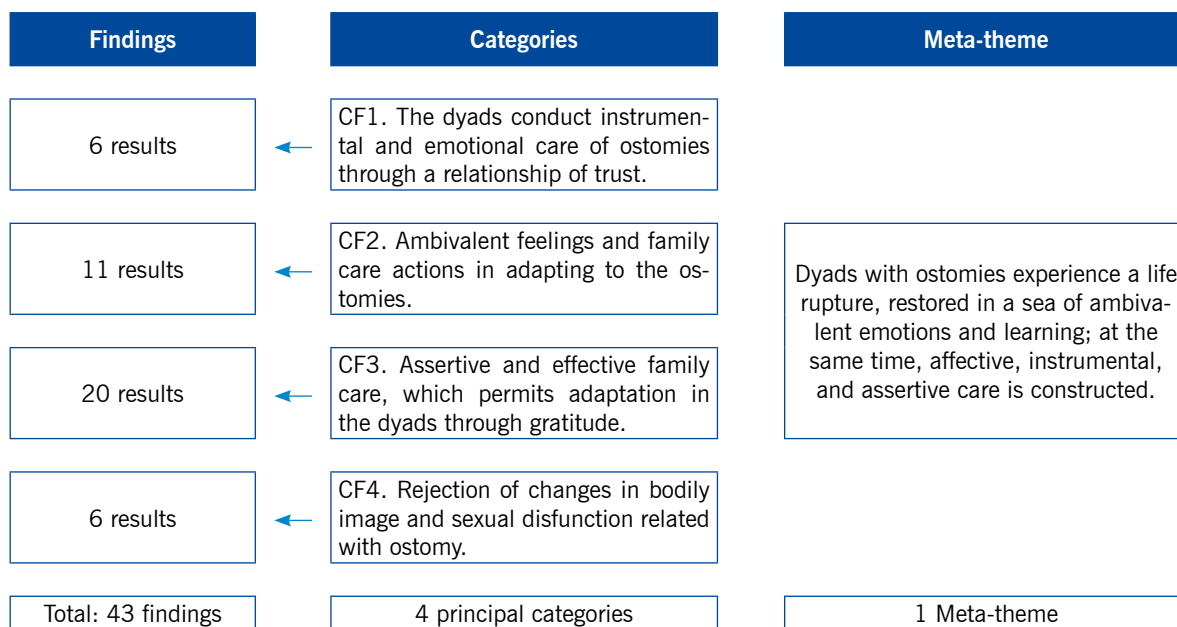


Figure 2. Results of the meta-synthesis of the findings

In the synthesis of perceptions and experiences of people with a permanent discharge ostomy and their informal caregiver, through the metaphor of a sea of emotions that integrates the resulting meta-theme (Figure 3), which – as

of the literature consulted – sought to interpret the different stages the dyad must go through to achieve the new normality. This includes an initial moment characterized by chaos and imbalance, where the ostomy originates and the dyad must

carry out instrumental learning on the principal care, likewise, it must gain knowledge on the diet and necessary clothing to maintain quality of life. At this point, the ostomized person requires psychological, emotional, economic, and social support to continue with the challenges of the new role. Some individuals may receive this support, which aids in the adaptation process, but – in contrast – some people receive little or no support, which causes greater stress and difficulty to reach acceptance of the new reality. Thereafter, comes a stage that again seeks equilibrium within that turbulent sea, where a higher level is reached in achieving competencies on instrumental knowledge and skills, as well as ambivalent feelings about carrying an ostomy, where positive and negative feelings are experienced

in the dyad to accept the new dynamics of life with the permanent discharge stoma in external environments, like the labor, social, academic, dynamics and in recreational settings, as well as in the intimate setting, like the perception of self-image, self-esteem, the relationship a partner and sexuality, reaching as maximum goal empowerment and acceptance of the new reality through acceptance or from spiritual support strengthened by faith and resignation. Finally, in the last stage where a peaceful sea is presented; complete acquisition of instrumental skills is achieved and knowledge is perceived with greater confidence; the dyad expresses dominance in the daily activities of ostomy care and reaches a bond based on gratitude and on the assertive relationship.

Adaptation of the ostomy-carrying dyad



Figure 3. Scheme of the meta-theme. Source: by the authors.

The following categories identify the interpretation of the findings and *in-vivo* codes that structured four principal thematic categories:

Category 1. Capacity of the dyads to perform instrumental and affective/emotional care of the ostomies mediated by a relationship of trust and bonding

This category shows a positive relationship of the dyads where their partners and caregivers display that learning intention to support not only physical but emotional care, allowing individuals to develop independence in their self-care; this is given in the following dialogues:

Altschuler et al.,⁽¹⁵⁾ pg. 533: ... ¿(your husband) does he refuse to help with your ostomy?

P: No, in fact, he says he wants to help me. He wants to be a caregiver. He's learning very slowly and I guess I hope that by the time I really need help, he'll have trained well enough to not only do the physical stuff, but be there for me emotionally.

Villa et al.,⁽²⁴⁾ pg. 49: It was difficult at the beginning. My wife helped me change two or three times, but then I started doing it on my own and now I am increasingly faster.

Villa et al.,⁽²⁴⁾ pg. 50: Then I have to change the bag when it is almost full and the plate every other day. I can do it on my own, but I prefer if it's both of us doing it... my wife helps me.

Category 2. Ambivalent feelings and family care actions in adapting to the ostomies

Relationships of care are characterized by moments where contrasting emotions exist, given that family support is manifested with episodes of fear, resignation, frustration, denial in the dyad, exhaustion and tiredness by the caregiver; this within a context in which care is seen as

demanding human and economic resources. The relationships of the dyads are ambivalent in that family support is manifested during its initial phases in processes that fluctuate between fear and grief. Over time, acceptance of the disease is achieved, as well as the search for support and acquisition of abilities to adapt to the new life reality. The dialogues evidence the initial processes of rejection and difficulty in accepting the process of living with an ostomy:

Poletto and Silva,⁽¹⁶⁾ pg. 535: It was a nurse who did the cleaning and showed my daughter how the cleaning would be done. There, she did it near my daughter and showed how it was done, so it works... So, it's one thing that leaves us scared from the start. It is something new that you know nothing about, you don't know the procedure...

McMullen et al.,⁽¹⁹⁾ pg. 58: My wife said: No, I love you, but I will not do that [tubes for washing and changing bandages].

Further, the dialogues show resignation as part of acceptance and adaptation:

Halliday et al.,⁽¹⁷⁾ pg. 5: Yeah, well, it's, I mean, as much as you've been sorry about it sometimes: that damn thing. You know, that's been your lifeline.

Tao-Maruyama,⁽²⁰⁾ pg. 135: For her, the colostomy is a necessity she had. She had no other solution for this... Today, I am used to it, I never touched it or asked about it because I know she strays from it a bit.

Finally, and after some time, people with ostomies manifest adaptation to living with and caring for their ostomy; some have support from their partners or families; they even mention processes of overprotection that reduce their independence.

Silva and Shimizu,⁽²¹⁾ pg. 309: I have much support from my family. I am very spoiled.

Sometimes I even say, people, I'm not dead... (Rita).

Silva and Shimizu,⁽²¹⁾ pg. 310: My kids don't want me to do anything, but I don't have the nature to sit still. I grew up on the farm with a heavy work and if I shut up, I think it's bad.

Category 3. Assertive and effective family care, which permits adaptation in the dyads and expressed through gratitude

The dyads of person with ostomy and family caregiver evidenced adaptation processes, characterized because positive coping is assumed from the new condition that allows individuals to rejoin their daily life and project themselves with a future life expectancy; in some dyads and families, the spiritual dimension represents strength in these adaptation processes. The importance of family support for the person with ostomy is highlighted in terms of generating motivation, companionship, an environment that facilitates acceptance, self-esteem, and adaptation to the changes caused by having an ostomy; given by gratitude, bonding, trust, recognition, and empowerment. The dialogues describe positive adaptation processes, more advanced in caring for the physical integrity of the skin, companionship and gratitude, emotional support, and motivation:

Halliday et al.,⁽¹⁷⁾ pg. 5: I'm thankful that the girls are young and totally motivated, you know, to help me. If I were alone, I would find it very difficult, quite difficult... (Female patient)

Tao-Maruyama,⁽²⁰⁾ pg. 250: I did not move until my son said: Mom, stop crying, stop being scared, you will be well, you can change the bag! and there I started. Now I change it and clean myself!

A specific dialogue identifies that feelings of fear are hidden, to show courage in front of their children; like the following:

Altschuler et al.,⁽¹⁵⁾ pg. 50: I wanted to act like a heroine, I wanted to pretend that it was nothing, I wanted to pretend to be a woman who was not afraid of anything, to encourage myself. But I was terribly scared. But, since I knew that my children were waiting for me upstairs, this encouraged me.

Other dialogues show spirituality and identify it as part of the positive adaptation processes:

Tao-Maruyama,⁽²⁰⁾ pg. 204: We ask God to give us strength. He is the only one who can give us strength, to endure all the problems.

Category 4. Rejection of changes in bodily image vs. sexual problems along with sexual dysfunction related with the ostomy

People with ostomies describe loss of integrity in bodily image, which may – in some cases – affect the couple's relationship, their sex life, and lead to its dysfunction. It should be noted that for the person with an ostomy, their corporeality is fundamental, thus, they experience much anxiety and concern regarding their sexual pattern:

Tao-Maruyama,⁽²⁰⁾ pg. 234: The only thing I still feel, still fear, is to have an intimate relationship with my husband. He does not accept to see me whole [...]

Tao-Maruyama,⁽²⁰⁾ pg. 122: He (husband) had never seen my colostomy until today. Never, ever (...). Until today, he does not accept this change in my body [...].

Some people are deeply affected by their pathology, which is why they would like to forget their situation and perceive the stoma as an indicator to remember it:

Swenne et al.,⁽²²⁾ pg. 195: I have not initiated any intimate relationship with my spouse. I can't imagine how I would manage with the stoma.

There are so many barriers I must overcome... If I had not had it (the stoma)... it would have been possible to forget all this damn disease as soon as I started to improve, but now I can never do so.

Discussion

The meta-syntheses are novel designs that comprised evidence of primary qualitative studies to construct, describe and/or explain phenomenon of interest in research.^(25,26) The validity of this methodology is given – among other aspects – by the evaluation of quality of the studies, *in-vivo* identification of concepts, construction of descriptive categories and the meta-theme. With regard to the evaluation of quality of the individual studies, it permits critical reading of the objective, sampling, collection and analysis of information;⁽²⁷⁾ for such, some of the tools that contain the minimum standards of qualitative studies are: Consensus-based Checklist for Reporting of Survey Studies (CROSS);⁽²⁶⁾ improving reporting of Meta-Ethnography (eMERGe);⁽²⁸⁾ qualitative research review guidelines (RATS);⁽²⁹⁾ and Consolidated criteria for reporting qualitative research (COREQ).⁽³⁰⁾ For this study, COREQ was the tool selected, given that it establishes essential aspects and transversal to the distinct types of qualitative studies. Overall, this methodology represents a more-comprehensive interpretation of phenomena, through constant comparison and integration of the findings; its development allows broadening the relevance and usefulness of qualitative studies.⁽²⁶⁾

In relation to the results of this qualitative meta-synthesis, as core elements of the meta-theme, it is highlighted that these dyads experience a life rupture, restored through affective, instrumental, and assertive care. In this regard, studies with similar methodology have identified related findings; highlighting the study by Capilla-Díaz *et al.*,⁽³¹⁾ which conducted a qualitative systematic

review also under the Sandelowski theory and evidenced that the experiences of people with ostomy are explained under acceptance, adaptation, and autonomy; these aspects are complemented in that the present study demonstrates that this acceptance and adaptation is facilitated with existence of Assertive and Effective Family Care.

In turn, Pape E *et al.*,⁽³²⁾ through a thematic-type synthesis review evidenced from the experiences of the patients how care must focus on management strategies and emotional support; these findings are complemented with those disposed from the first analysis category in the present study that identifies that the dyads conduct instrumental and emotional care of the ostomies through a relationship of trust; within this context, by this being a complex process, it becomes absolutely necessary to involve spouses and close relatives,⁽³³⁾ with an approach toward the psychosocial aspects of the creation of the ostomy that extends to tangible support to spouses and relatives from the health sector, making it necessary to carry out further research centered on the spouses or relatives⁽³⁴⁾ in relation to how these dynamic relationships of mutuality and support take place.

Similarly, the different studies analyzed show people who experience having a permanent discharge ostomy express rejection to change in bodily image due to a rupture in their physical integrity related with the ostomy; likewise, alteration in the sex life and the couple's relationship is noted – leaving as a result, sexual problems along with sexual dysfunction, as confirmed by García and González in their respective 2020 studies.⁽³⁵⁻³⁶⁾ It was possible to see some behaviors between the spousal dyads from their sexual needs, such as: shame, fear, discomfort, and rejection due to the loss of their physical dignity.⁽³⁵⁾

Among the study findings, it is considered that women are the most affected in their relationship; it is much more difficult to accept or cope with

changes in bodily image; their sex life is altered, causing a disfunction of such, related with that of carrying a permanent discharge digestive ostomy.^(35,36) Due to this, future research should to delve on the male gender and his dyad, as well as on his perceptions from the sexual perspective related with the ostomy.⁽³⁵⁾ Thus, ostomized people and their dyads have sex problems after surgery;^(35,36) sexuality is an important aspect in the spousal dyads, besides being closely linked to the bodily image.⁽³⁶⁻³⁷⁾ However, the ways of life and culture of each dyad can make a difference with respect to how to cope with the new situation in their lives.⁽³⁵⁾

Further, regarding the category of Assertive and Effective Family Care, which permits adaptation in the dyads and is expressed through gratitude; the finding coincide with the care needs of the evident life change and role that impacts upon the dyad with ostomy, in multiple and complex factors related with physical, physiological, mental, and emotional aspects in which – to ensure positive adaptation, these must be satisfied first by the caregiver and secondly from the integral service by the health staff.⁽³⁷⁾ Also, Araujo *et al.*,⁽³⁸⁾ mention in their study to keep in mind the family as principal element in adapting to the stoma, being that it is in charge of providing emotional and social support to confront problems upon this new situation and achieve adequate self-care and autonomy of the subject. Lastly, it is necessary to corroborate that the power of adaptation has a component from the subjectivity of each member of the dyad, having as starting point circumstances of biographic situation, body of knowledge, and prior experiences.^(39,40)

With respect to the category of the Capacity of the Dyads to Perform the Instrumental and Affective Care of the Ostomies mediated by a relationship of trust and bonding, as mentioned by Villa *et al.*,⁽²⁵⁾ people consider the family the principal source of support; it is facilitating at the beginning, but the ideal is for patients to assume their self-care.⁽⁴¹⁾ Due to the foregoing, follow-up and health education processes must be carried

out in personalized manner, from specific learning needs as indicator of successful management of the recovery after the hospital discharge.⁽⁴²⁾

To conclude, the studies analyzed indicate that people who experience having a permanent discharge ostomy and their caregivers undergo a life rupture, which is restored in a sea of ambivalent emotions and learning; while constructing affective, instrumental, and assertive care, as reflected in the meta-theme. Likewise, caregivers and the families become the principal source of support by being facilitators in self-care, through relationships of mutuality and reciprocity. As direct implication for the transdisciplinary clinical practice is the need to assess the individual needs of each care dyad, not merely on instrumental themes and health education, but upon perceiving it integrally, also considering the physical-emotional support and companionship they require; in this sense, these care dyads need to have from health systems formal support and follow-up strategies, including things as important as guaranteeing the necessary supplies.

Regarding the nursing practice, the importance is highlighted of enhancing academic curricula with thematic contents related with this research phenomenon and the literature evidences the need to strengthen education for people with ostomies and their caregivers, given that when leaving the hospital, they must deal with the reality of assuming care independently and can experience initially feelings of fear and distrust related with not knowing about self-care activities and practices. Moreover, for the different health service provider institutions, it would be recommended to implement support groups to ostomized individuals that include therapeutic approach from different professions, like medicine, psychology, social work, nursing, nutrition and dietetics that offer tools to the dyads and guarantee monitoring to evaluate the capacity to adapt to new changes and roles.

As limitations to this study, it can be recognized that few qualitative studies exist on the theme

that – in turn – consider the perceptions of people with permanent discharge ostomies and of their informal caregivers; likewise, many of the primary qualitative studies analyzed do not comply with the minimum methodological parameters provided by the COREQ checklist, given that frequent methodological shortcomings were found in the reports regarding insufficient

information on the participants, data collection and analysis, and not contributing significant findings to the research question, aspects that suggest the need to strengthen qualitative studies on this phenomenon in terms of its quantity and quality; besides, the foregoing permits reflecting upon the need to enhance skills in qualitative health research in different academic scenarios.

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Nursing students experience during the COVID-19 pandemic: a qualitative research



Original article



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Nursing students experience during the covid-19 pandemic: a qualitative research

Abstract

Objective. To describe the professional practice experiences of fifth year nursing students during the COVID-19 pandemic. **Methods.** Qualitative research design with content analysis. Participant sampling was purposive. 13 fifth-year nursing students participated. All of them completed their professional clinical practice in public hospitals and private clinics who cared for COVID-19 patients in Chile. The data were obtained through guided online written self-reflections. **Results.** Three main themes were inductively identified: (1) Facing with a very difficult and stressful situation, due to the permanent use of personal protection elements, multiple emotions, and physical fatigue, as well as facing ethical-clinical dilemmas in daily tasks; (2) Recognising different coping styles in difficult moments, highlighting contact with significant people and combination form of support

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and harmful ways of coping with stress; and (3) Experiences disciplinary learning and personal growth, such as: nursing care management, interpersonal skills in times of crisis and having contributed to the country in this adverse context.

Conclusion. The clinical experience of the students in times of COVID-19, was an opportunity to learn how to perform nursing care in times of crisis, humanize care and support health teams in some of the country's hospitals.

Descriptors: COVID-19; pandemics; students, nursing; nursing care; qualitative research.

Experiencia de los estudiantes de enfermería durante la pandemia de covid-19: una investigación cualitativa

Resumen

Objetivo. Describir las experiencias de la práctica profesional de los estudiantes de quinto año de enfermería durante la pandemia de COVID-19. **Métodos.** Diseño de investigación cualitativa con análisis de contenido. El muestreo de participantes fue intencional. Participaron 13 estudiantes de quinto año de enfermería. Todos ellos realizaron su práctica clínica profesional en hospitales públicos y clínicas privadas atendiendo a pacientes con COVID-19 en Chile. **Resultados.** Se identificaron inductivamente tres temas principales: (1) Enfrentarse a una situación muy difícil y estresante, debido al uso permanente de elementos de protección personal, a las múltiples emociones y al cansancio físico, así como enfrentarse a dilemas ético-clínicos en las tareas diarias; (2) Reconocimiento de los diferentes estilos de afrontamiento en momentos difíciles, destacando el contacto con personas significativas, y la combinación de formas de apoyo y formas perjudiciales de afrontar el estrés; y (3) Experiencias de aprendizajes disciplinares y de crecimiento personal, tales como: gestión de cuidados de enfermería, habilidades interpersonales en momentos de crisis y haber contribuido al país en este contexto adverso. **Conclusión.** La experiencia clínica de los estudiantes en tiempos del COVID-19 fue una oportunidad para aprender a realizar cuidados de enfermería en tiempos de

crisis, humanizar la atención y apoyar a los equipos de salud en algunos hospitales del país.

Descriptor: COVID-19; pandemias; estudiantes de enfermería; atención de enfermería; investigación cualitativa.

Vivência de estudantes de enfermagem durante a pandemia de covid-19: uma pesquisa qualitativa

Resumo

Objetivo. Descrever as experiências de prática profissional de estudantes de enfermagem do quinto ano durante a pandemia de COVID-19. **Métodos.** Desenho de pesquisa qualitativa com análise de conteúdo. A amostragem dos participantes foi intencional. Participaram 13 estudantes de enfermagem do quinto ano. Todos eles realizaram seu estágio clínico profissional em hospitais públicos e clínicas privadas atendendo pacientes com COVID-19 no Chile. **Resultados.** Três temas principais foram identificados indutivamente: (1) Enfrentar uma situação muito difícil e estressante, devido ao uso permanente de elementos de proteção individual, emoções múltiplas e cansaço físico, bem como enfrentar dilemas ético-clínicos nas tarefas diárias; (2) Reconhecimento dos diferentes estilos de enfrentamento em momentos difíceis, destacando o contato com pessoas significativas, e a combinação de formas solidárias e prejudiciais de enfrentamento do estresse; e (3) Experiências de aprendizagem disciplinar e crescimento pessoal, tais como: gestão do cuidado de enfermagem, habilidades interpessoais em tempos de crise e ter contribuído para o país neste contexto adverso. **Conclusão.** A experiência clínica dos alunos em tempos de COVID-19 foi uma oportunidade para aprender a realizar a assistência de enfermagem em tempos de crise, humanizar o atendimento e apoiar as equipes de saúde em alguns hospitais do país.

Descritores: COVID-19; pandemias; estudantes de enfermagem; cuidados de enfermagem; pesquisa qualitativa

Introduction

A new global virus called SARS-CoV-2 emerged in the Chinese city of Wuhan in December 2019, it was called COVID-19 by the World Health Organisation.⁽¹⁾ It has caused a great impact in the lives of people, causing more than 3 million deaths globally and has impacted every country. Chile has not been the exception with ominous effects on the economy, politics and education, and at personal and family level of every citizen.⁽²⁾ In March 2020, the WHO announced a pandemic for COVID-19. In Chile, a catastrophic constitutional state of exception was decreed, to contain and overcome the health crisis.⁽³⁾ The transmission and severity of the disease has caused the death of more than 35,000 people in the Chilean population as of October 2021.⁽⁴⁾ Similar to the situation with SARS in 2002 and a H1N1 influenza in 2009, many healthcare workers have been the front line.⁽⁵⁾

Both pandemics presented a threat for the development of emotional disorders such as stress and anxiety in the healthcare corps from the risk of infecting their families, stigma and post-traumatic stress.^(6,7) Healthcare students are a special group to be considered when analysing the consequences of stress and anxiety because of the impacts on learning. A study on nursing students during the H1N1 pandemic determined that the main concerns were infection risk and the negative reactions of other persons that don't work in health area, evidenced by a behavioural change towards them.⁽⁵⁾ All this fortified students' professional identity in disciplinary, social, and individual senses, favouring a perception of belonging, connection, morality, and emotionality. By contrast, in the current epidemiological situation, anxiety and fear have been described in nursing students,⁽⁸⁾ being an important substratum for stress, having a great group and individual influence, highlighting the risk of psychological crisis.⁽⁸⁾

During curricular practice, nursing students develop personal confidence and strengthen professional competencies.⁽⁹⁾ However, insecurity, fear, impotence, and uncertainty are important stressors that could worsen clinical experience. There are also high burnout levels,⁽¹⁰⁾ which is pernicious to professional training.⁽¹¹⁾ Reflective learning strategies during the professional education are key for developing professional competence.⁽¹²⁾ Reflective practice stimulate critical examination of self-assumptions, decisions, and conclusions regarding a particular problem, which at the same time, improve clinical judgment by reducing mistakes and increasing capacities. Self-reflection in professional nursing training helps students to develop a greater level of consciousness of events and experiences by expressing feelings and emotions, as well as, validating clinical knowledge, and reflecting on their own behaviour.⁽¹³⁾ In Chile, studies exploring health care student's perceptions and experiences during this pandemic were not found. Considering the pandemic situation in various hospitals nationwide, there is a need to deepen the meanings in this context

for final year nursing students who are providing care to COVID-19 patients. The research question guiding this study is: How is the nursing students' experience of performing professional experience in the context of COVID-19 Pandemic?

Methods

Design. A qualitative study design with content analysis^(14,15) was conducted based on the self-reflections of fifth-year students performing their professional nursing practice in clinical units where patients with COVID19 were treated. Because of the nature of this study, qualitative methodology is the most appropriate approach for describing and understanding the experiences of the phenomenon under study. The study was guided by the Consolidated Criteria for Reporting Qualitative Research (COREQ).

Setting and participants. The study was done in a university in Chile, with nursing students, who obtain their degree after 5 years of training. In their last year they complete 540 hours of clinical practice, for 16 weeks. Participant sampling was purposive. All nursing students ($n=25$) doing professional clinical practice in 2 public hospitals and 2 private clinics in Chile, who cared for COVID-19 patients, between the months of March and August 2020 were invited. The study included 13 students, 11 women and 2 men, who voluntarily accepted to participate. Their ages ranged between 22 and 28 years, with average age being 23.4 years. 72% lived with their families, 83% were religious and 2% agnostic, and all were single. The students were invited via email by the secretary of the school of nursing, who is a person external to this study, for diminishing possible conflicts of interest. Subsequently, a videoconference was done to divulge the aim and purpose of this study by the researchers.

Data Collection. Information was gathered through guided written self-reflections by

submitting a different open-ended question each week via the Google Forms platform. This was done over a period of 7 weeks until the meaning saturation criterion was reached. Participants were given 500 words to answer the open-ended question. They were invited to find a time of day that best suited them and to create a special space. It was suggested that they light a candle, take a deep breath and inhale to respond from within. The questions that guided students' self-reflections each week were: (1) How has been your experience completing your professional practice during COVID-19 pandemic?, (2) What has meant for you to do your professional practice providing care to COVID patients?, (3) What has been your experience of preserving human dignity during your clinical practice? How have you dealt with it in your personal and professional life?, (4) What and/or who has helped you in difficult moments you have experienced during practice? How has the help been?, (5) How has your learning experience been from the perspective of nursing management, focused specially on patient in Pandemic framework?, (6) How have you worked communication with patients and their families in COVID-19 times?, and (7) What has your experience of writing and self-reflection been like? Written self-reflections provided an opportunity to know students' thoughts, feelings, emotions, and experiences during their professional practice. It also allowed them to freely express themselves without judgment, as a benefit for the participants. The researchers of the study are female nursing school professors and only they had access to the data collection. All the researchers have clinical and theoretical teaching experience with nursing students. The first two researchers have worked with qualitative methodology before. All of them have a master's degree. Each student was asked to use a pseudonym to protect their anonymity. Reflections were protected with a password and were later erased. The process ended when the meaning saturation criterion was fulfilled⁽¹⁵⁾ and the researchers collectively decided to finish the reflections. Prior data collection, a pilot test was conducted with two nursing students, were the

experience of performing clinical practice with COVID-19 patients was revealed. This information was not included in the analysis.

Data analysis. Qualitative content analysis was done according to the guidelines of Graneheim & Lundman.⁽¹⁴⁾ Students' written self-reflections were the analysis unit. The analysis process was inductively and included the following steps: (1) Begin with researcher's individual reading and re-reading of the reflections one by one, to obtain a global perspective of the contents and familiarize themselves with the information. (2) Meaning units were identified. (3) The condensation process was done, abridging the text, and conserving the essence by making the most faithful possible description of what was said. (4) Next, a code was generated, with the manifest content (the evident) (5) After that, categories were created based on similarities and differences in the content analysis. (6) Finally, the results were discussed between the researchers until they agreed on the codes in discrepancy, categories and themes identified. The analysis was conducted by the investigators. All were nursing professors who supervised the curricular practices. The professors did not know who the participants in the study were, to avoid conflict of interest.

Rigor. Methodological rigour was assured via the criteria of Lincoln and Guba.⁽¹⁵⁾ *Credibility* was manifested by presenting the results to participants, who recognised themselves in the experience (member checking). The *trustworthiness* criterion was achieved by detailing the methodology and analysis of the study (audit trail). To guarantee confirmability, the entire study process was recorded, giving evidence of participants' and researchers' testimony by writing their personal reflections in a field notebook during the study. Finally, to facilitate *transferability* the participants' characteristics and the study scenario were described in detail.

Ethical Considerations. This study was approved by the scientific ethics committee of a Chilean University. Number of certificates: CEC202043.

All study participants previously signed an informed consent release, ensuring their voluntariness, information confidentiality and data anonymisation.

Results

Three main themes emerged from the analysis of the written self-reflections describing what this experience meant: (1) facing a highly difficult and stressful situation, (2) having significant support to face difficult moments, (3) learning experience and professional and personal growth. (Table 1).

Theme 1. Facing a very difficult and stressful situation

Global and national Pandemic context: changes or worsens the conditions for clinical practice

As the academic year begun in March 2020, the final year nursing students started their professional practice at the same time the COVID 19 pandemic was confirmed worldwide and nationwide. This situation generated changes or worsens the conditions for clinical practice: various hygiene measures with several clothing changes when entering the clinical setting and returning home, changes in the working hours and fear of infecting their families: *Coronavirus cases in Chile and their spread weren't traceable anymore. That's where the anxiety started and the fear of entering a clinical setting (E1). Taking the bus and the underground wearing mask and gloves was the weirdest thing I'd done: When I got to the Clinic I changed my uniform and clothes three times a day...when I got home, I did it again... (E2).*

Personal protection elements provide security and tiredness

COVID-19 caused the mandatory use of personal protection elements (PPE), posing a

Table 1. Overview of data analysis

Major themes	Subthemes	Codes / unit of meaning
Facing a very difficult and Stressful situation	Global and national Pandemic context: changes or worsens the conditions for clinical practice	Fear of infecting family Work shifts
	Personal protection elements, provide security and tiredness	Lack of personal protection elements
	Physical exhaustion, feelings and emotions	Sleepiness Fear of infection Uncertainty Stress Angst, sorrow, anxiety
	Ethical-clinical dilemmas around dignity in care and justice	Dehumanization around dignity in care Dying alone Unequal resource distribution
Recognized the different coping styles in difficult moments.	Contact with significant people	Company of the Family, friends, health team, teachers, guiding nurse, patients during process
	Combination form of support and harmful ways of coping with stress	Phone calls, letters Words of thanks of the patient Having faith Natural medicine and yoga
Experience of disciplinary learning and personal growth	The importance of humanised and transcendent care	Consumption of alcohol and sedatives Being next to patient Holding hands Listening to patient Videocalls Communication Interpersonal relations
	Learning from nursing care management	Action and decision Leadership Teamwork Ethics Time organisation Care prioritisation
	Personal growth during practice	Stress management Ability to adapt to change
	Thankfulness and satisfaction for having the opportunity to carry out a clinical internship	Increased empathy Understanding and accepting emotions Self-reflection
		Being able to accomplish clinical experience Being part of a team Feeling lucky Feeling happy when caring and treating Adding my grain of sand

challenge for nursing students in their professional practice; extensive workdays led to physical and psychological irritation. However, these measures granted greater security: *My clinical practice become a daily challenge of body, mind and soul...Every day it's heavier and harder to think... how heavy your legs are, how your hands burn from so much washing, your face hurts from using the mask and the suffocation you get from using it, plus all the aprons and the facial shield (E5).*

Physical exhaustion, feelings and emotions

For nursing students, professional practice turned out to be a great challenge involving physical exhaustion and various feelings and emotions: sleeplessness, uncertainty, stress, anxiety, fear, angst, and sadness over their families' distance: *Physically it's got really exhausting, since we've had to do 24 hour shifts from the first day... talking about the situation with my family generates more chaos, stress, angst and worry (E5); There's physical and emotional exhaustion within the team... The different protocols and changes we'd face every day made me feel constant angst (E6); It's meant facing my own fears. It was a hard process I never thought I'd go through... (E3).*

Ethical-Clinical Dilemma: around dignity in care and justice

Students' experience involved facing difficult situations related to ethical aspects of patient care, including dehumanisation around dignity in care, facing dying alone, and unequal resource distribution. There were times when they omitted activities that were not a priority, to optimize care times, which was perceived as a form of dehumanization of care, taking distance from the patient, and not delivering comprehensive nursing care: *...I think this pandemic dehumanised care, since it's so protocolised and you always try to go into the patient's room the least number of times...forcing you to provide colder and more distant care than we're used to (E8); ...I've*

thought about omitting some care, so I can progress with my work and finish on time... (E12). The dignity of the person was perceived from different perspectives, recognizing its intrinsic value in a particularly vulnerable period. Dignity is when you make them feel like a person again and you don't treat them like a disease...it is through human interaction that you reach and reinforce that dignity (E6). However, there were times when this was compromised: Patients are treated as mere diseases (E7); Some nurses or technicians are in such a hurry that patient care is not kind or personal (E10).

For some students was the first encounter with death. It was difficult considering patient's loneliness and isolation from the loved ones, and not receiving end-of-life care based on human dignity. Some students were irritated and angry because the right of the patient and their family to die with company was violated: *We've tried to let the family see them for at least 10 minutes, from a distance with PPE. But I think it's not enough. How are you going to say goodbye to someone who was important to your life in 10 minutes? That's the other side of COVID... Then they're wrapped in the shroud and then in a sort of plastic bag, they're sealed and then put in the freezer (E9); I feel a deep sorrow in those people who cannot experience a dignified death, being surrounded by a hostile, oppressive, distant and mechanized environment. This is how I would describe the environment that exists in critical patient wards (E4). Finally, another highly relevant ethical dilemma described by some participants was the way of assigning and using resources among the elderly, generating questions about inequity affecting the principle of justice, where the age of the patient was perceived as an indicator for making decisions: *I've felt that doctors try to hurry up some older patients' deaths... they lower their oxygen to free up the negative pressure room for other patients that're younger and more critical (E10); Patient's dignity is violated when we don't have the means necessary to care for everyone equally... we can't appropriately care for our**

population, since we have to choose who we treat and who we won't (E4).

Theme 2. Recognized the different coping styles in difficult moments

Significant people

Students in professional practice had different significant people to better face all the difficult moments previously described. They highlighted support from family, friends, hospital teams, partners going through similar experiences, guiding teachers and instructors: *...Right now I'm getting a lot of support and care from all of my family, friends, teachers, boyfriend, etc. which makes me feel like I'm not alone in this process (E13); I was lucky enough to have an excellent nurse to guide and mentor me who's supported me unconditionally, as well as a really great teacher, understanding and kind (E7).*

Combination form of support and harmful ways of coping with stress

Students described in detail the different forms of support to decrease distress, anxiety and improve sleep, such as: phone calls, letters, patients' words of thanks, the teacher answering her phone after hours, faith, yoga, and natural medicine: My family has been an absolute pillar, in long phone calls, since distance separates us (E3); Patients are very thankful for how we've listened to them. That makes me want to carry on, keep going and receiving that affection that is so reassuring, so that, at least for a few hours, all your fears get left aside (E2); The one who's helped me most in every tough moment, is Jesus... he helps me to find deep meaning at every shift. I personally always have a precious cross in my pocket and every time I'm going through a rough patch, I squeeze it really hard, so I don't feel alone (E10). They also manifested detrimental ways of coping, behaviour that was subsequently modified: I hit the bottle a lot of times too, one glass as a nightcap to calm the nerves, the anxiety and the angst that would come over me suddenly, or some strong pill to get

to sleep. Now I've dropped the earlier doses and concentrated on yoga, having more contact with my friends and natural medicine (E5).

Theme 3. Experience of disciplinary learning and personal growth

The importance of humanised and transcendent care

Over time, students caring for patients with COVID19 recognized that care was not only clinical but realized how important it is to provide holistic and humanized care. They identified the emotional and spiritual dimensions through the pain, loneliness, and fear of the patients: *...I'm not talking about putting up a screen, I'm talking about something deeper, interpersonal relations and communication where we can know each other... finding out new needs, giving integral care when I can know the patient, talk about their family, laugh, know their worries, help them. I feel like it was a job well done (E6). Entering the room all covered being unable to show a smile, an expression, is tough. Hearing some people saying there's nothing else to be done, makes me angry and sad...we can always do something else (E11); ...A patient was really depressed and started to desaturate...she didn't know how to use the videocalls...I showed her, and she could talk to her kids and grandkids... it changed her mood 100% and her saturation rose (E10).*

Learning from nursing care management

For the discipline, learning is described on the base of clinical management, action and decisiveness, leadership, teamwork, learning from the professional and acting ethically with care prioritisation, fortifying, or accelerating the encounter with the essence of care: *It's hard to organise times and manage patients' care in an integral fashion... but if the nurse won't do it nobody will. The spiritual and psychological side strongly influence their recovery (E10); For me, doing this clinical experience has meant re-encountering Nursing (E13).*

Personal growth during practice

Students on practice referred not only having learned from the perspective of the discipline, but also from a personal growth experience, reflected in adaptation, empathy, flexibility, stress management and frustration: *It's an experience that taught me a lot, helped me grow and increase my ability to adapt, my empathy and my teamwork (E6); It's true that we're learning to manage the stress and frustration of situations like what we're going through, which we probably wouldn't learn in practice under normal conditions (E13)*. Furthermore, students indicated that self-reflection let them put their thoughts in order and express in writing their experiences: *It's helped me (the self-reflection) to get my head together about what I think and feel, to hear my feelings, to reflect on how I want to be a nurse tomorrow regarding patient treatment...writing reminded me of various scenes that made me explode, which I find good because that way I could express it and release it (E10)*.

Thankfulness and satisfaction for having the opportunity to carry out a clinical internship

Finally, in the middle of this adverse context there are thanks, achievements, and satisfaction from students for the opportunity to do their clinical experience reflected in elements such as being part of the team, being on the front line, feeling lucky, being happy giving care, contributing and learning in an unrepeatably context: *At the end of the day I've got the chance to make history...I was together with my future colleagues helping my country (E11): We all know that what we're doing is just a drop in the ocean. But if it wasn't there, the ocean would lack something (E6)*.

Discussion

The objective of this study was to describe the experience of students doing their professional

practice in units with patients with COVID-19. Students acknowledged that curricular practice in a pandemic context entailed difficulties and might not have been the most favourable stage for their professional training, coinciding with Peres.⁽¹⁷⁾ However, for others, it meant personal growth and an encounter with the essence of nursing. A predominant theme in the results of this study coincides with the research conducted in nursing and medical students, who expressed concern about their own health and negative feelings, such as fear of infection, uncertainty and anguish, marking the learning process.^(18,19) These same reactions were described by healthcare professionals, who demonstrated increased fear of the risk of accumulating stress-related traumas and psychological complications.⁽²⁰⁾ Other aspects included social isolation to avoid contagion, lack of knowledge about this new disease and protocols, and lack of personal protection elements.⁽²¹⁾

Additionally, students' self-reflections show that they require more tools for deliberating and decision-making regarding complex ethical and clinical situations⁽²²⁾ and facing dehumanised death processes during the pandemic.⁽¹⁸⁾ A relevant theme that generated doubts among students was the way of assigning and using resources, where patient age is an indicator for taking therapeutic decisions.⁽²³⁾ Another reported result was the need to have significant support to face adverse situations and stress during professional practice. Little information is available regarding how students face clinical practice during COVID-19. However, studies on nurses showed various ways of handling stress and its effects.^(24,25)

Within the results of this study, faith is described as a form of help in coping with complex moments. This has not been reported in other studies. On the other hand, coinciding with some accounts from the students in this study, a 2021 report on health professionals in Chile revealed an increase in the consumption of alcohol and sedatives during the pandemic.⁽²⁶⁾ Therefore, it is necessary to be aware of this reality and identify

risk behaviours early to promote healthy lifestyle habits in students. These results suggest that the method of weekly reflections during the clinical practice was very helpful and could be another form of protection and mental health promotion for students.

From the perspective of professional learning, a major challenge in this pandemic is humanising care when facing with the depersonalisation of treatment. This requires nurses who are “partners in human transactions” and can be humanitarian and ethical agents.⁽²⁷⁾ From this perspective, students apply knowledge and learn with spiritual and biopsychosocial vision, dedicating quality time and dignified treatment despite the workload and “protocolisation” as the driver of such depersonalisation.

This study has several limitations. This research was done with nursing students, in the intra-hospital setting in Santiago, so generalization could be limited. Students’ experiences in primary care are unknown, as are the experiences of other healthcare students. Most of the participants were women. The researchers were also teachers supervising some of the students on practice, which may have conditioned the students’ self-reflections to be less critical in their discourse. However, their data confidentiality and anonymity were assured.

In conclusion, this study allows us to understand more deeply the students’ experience in performing their professional practice during the COVID-19 pandemic. Despite the difficulties, the students recognized the importance of the support received and the provision of humanized care, such as: body language, conscious eye, and physical contact, even without dialogue, establishing itself as an element of relief and a relationship of trust between the patient and the nursing student. The accounts of the students

in our study express methods of care oriented to prioritize close treatment, valuing the role of nursing as an integral discipline.

A Brazilian study whose objective was to reflect on the work experienced by nurses in dealing with the COVID-19 pandemic in a public hospital indicated that despite the various barriers: emotional commitment, fear of contagion, lack of human resources and personal protection elements, the nurses were able to practice with satisfaction and leadership, contributing to the improvement of public health.⁽²⁸⁾ The experience was an opportunity for personal and professional growth and encountering the essence of nursing. This study also provides relevant information about what could help improve students’ teaching/learning process. Nursing schools should make a strategic plan to support students’ needs and strengthen coping tools in health crisis situations.

Relevance to clinical practice. This study provides relevant information on what could help improve the teaching/learning process for students and thus have a positive impact on the quality of care for patients and their families. Nursing schools should develop a strategic plan to support students’ needs and strengthen coping tools in future health crisis situations. The results of this study reinforce the need to address mental health with active self-care strategies for students and health professionals especially in times of crisis.

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Social Determination of the Health of Families from Two Neighborhoods in Medellín, Colombia

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Original article



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Social Determination of the Health of Families from Two Neighborhoods in Medellín, Colombia

Abstract

Objective. To understand the health process, from the approach of the social determination of health in two neighborhoods in Medellín - Colombia, to contribute to the care of people, families, and collectives in their multidimensional reality. **Methods.** Qualitative research from the ethnographic perspective, approaching the general dimension with documentary analysis of social policies and community documents, the particular dimension through focal groups and interviews to community leaders, and the singular dimension with the family visit. **Results.** Families and collectives live within a sociocultural setting of resistance, overshadowed by moments of flight and displacement derived from violence, with scant participation in city plans and programs and with structural problems of economic and political exclusion. They constructed the territory as space and shelter in the

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weave that protects and violates them, with processes from uprooting to rooting. The families have maintained protective processes, like family participation in decision making, knowledge on health care, among others, and destructive processes, like informal labor and job instability, without spaces for recreation and with limitations in transportation, in access to health programs and in obtaining food. **Conclusion.** The health of the families has been determined by historical exclusion to work to obtain resources for a minimum vital subsistence, which is why they suffer social vulnerability due to few opportunities for development; they have lived a transformation process of the territory with resistance, solidarity, and construction of social networks.

Descriptors: community health nursing; social determination of health; health-disease process; public health; human migration.

Determinación social de la salud de las familias de dos barrios de Medellín, Colombia

Resumen

Objetivo. Comprender el proceso salud, desde el enfoque de la determinación social de la salud en dos barrios de Medellín, para contribuir al cuidado de las personas, familias y colectivos en su realidad multidimensional. **Métodos.** Investigación cualitativa desde la perspectiva etnográfica; abordó la dimensión general con análisis documental de políticas sociales y documentos comunitarios, la dimensión particular a través de grupos focales y entrevistas a líderes comunitarios y la dimensión singular con la visita familiar. **Resultados.** Las familias y los colectivos viven en un espacio sociocultural de resistencia, matizados por momentos de huida y desplazamiento derivados de la violencia, con escasa participación en los planes y programas de ciudad y con problemas estructurales de exclusión económica y política. Construyeron el territorio como espacio y refugio en la urdimbre que los protege y vulnera, con procesos del desarraigo al arraigo. Las familias han mantenido procesos protectores como la participación familiar en toma de decisiones, conocimientos del cuidado de la salud, entre otros, y procesos destructivos como el trabajo informal e inestabilidad del empleo, sin espacios para la recreación y con limitaciones en el transporte, en el acceso a programas de salud y en la consecución de alimentos. **Conclusión.** La salud de las familias ha estado determinada por la exclusión histórica al trabajo para obtener los recursos para un mínimo vital de

subsistencia, por lo que sufren vulneración social por escasas oportunidades para el desarrollo; han vivido un proceso de transformación del territorio con resistencia, solidaridad y construcción de redes sociales.

Descriptor: enfermería en salud comunitaria; determinación social de la salud; proceso salud-enfermedad; salud pública; migración humana.

Determinação social da saúde das famílias em dois bairros de Medellín, Colômbia

Resumo

Objetivo. Compreender o processo de saúde, a partir da abordagem da determinação social da saúde em dois bairros de Medellín, para contribuir com o cuidado de indivíduos, famílias e grupos em sua realidade multidimensional. **Métodos.** Pesquisa qualitativa na perspectiva etnográfica; abordou a dimensão geral com análise documental de políticas sociais e documentos comunitários, a dimensão particular por meio de grupos focais e entrevistas com lideranças comunitárias e a dimensão singular com a visita familiar. **Resultados.** Famílias e grupos vivem em um espaço sociocultural de resistência, matizado por momentos de fuga e deslocamento derivados da violência, com pouca participação nos planos e programas da cidade e com problemas estruturais de exclusão econômica e política. Construíram o território como espaço e refúgio na urdidura que os protege e os viola, com processos de desenraizamento ao enraizamento. As famílias têm mantido processos protetivos como a participação da família na tomada de decisões, o conhecimento dos cuidados de saúde, entre outros, e processos destrutivos como o trabalho informal e a precarização do emprego, sem espaços de lazer e com limitações no transporte, no acesso aos programas de saúde e na obtenção de alimentos. **Conclusão.** A saúde das famílias tem sido determinada pela exclusão histórica do trabalho para obtenção de recursos para um mínimo vital de subsistência, pelo qual sofrem vulnerabilidade social devido às escassas oportunidades de desenvolvimento; vivenciaram um processo de transformação do território com resistência, solidariedade e construção de redes sociais.

Descritores: enfermagem em saúde comunitária; determinação social da saúde; processo saúde-doença; saúde pública; migração humana.

Introduction

Achieving the well-being of humans has been the interest of health sciences, specially of nursing, which has advanced in comprehending the health-disease process⁽¹⁾ through theoretical, investigative, and practical construction, in search of caring for people, families, and communities, in complex sociocultural settings woven into everyday life.⁽²⁾

This research emerged from two neighborhoods of the 15 that make up commune three of the city of Medellín, Colombia, on the formation of nursing students and with the construction of solidarity projects at Universidad de Antioquia. The work assumed the approach of the social determination of health from the critical epidemiology to comprehend the health process in its complexity configured from three dimensions or domains: general, particular, and singular,^(3,4) and which establishes the ways economic, social, and political relations are produced and reproduced. Eslava⁽⁵⁾ states that social determination is a holistic and dynamic view of the social events that affect life.

The people, families, and communities that inhabit the territory of the neighborhoods La Honda and La Cruz, peripheral zone of the city, have experienced historical and political processes that have conditioned in differential manner their ways of living, getting sick, and dying for over three decades and after suffering displacement, as stated in their community diagnosis by the Community Organizations Network of the La Cruz and La Honda neighborhoods (RIOCBACH, for the term in Spanish);⁽⁶⁾ hence, requiring to document and recognize these processes, seeking to provide health care actions. For the families, the scourge of fleeing their homelands due to acts of violence has marked significantly their life trajectories, reconfiguring new settlements in the city slopes, under unfavorable conditions for their well-being, dignity, inclusion, and democracy⁽⁶⁾

Knowing the determination of the health of these families permits understanding the current conditions and urban-popular population dynamics that affect ownership and the political-administrative recognition as neighborhoods, access to health and social services, quality of housing, education, work, and possibilities for personal and collective development, as evidenced by other studies that have shown situations of inequality of the people who live in peripheral zones, affected by phenomena of the armed conflict, displacement, and the devastating land dispossession, which even has, throughout the country, a historical accumulation of nearly 8.1 million victims from 1985 to 2020.⁽⁷⁾ Some investigations on the social determination of health reveal the problems of urban and rural communities in Colombia, as is the case of Indigenous peoples, according to Lozano and Salazar⁽⁸⁾ and Ramírez *et al.*;⁽⁹⁾ malnutrition and impaired child development due to historical poverty, in works

by Carmona;⁽¹⁰⁾ and the worsening of the health situation of the child population with disabilities, exposed by Hurtado and Arrivillaga.⁽¹¹⁾

In this sense, the social determination of health provides knowledge, methods, and techniques for critical reflection, contextual and complex multidimensional analysis of health processes, caring for life, well-being, and collective health; all crucial for the effectiveness of policies, programs, and projects that seek to promote health and prevent disease in human groups. The aim of this research was to understand the health process of families, from the approach of social determination; focusing its interest on dynamics of adaptation and solidarity weaved and which permit survival, to contribute to the comprehensive care of people and collectives in their multidimensional reality; besides contributing to the planning and management of territorial health.

Methods

Qualitative research from the ethnographic perspective; data collection and analysis integrated different techniques and instruments that permitted the complex and holistic comprehension of the social determination of the health of families from two neighborhoods in Medellín from 2019 to 2020. The general dimension contemplates the historical logics of political, economic, ideological, and cultural order that comprise the social structure.^(3,12) Documentary analysis was performed on 55 planes, policies, programs or projects, memories, diaries, cartographic material and other documents, and complemented with interviews, which accounted for how the country, the department of Antioquia, and the city of Medellín have been affected with the phenomena of violence and displacement.

Interpretation of this dimension was conducted through Walt's analytical proposal⁽¹³⁾ which approaches the analysis of public policy and

which is pertinent to reveal the relations and dynamics present in the general dimension; the author proposes five analysis categories: context, process, content, actors, and effects. A matrix was constructed that permitted the organization, classification, comparability, and analysis of content and identified emerging categories and subcategories. The particular dimension comprises the relational processes of the social groups, which take place due to the structural logics and explain the possibilities of their ways of life, which according to Breilh⁽³⁾ and reaffirmed by Carmona⁽¹⁴⁾ "establishes the mediation conducted by the groups in their creative and resilient action to progress in the conquest of their rights; social class, gender, and ethnicity, are determinant in the ways of life". This dimension was identified through the focal-group technique, aimed at identifying needs, practices, and actions carried out by social and community groups that inhabit the territory in the daily transformation they confront to solve their collective problems.

Three focal groups were held with participation by seven leaders from the network of caregivers and two interviews to members of the Community Action Board to understand their ways of life; this was complemented with a reflexive process with observation and field diaries. The information was coded and interpreted in search of meanings to, then, construct the subcategories and recognize the central category; also creating the analytical memos and conceptual maps. The singular dimension expresses that which "corresponds to the individual, where the genotype and phenotype are located in binding manner with the general and particular levels, determining the lifestyles"⁽¹⁵⁾ This was conducted through the observation and family visit that adopted and updated the instrument of the Primary Health Care model of Antioquia.⁽¹⁶⁾

The families were selected through invitation, in a non-probabilistic sample; choosing 40 families with which there were links through the community leaders and support networks,

or whose situation of vulnerability required their prioritization for social and health care. The information was grouped into the following categories: sociodemographic aspects, housing characteristics, and protective and unhealthy processes. The analysis was performed through descriptive statistics, using Office Excel and SPSS version 25.

The research was of minimum risk and had a process of ethical reflection, respecting the right to freely participate in the study, as well as dignified and comprehensive treatment of the participants. Authorization and signed informed consent were obtained from the members of the Community Action Board, the health care givers network, and the participating families.

A reflexive meeting was carried out with the community and the booklet "I take care of myself, we take care of ourselves and we take care of our territory" was delivered as contribution to the social appropriation and to the gratitude with the territory. The research was approved by the Research Ethics Committee and the Technical Research Committee of the Faculty of Nursing at Universidad de Antioquia.

Results

General dimension: political, social, and economic actions and their expression in the territory

The general dimension analyzed the historically imbricated reality through political, social, and economic actions that have transformed cultural practices in the constitution of the territory of both neighborhoods, as places and spaces for the reception of displaced families. The people and families who live there had their lands taken from them; their experiences for over 20 years have been overshadowed by moments of flight and displacement from the departments of Chocó,

Córdoba, and Antioquia; they have come to take refuge on the slopes of the city, which has allowed them to create a diverse socio-cultural space. In the new neighborhoods they inhabit, they have been witnesses and builders of the physical, social, and cultural transformation, with resistance and solidarity processes that today leave a mark in the city, with cultural practices that have saved their community from disappearance, eviction, relocation, and concealment. In the participatory diagnosis document, community leader Cárdenas Avendaño expresses:⁽¹⁷⁾ *I arrived 20 years ago to the neighborhood, to the hillside, it took me in with my family, it was the shelter against our flight. To this live space I owe my experience and my struggles. It was in the neighborhood where I learned of the invitation to work, solidarity, of giving and receiving, of persistence; women and men that have been maintained, remained and resisted as the mountain does with the neighborhood, that mountain that shelters us.*

In the absence of public policies, inclusive and continuous city plans and programs in the territory, community mobilization has generated territorial autonomy through collective actions, like invitations and communal work; they have had achievements, such as access to public transportation, drinking water, inviting people from both neighborhoods to work in the physical infrastructure and sanitation works, construction of the school, house of prayer, and main road; work is still under way to complete the construction of the sewer system, waste disposal and garbage collection, access roadways, sports venues, health services, and property legalization.

Even now, their space unveils historical inequalities, compared with other communes in Medellín, like El Poblado, where the Multidimensional Index of Living Conditions (IMCV, for the term in Spanish) is 76.6 and that of commune #3, Manrique, is 37.5;⁽¹⁸⁾ which hinders the survival of over 20,000 who live there, most with wages from informal labor, routes to the city center, and some from drug micro-trafficking, which although occult in

the territory, continues being one of the ways that most seduces mainly the youth in search of their economic support.

The process of implementing and contents of policies, plans, and programs in the territory has been fragmented and not prioritized; although at the beginning of the constitution of the geographic space, the participation process was strong, as expressed by the leaders, at the moment it vanishes due to the lack of new leadership, wear of the first inhabitants and, in the technical, due to the political-administrative division of the city to assign resources granted for the entire commune, with less possibilities for the neighborhoods of La Cruz and La Honda; with a trend during the last decade toward incorporating technology, but still with limitations in access for people from the outskirts.

Analysis of the interactions by the players in city programs and projects that include these neighborhoods indicated those who formulate policies, who are usually part of political-governmental organizations; who execute programs and projects, like interdisciplinary work teams; and, finally, converge people and community leaders, who receive the effects of the policies, with scarce opportunity in decision-making settings. Comprehension of the general dimension and its articulation with the particular and singular was expressed by the persistence of critical processes derived from displacement due to violence against people, families and territory collectives. This is the most dramatic experience they have endured and this condition has worsened their economic situation, which has brought them unemployment, hunger, and poverty; they have had to build again with minimal resources available to them.

Particular dimension: the weave between that which protects us and makes us vulnerable

This dimension contemplated the ways of life of the work of groups of women and men who have

woven with their hands the space, as shelter for their survival; the central category *from uprooting to rooting* emerged from the focal groups, which unveiled voices, creations, expressions they experience daily and give sense and meaning to the collective and reflecting an imminent need for the other. In the words by one of the participants of the focal group: *I came to a neighborhood that is also of much violence, of hit men and gangs, that is, the people here in Medellín we all come from a municipality, from towns, from farms, right? Here, we got somewhat civilized because we study, work, we relate because there are more ways to do so.* Another participant expressed: *I am from a town in Antioquia; I am displaced from Urabá, I lived there for 25 years; because of the violence, we had to come here to Medellín; displacement is permanent in our communities, families constantly arrive here at the hill with nothing.*

The path to rebuilding and returning to being has been conceived a trajectory of suffering upon the death of a loved one, of the dispossession of their land, the roofs over their heads, their sustenance, their social groups, their work, of belonging, of leisure, and of freedom; as one of the participants stated: *It is like being in a hole*, experience that prompted them to transform, with the stamp of longing, of common stories and of the collective mourning that is still present, even if the situation was experienced two or 20 years ago.

The transformation takes place fundamentally from the being and the new territory allows them to construct a better future; they are peasant families that return to plow the mountain, with a leading role by women, who have been and continue being support in life processes and practices. They have assumed care and the responsibility of protection: they feed, struggle, lead, build homes, paths and through invitation reconstruct the territory in a before and after. As stated by one of the female leaders: *it was very hard for us to enter those work sites so that the car could build the roads, because that was like*

a bridle path; we cleared that with a pick and shovel, we used to get together up to 150 people to work.

Rooting and uprooting are two interrelated concepts that have been woven in everyday life, with intercultural processes; they have been forged in solidarity, union and in generating ties and bonds; as expressed by one of the participants: *we got here in different ways, some with nothing and others with almost nothing, but we are all one, to subsist and take over the hill.* They created the territory with their own hands and, although they are fine because they so state it, they continue to evoke moments lived, places, people, paths and their lands. The dynamics that have been constructed in the new territory determine living in community, which favors permanence and salvation in search of shelter to face their dispossession that left them without any material possession, with fear and aimlessly; now there are new roads, houses, schools, collective spaces. In collective work, they have constructed shelters for their families; materials, such as plastic, have been borrowed to provide shelter; they have accepted invitations to work, they have collected money and have supported some people to make the route that consists in going to the center of the city.

Rooting and uprooting take place during all moments of violence and displacement, that is, their definition and temporal location is diffuse, given that many people or families have experienced these simultaneously, becoming a process of acceptance and adaptation that has entailed from having to leave something to adapting to a new world, which could be expressed in ceasing to exist in a world to inhabit or exist in a new one. The participating community leaders state that: *the mountain shelters us, they want to construct their mountain or the hillside speaks to the city, but they do not only refer to the physical; they talk to the hillside, and testimonies affirm that this is the best air you breathe in the city is here in the mountain, the most beautiful balcony; up here, we have no contamination;*

all these adjectives are meanings they have given to their habitat. Under this perspective, those residing in the neighborhoods have already transcended from the dream of seeing it as they imagine it to building it with their own efforts, with their hands and those of their neighbors, with or without state interventions; they are aware that those ideals require time, making structural and behavioral transformations necessary. They have already traveled a path of sum of efforts: there are projects, leaders, networks, love, and identity. Reflections in the field diaries expose existence of other unhealthy processes that weaken the lives of groups and families, as occurs with phenomena, like landslides with land removal causing structural damage to sewers, access roads and homes.

Singular dimension: families from the La Cruz and La Honda neighborhoods

The singular dimension, from the voices of the families, revealed their needs, potentialities and, specially, the skills they have to move resources, the ways they have established support networks and the solidarity efforts they undertake day to day to survive with creativity, which has favored social and economic ties for adaptation and resilience.

The study had the participation of 40 families; 29 have suffered situations of displacement, some from diverse regions of the country and from the department of Antioquia, five with internal displacement in Medellín and three of them immigrants from Venezuela. These families are made up of 139 members, finding an average of four people per family, with ages ranging between 5 months and 92 years; the femininity index is 15 women per every 10 men. The population pyramid represented, in the families visited, a greater number of people < 40 years of age and a lower number in their 40s and 60s, a situation that can be explained by the processes of violence lived between 1980 and 1990, which meant disappearances, deaths and fleeing from the territory; people 60 years of age or older are

mostly women, who – according to the information – settled there after being displaced with their children and in absence of their life companions (Figure 1).

The dependency index showed that for every 100 people in productive age there are 81 people dependent on care; also, the aging index indicated that for every 100 people ≤ 15 years of age, there are 90 people > 60 years of age, which permitted unveiling intergenerational dynamics and the necessities for care that could be required in the mid to long term in this population. The marital status with the greatest representativeness was couples in free union and married, with 45%, followed by those who are single with 36%. The study obtained the educational level of 121 participants, finding that 20 of them are illiterate, 40 have basic primary studies, 55 secondary education, and six have higher education, a critical situation for human needs,

like understanding, protection, and community and social participation.

The work found 92 people in economically active age, 28 of them with unpaid family work, 24 with informal labor, and 16 unemployed (Table 1); another 47 are in situation of economic dependence, who are students, caregivers of children and the elderly. Twenty-six people were found with labor relations without social security, corresponding to those working in informality as domestic workers, garment workers, construction workers, informal vendors and community workers. It was observed, in the neighborhoods, offers of services, like child care, laundry services, motorcycle and bicycle rental, hairdressing businesses, miscellaneous shops, stores selling food, and hardware stores; other families live off activities, like recycling and the route consisting in going to the city center where they get some food; in the market place the merchants donate what is going to perish and is useless for the following day.

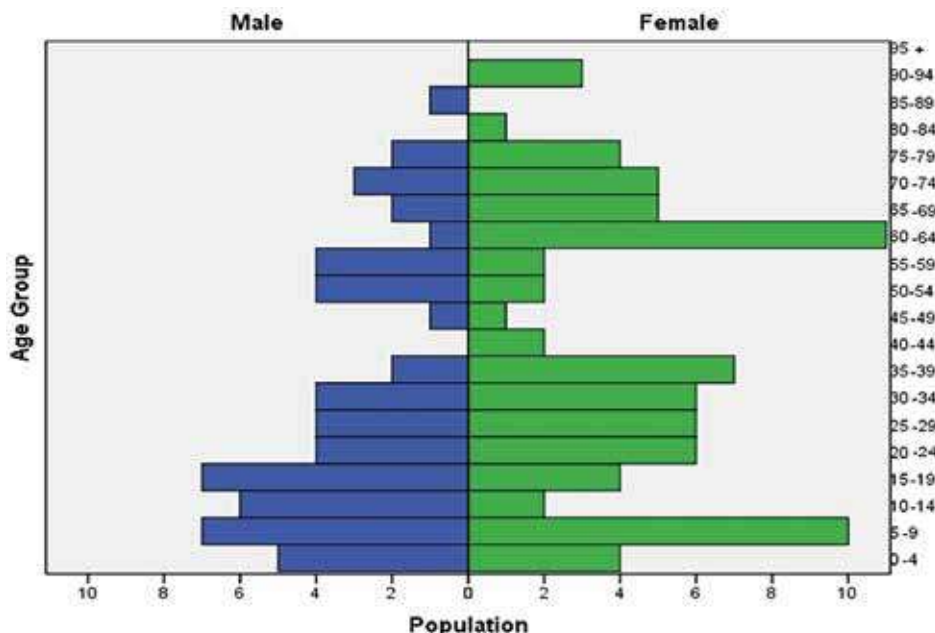


Figure 1. Population pyramid of 139 people from the La Cruz and La Honda neighborhoods. Medellín; 2020

Table 1. Type of occupation of 92 people from the La Cruz and La Honda neighborhoods. Medellín; 2020

Occupation	Frequency (%)
Unpaid family work	28 (30.4)
Independent informal work	24 (26.1)
Dependent formal work	17 (18.4)
Unemployed	16 (17.4)
Independent formal work	3 (3.3)
Community work	2 (2.2)
No data	2 (2.2)

It was found that for every 10 women there are six men unemployed and unpaid family work showed 27 women for every man. The registries of the field diaries indicate that the women from the territory are mostly mothers who are heads of household, with high workloads, greater problems of intrafamily violence and exclusion from opportunities to study and work. People value the work that becomes their fundamental basic need; nonetheless, the circle of inequity, scant educational offers, and lack of a decent work aggravate their situation of shortcomings, like food, education, public utility services, recreation, leisure, and enjoyment of playtime activities, which prevents a more harmonious development.

The protective processes of the families were represented most frequently by family participation in decision making (92%), knowledge regarding health care (79.5%), schooling for children and adolescents (79.2%), and care of housing, like cleaning, physical repairs, improvement of gardens, orchards, floors, roofs, and lighting (79.1%). The unhealthy processes found most corresponded to the barrier with the transportation service (61.4%), children in labor activities (54.5%), and difficulty in exercising the right to health and procurement of food (47.7%).

Discussion

This research, from the perspective of the social determination of health, found forced displacement as a phenomenon that cuts across the social reality of people, families and groups in their interaction with the territory, from the general dimension to the singular, and which has affected the Colombian population in all regions and, specifically, in Antioquia. Conditions, like the armed conflict, dispossession of land and deterioration of life have been unhealthy processes that reproduce historically inequality, exclusion from means of production and necessary consumption for survival. An example of the foregoing are the families participating in this research who went from owning their lands to being dispossessed and without a roof over their heads, due to the heartbreaking phenomenon of violence and the abuse of power by armed groups, which in the words by Breilh,⁽³⁾ affect differentially people, families, and collectives within a complex context.

Dispossession of land due to violence and displacement in Colombia has been addressed by

Paredes⁽¹⁹⁾ who states that it is a phenomenon of class contradictions and economic interests that thrive in spaces and times and which deteriorate health. As in our study, the author expresses that farming peasant displacement is linked to territory struggles by armed groups and to the use of the land for production logics and that, therefore, the populations present extreme vulnerability that moves them to uprooting, a consequence of the geopolitical dispute, alienating them from their conventional modes of production. In Colombia, authors, like Molano A⁽²⁰⁾ and Uribe MT,⁽²¹⁾ state that violence is a structural phenomenon determined by political and economic causes; also, Ronderos MT⁽²²⁾ exposes that violence is historical and has been transformed over time with the participation of different players, like common crime, narcotics trade, guerrilla groups, State forces, para-military groups, among others; and from the perspective by Breilh,⁽⁴⁾ violence generates dispossession with a practice of extraction of natural resources, under the accumulation model that produces extreme impoverishment, destruction of living conditions, and deterioration of the environment.

Similar to that found in our study, López, *et al.*,⁽²³⁾ affirm that the general dimension subsumes the ways of lives of families and communities, in the particular and singular levels, translated into difficulties in access to education, health, dignified housing, and social inclusion, as well as the enjoyment of decent work and family and community well-being, which expresses social asymmetry in class, gender, and ethnic relations in rural and urban areas.

This research revealed that the settlement took place as a result of fleeing and meant a transformation in ways of life, with constructions from resistance and resilience, a finding also described by Louidor⁽²⁴⁾ when exposing processes of uprooting and rooting as expressions of ambivalent social realities, spaces of cultural heterogeneities, resulting from historical inequality and structural detachment. Other authors, like Borde and Hernández,⁽²⁵⁾ in their research on social

determination in Latin American cities, expose the existence of the denaturalization of the territorial order with long-term configurations, where the situations and relationships of the dynamics of human production and reproduction are tied to social constitutions with biased privileges and cyclical problems, mediated by power relations; nevertheless, according to the authors, these articulations generate life-promoting processes, of resistance and re-existence.

Another finding, herein, regarding the singular dimension, revealed that the working modes are also determined by power, access to education and to opportunities for human development; similar to that found by Fuentes, *et al.*,⁽²⁶⁾ in which they explain marked spatial differences in manual workers and low-status routine occupations, all conditioned by geographic inequalities that differentiate access to education and income, a phenomenon contrary to that expected, but which is increasingly accentuated and consolidated.

The research presents the historical-social dynamics and their comprehension in space and setting, which make sociological and geographic sense, with transit from uprooting to new rooting, issues that in Colombia – within the framework of conflict and violence – have been described by Salazar *et al.*,⁽²⁷⁾ Molano,⁽²⁰⁾ Uribe MT⁽²¹⁾ and Ronderos.⁽²²⁾ Although the people and families participating in this study long for their places of origin, this space they now inhabit gives them hope, progress, tranquility; where the construction of ties and networks, physical and of coexistence, make them feel useful. We could state that, according with Tuan,⁽²⁸⁾ people have a “sense of place” where they carry out actions and decisions anchored to a behavior, in the individual, the collective, and in cultural perspectives, which transforms them and neighbors.

As expressed by the leaders and participants in this study, during moments of adversity, human suffering, and dispossession “community living saves you”; actions like the invitation to collective

work, collective construction, and solidarity are healthy processes that perpetuate the lives and dignity of the people, families, and human collectives. According to such and as expressed by Soliz:⁽²⁹⁾ “territories are living socioecological settings that are transformed and – in turn – also transform the people”.

Conclusion. The social determination of the health of families comprises the interrelation of historical-social and personal processes centered on the being that have unveiled in the general, particular, and singular dimensions. Their health has been determined by processes of violence, displacement, fleeing and by historical exclusion from modes of production and the social vulnerability they have endured, in turn, leading to few opportunities for their life projects and which place the families in conditions of inequity and inequality in the city they inhabit and that are not alien to the situation of the department of Antioquia, the country and the world during the last decades. The families have experienced a process of transformation of the territory with resistance, solidarity, rooting and collective constructions; however, there is an urgent requirement for political and social will committed to the inclusion of vulnerable people and territories

in the construction and implementation of policies that forge well-being and flourishing development, as well as continuity of the territorial autonomy.

Limitations of the study: No Access was obtained to some documents of the city’s policies and programs that could expose specific actions with people from the territories of La Cruz and La Honda. In addition, the time of the Covid-19 pandemic affected being able to carry out some family visits in the territory.

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Efficacy of Motivational Interviewing and Brief Interventions on tobacco use among healthy adults: A systematic review of randomized controlled trials

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Abstract

Objective. To assess the effectiveness of a brief intervention and motivational interviewing in reducing the use of different tobacco-related products in adults. **Methods.** For this systematic review, PubMed, Web of Science, and PsychINFO databases were electronically searched for randomized controlled trials on the effect of a brief intervention and / or motivational interview on tobacco reduction among healthy adults published between January 1, 2011 to January 1, 2021. Data from eligible studies were extracted and analyzed. CONSORT guidelines were used to assess the quality of the studies by two reviewers for the included studies. The titles and abstracts of the search results were screened and reviewed by two independent reviewers for eligibility criteria per the inclusion and exclusion criteria. Cochrane review criteria

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were used to assess the risk of bias in included studies. **Results.** A total of 12 studies were included in the final data extraction of 1406 studies. The brief intervention and motivational interviewing showed varied effects on tobacco use reduction among adults at different follow-ups. Seven of the 12 studies (58.3%) reported a beneficial impact on reducing tobacco use. Pieces of evidence on biochemical estimation on tobacco reduction are limited compared to self-reports, and varied results on quitting and tobacco cessation with different follow-ups. **Conclusion.** The current evidence supports the effectiveness of a brief intervention and motivational interviewing to quit tobacco use. Still, it suggests using more biochemical markers as outcome measures to reach an intervention-specific decision. While more initiatives to train nurses in providing non-pharmacological nursing interventions, including brief interventions, are recommended to help people quit smoking.

Descriptors: motivational interviewing; tobacco use cessation; tobacco use; adult.

Eficacia de la entrevista motivacional y de las intervenciones breves sobre el consumo de tabaco en adultos sanos: Una revisión sistemática de ensayos controlados aleatorizados

Resumen

Objetivo. Evaluar la eficacia de una intervención breve y de la entrevista motivacional para reducir el consumo de diferentes productos relacionados con el tabaco en adultos. **Métodos.** Para esta revisión sistemática, se buscaron en las bases de datos PubMed, Web of Science y PsychINFO ensayos controlados aleatorizados sobre el efecto de una intervención breve y/o una entrevista motivacional en la reducción del consumo de tabaco entre adultos sanos, que hubieran sido publicados entre el 1 de enero de 2011 y el 1 de enero de 2021. Los títulos y los resúmenes de los artículos incluidos fueron evaluados por dos revisores independientes para determinar los criterios de elegibilidad, se analizó la calidad de los estudios con la guía CONSORT y se utilizaron los criterios de Cochrane para evaluar el riesgo de sesgo. **Resultados.** Se incluyeron un total de 12 de los 1406 estudios que arrojó la búsqueda. La intervención breve y la entrevista motivacional mostraron efectos variados en la reducción del consumo de tabaco entre los adultos en diferentes seguimientos. Siete de los 12 estudios (58.3%) informaron de un impacto beneficioso en la reducción del consumo de tabaco. La utilización de indicadores bioquímicos de la reducción del consumo de tabaco fueron limitados en comparación con los autoinformes. Los resultados sobre el abandono y la cesación del tabaco fueron variados con diferentes seguimientos. **Conclusión.** La evidencia apoyó la efectividad de una intervención

breve y de la entrevista motivacional para la cesación del consumo de tabaco. Sin embargo, se sugiere realizar más estudios con marcadores bioquímicos como medidas de resultado para llegar a una decisión específica de la intervención. Se recomienda formar a los enfermeros en la realización de intervenciones de enfermería no farmacológicas, incluidas las intervenciones breves, para ayudar a las personas a dejar de fumar.

Descriptor: entrevista motivacional; cese del uso de tabaco; uso de tabaco; adulto.

Eficácia da entrevista motivacional e intervenções breves sobre o uso de tabaco em adultos saudáveis: uma revisão sistemática de ensaios clínicos randomizados

Resumo

Objetivo. Avaliar a eficácia de uma intervenção breve e entrevista motivacional na redução do uso de diferentes produtos relacionados ao tabaco em adultos. **Métodos.** Para esta revisão sistemática, se buscou nas bases de PubMed, Web of Science e PsychINFO ensaios controlados aleatórios sobre o efeito de uma breve intervenção e/ou entrevista motivacional na redução do uso de tabaco entre adultos saudáveis, publicados entre 1º de janeiro de 2011 e 1º de janeiro de 2021. Os títulos e resumos dos artigos incluídos foram avaliados por dois revisores independentes para critérios de elegibilidade, a qualidade do estudo foi avaliada usando a diretriz CONSORT e os critérios Cochrane foram usados para avaliar o risco de viés. **Resultados.** Um total de 12 dos 1.406 estudos retornados pela busca foram incluídos. Intervenção breve e entrevista motivacional mostraram efeitos mistos na redução do uso de tabaco entre adultos em diferentes acompanhamentos. Sete dos 12 estudos (58.3%) relataram um impacto benéfico na redução do uso de tabaco. O uso de indicadores bioquímicos de redução do uso de tabaco foi limitado em relação ao autorrelato. Os resultados sobre parar de fumar e parar de fumar foram variados com diferentes seguimentos. **Conclusão.** As evidências apoiaram a eficácia de uma intervenção breve e entrevista motivacional para a cessação do uso do tabaco. No entanto, mais estudos com marcadores bioquímicos como medidas de resultados são sugeridos para chegar a uma decisão de intervenção específica. Recomenda-se que os enfermeiros sejam treinados na execução de intervenções de enfermagem não farmacológicas, incluindo intervenções breves, para ajudar as pessoas a parar de fumar.

Descritores: entrevista motivacional; abandono do uso de tabaco; uso de tabaco; adulto.

Introduction

Tobacco in any form is harmful and affects millions of lives every year.⁽¹⁾ In 2017, 8 million lives were lost due to smoking-related diseases.⁽²⁾ Tobacco-related deaths are rising even after a decline in tobacco use trends because of the chronic nature of conditions.⁽³⁾ In 2000, around 33.3% of the global population over 15 years old were current tobacco users.⁽³⁾ The negative consequences of tobacco use are well known and extend beyond individuals and countries regarding increasing health care expenditure and loss of productive life.⁽⁴⁾ The tobacco consumption trend was three times higher in males than females in 2000, which was increased to four times in 2015 and is projected to be five times by 2025.^(1,3) Notably, the detrimental effects of tobacco use gravely affected lower socio-economic populations with higher smoking prevalence.⁽⁵⁾ However, tobacco use practices are varied and influenced by the locally available tobacco products in the different regions worldwide.⁽⁶⁾

Smoking is one of the modifiable risk factors for many life-threatening health problems, including respiratory and cardiovascular health and genitourinary problems.⁽⁷⁾ It has been estimated that 50% of smokers who start smoking in adolescence die due to tobacco-related health problems.⁽⁸⁾ Thus, an effective measure to control tobacco addiction is paramount. Implementing a wide range of interventions and strengthening tobacco control policy, including taxation, ban on tobacco use in public places, restriction on advertising of tobacco products, and creating smoke-free zones in educational institutions, brought a substantial decline in tobacco use in recent decades.⁽⁴⁾ In addition to government initiatives to curb tobacco use, many pharmacological and non-pharmacological approaches are also involved in reducing tobacco-associated mortality and the burden of diseases.^(6,9) Earlier studies reported that using a combination of pharmacologic and non-pharmacologic intervention is highly effective in reducing tobacco use.⁽¹⁰⁻¹²⁾ However, non-pharmacological interventions have advantages over pharmacological interventions, including no side effects, long-term behavior changes,⁽¹³⁾ knowing the real health hazards of long-term tobacco use, and cost-effective to show higher compliance.^(11,12,14)

Non-pharmacologic interventions for tobacco cessation include telephone counseling, individual and group counseling, health care provider interventions, exercise programs, and self-help programs.⁽¹²⁾ Brief intervention or motivational interview is a brief yet realistic strategy offered to those who have a low motivation to quit.⁽¹⁵⁾ Brief intervention is goal-directed but non-directive communication designed to improve motivation for change in quit behavior by eliciting feedback to plan for change.^(12,16-20) The terms brief intervention (BI) and motivational interview (MI) are used with a common principle of active engagement of the client in the process of reduced use and teaching alternative coping skills.⁽²¹⁾ These interventions are based on

the philosophy that the client holds a key role in showing commitment and successful recovery.⁽²²⁾ Brief intervention sometimes follows the principles of the motivational interview to motivate the specific behavior of an individual to reduce or quit substance use.⁽²³⁾

However, these interventions are substantially modified in the delivery approach, format, and content in earlier published work.⁽¹²⁾ Brief intervention primarily focuses on present concerns and stressors rather than exploring the historical antecedents of an individual and is conducted by a trained therapist.^(20,24) Earlier work on the efficacy of brief intervention reported evidence that brief intervention increases the motivation to quit short-term use.^(18,25) However, the evidence on long-term effects of brief interventions is equivocal, with no reduction of tobacco use at three months while higher self-reported abstinence at 1-year post-brief intervention.⁽²⁶⁾ Conversely, the brief intervention was found to be effective in improving quit rates, prolonging abstinence, and improving self-reported continuous abstinence among smokers at six months⁽²⁷⁾ and 1-year post-intervention⁽²⁸⁾ in other work. Still, there is a lack of consistent evidence on brief interventions to reduce use or quit tobacco use among the adult population.

Nurses are an essential attribute of the health care system and play a vital role in delivering various interventions. It is natural to expect that nurses with adequate knowledge and skills in the brief intervention will do more to help their patients quit smoking. This meta-analysis will highlight the need for encouragement and opportunities to nurses to receive training on smoking cessation interventions. In addition, this will be insightful for the nurses to understand the significance of a non-pharmacological intervention to quit smoking. Towards this end, training nurses in the brief intervention using motivational interviews may be helpful to smokers and their families. Consequently, this systematic review aims to assess the effectiveness of the brief intervention in reducing tobacco use among adults.

A literature review was conducted with online databases PubMed, Web of Science, and PsychINFO. A literature search was completed using Boolean operators and truncations for the following key terms: (1) "Brief Intervention, (2) OR Screening and Brief Intervention" "tobacco products" AND (3) "Tobacco OR "tobacco products," (MESH terms are also included in the search). The problem/disease was tobacco use among adults in the experimental group. The primary outcomes of interest were cessation in tobacco use, motivation/readiness to quit, reduction in tobacco quantity, days, abstinence days, quit attempts, and point prevalence measured by self-reported methods or biochemical verification at different intervals.

Selection criteria and data extraction. The inclusion criteria for the studies included in this review were as follows: (1) the content of the article mainly focused on the provision of brief intervention and/or motivational interview for tobacco use reduction or cessation; (2) the participants were current smokers and adults; (3) the articles were published in peer-reviewed journals within the last ten years; (4) the study method reflected a randomized control trial (RCT). Articles were excluded if they focused primarily on other pharmacologic interventions, included any other substance use, were not designed as an RCT, or had mixed interventions. The search strategy was based on the population, intervention, control, and outcomes (PICO) approach with a PICO question, 'does *motivational interviewing and brief interventions helpful in reducing tobacco use in healthy adults?*'; where P- Healthy tobacco users, I- Motivational Interview and/or Brief Intervention, C- Usual care or on other interventions and O- Smoking cessation.⁽²⁹⁾ A total of 1406 articles were included for a title and abstract review; at least two team members discussed discrepancies. 77 articles met the inclusion criteria for a full-text review, and 12 articles were selected for data extraction. See the PRISMA framework (Figure 1) that guided the review process.⁽³⁰⁾

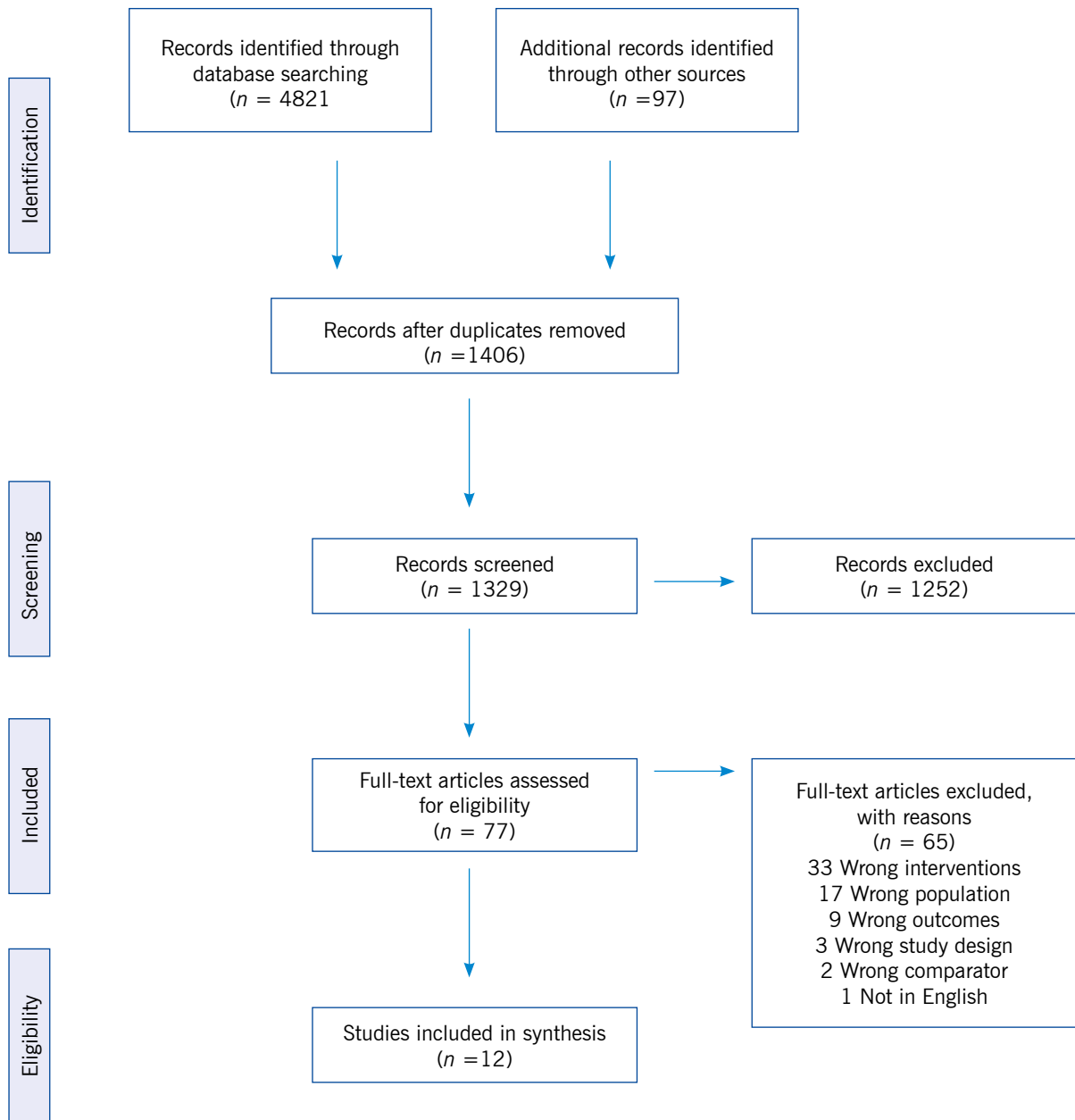


Figure 1. PRISMA Flow Diagram

Bias assessment. Cochrane review criteria were used to assess the risk of bias in included studies in the review (Table 1).⁽³¹⁾ All studies were evaluated on six evidence-based domains: allocation concealment, random sequence generation, participants and personnel blinding, outcome blinding, incomplete outcome data, and selective reporting.⁽³¹⁾ Allocation concealment refers to concealing the information on the randomization process to the subjects. Random sequence generation occurs when study participants are not aware of the random sequence generation process. Blinding of participants and personnel refers to when participants and team members do not know the intervention or control condition to which subjects are assigned. Blinding of

outcomes assessment refers to whether outcome measurement could have been changed by prior intervention knowledge to participants or team members delivered in work. Selective reporting refers to presenting only findings of interest. An incomplete outcome does not consider attrition while submitting the result.⁽³¹⁾ For each study, these components are shown in ‘high risk,’ ‘low risk,’ or ‘unclear’ as written in the published version of the manuscript to decide on bias assessment. In data extraction, two authors assessed each study for bias. The authors discuss the risk bias criteria of the study using a checklist and conclude. The discrepancies were resolved after a discussion with the third author Table 1.

Table 1. Quality assessment of the included studies

Sources	Random sequence allocation	Allocation concealment	Blinding of participants / personnel	Blinding of outcomes assessment	Complete outcomes data	Avoidance of selective reporting	Quality of study*
Catley <i>et al.</i> ⁽¹⁵⁾	✓	✓	X	X	✓	✓	Moderate
Mujika <i>et al.</i> ⁽³⁰⁾	✓	✓	✓	X	✓	✓	High
Virtanen <i>et al.</i> ⁽³²⁾	✓	✓	X	X	✓	✓	Moderate
Cook <i>et al.</i> ⁽³³⁾	✓	?	✓	X	✓	✓	Moderate
Steinberg <i>et al.</i> ⁽³⁴⁾	✓	?	?	?	✓	✓	Moderate
Ho <i>et al.</i> ⁽³⁵⁾	✓	✓	X	X	✓	✓	Moderate
Cabiale <i>et al.</i> ⁽³⁶⁾	✓	?	?	?	✓	✓	Low
Krigel <i>et al.</i> ⁽³⁷⁾	✓	✓	?	?	✓	✓	Moderate
Meyer <i>et al.</i> ⁽³⁸⁾	✓	?	✓	✓	✓	✓	High
Schane <i>et al.</i> ⁽³⁹⁾	✓	?	?	?	✓	✓	Low
Leavens ELS <i>et al.</i> ⁽⁴⁰⁾	✓	?	X	?	✓	✓	Low
Cabrales <i>et al.</i> ⁽⁴¹⁾	✓	?	X	X	✓	✓	Low

Results

The electronic search produced a total of 3162 articles. 1406 articles were found suitable after removing duplicate records. Abstracts of all articles were reviewed independently by two reviewers. A total of 1262 articles were excluded after careful scrutiny of abstracts. Full-text articles were retrieved for 79, and after reviewing these articles independently, 67 articles were further excluded for a specific reason. After applying the eligibility criteria, 12 articles were included in the present review. The PRISMA flow diagram (Figure 1) summarizes the study selection and scrutiny process used for the articles. A summary of the selected studies summarized by year of publication, author, setting, type of study, sampling techniques, sample size, eligibility criteria (inclusion and exclusion), intervention, outcomes, strengths and limitations, and any other specific notes to the study.

Study characteristics. Of the 12 included studies, eight were conducted in the United States, one in Sweden, one in Hong Kong, one in Germany, and one in Spain. All studies used a randomized controlled trials design with one or another trial feature, including allocation concealment and blinding. Of the 12 studies, 3 studies used brief intervention or brief advice,^(30,32,35,38,41) 6 studies used motivational interviews,^(15,30,33,34,37,40) and one study used brief counseling on harm to self and harm to others⁽³⁹⁾ and quit immediately award model based on brief intervention approach. Seven of the 12 studies (58.3%) reported a beneficial effect of brief advice or motivational interview on reducing tobacco use (Table 2).

Motivational Interviewing (MI). The concept and use of motivational interviewing as an intervention is not new in substance use,⁽⁴²⁾ smoking reduction,⁽⁴³⁾ chronic lifestyle disease,⁽⁴⁴⁾ health behavior,⁽⁴⁵⁾ medication adherence,^(46,47) oral health in adolescents,⁽⁴⁸⁾ and chronic pain management.⁽⁴⁹⁾ The concept was published by

Miller & Rollnick and presented as a therapeutic effort to strengthen personal motivation and commitment to a specific goal by eliciting and exploring the individual's reason for a change in behavior with compassion and acceptance.⁽¹⁶⁾

Motivational interviewing (MI) is a patient-centered, directive therapeutic style to improve readiness to change behavior by resolving the ambivalence.⁽⁴³⁾ MI was found to be an effective method in a series of addictive behaviors.⁽⁵⁰⁾ Some research⁽³³⁾ among healthy adult smokers tested multiple interventions revealed a promising effect of motivational interviewing on smoking reduction. However, the study concluded⁽⁵⁰⁾ that motivational interviewing and other interventions will produce the most consistent and marked reduction in smoking. A contrasting study⁽¹⁵⁾ used motivational interviewing over health education and brief advice but did not report any change in quit attempts at 6 months. However, the same study reported increased cessation of medication use, motivation, and confidence to quit compared to brief advice, which further indicates the effectiveness of MI in behavior changes to quit smoking. In a study⁽³⁴⁾ at a Northeastern US State, daily smokers attended brief motivational interviewing and significantly reduced cigarette use. Likewise, motivational interviewing effectively improved quitting smoking among nurses over brief advice in a study conducted in Spain.⁽³⁰⁾ However, in another work⁽³⁷⁾ on college tobacco smokers, the use of motivational interviewing over health education (HE) showed no significant reduction in motivation to quit, abstinence, and quit attempts. Likewise, the consistent findings are presented in earlier studies^(15,51) that reported no significant advantage of MI on smoking cessation compared to alternative interventions. In a recent work conducted in the Midwest United States, a brief motivational interview showed no improvement in reducing water pipe use⁽⁴⁰⁾; however, MI was found to improve awareness of risk perceptions, commitment, and confidence to quit waterpipe (WP) smoking.

Furthermore, in a recent meta-analysis, MI reported a modest yet significant beneficial increase in

quitting rates in a group that utilized motivational interviewing. Further, findings revealed that long-term motivational interviewing by a primary physician or counselor is more effective in quitting tobacco. However, there is no specific evidence on the duration and number of MI sessions on quitting the behavior. Another meta-analysis⁽⁵²⁾ reported a greater likelihood of abstinence behavior in the experimental arm comprising adults and adolescents when compared to the comparison group. Still, only a few older interventions and meta-analyses demonstrate the effectiveness of motivational interviewing in smoking cessation. There is evidence that motivational interviewing is less effective in low-motivation patients.^(18,53) However, the conclusive evidence to prove the quality and fidelity of MI implementation remains contentious concerning its effectiveness in smoking reduction.

Brief Intervention. Brief intervention or advice for harmful substance use has been practiced for many years.⁽⁵⁴⁾ It aims to identify the current and potential problems with substance use and motivate people to change high-risk behavior.⁽⁵⁵⁾ Brief intervention is a personalized, supportive and non-judgmental approach to treatment.⁽⁵⁵⁾ It is also defined as a verbal 'stop smoking' message loaded with harmful effects of tobacco use.⁽⁵⁶⁾ Brief intervention can be used in various methodologies, including unstructured counseling and feedback to formal structured treatment.⁽⁵⁷⁻⁵⁹⁾ World Health Organization uses education, simple advice, and brief counseling as alternative types of brief interventions for high-risk individuals with alcohol use disorders.⁽⁶⁰⁾ Brief intervention also uses screening and referral services and is therefore called screening, brief intervention, and referral to treatment (SBIRT).⁽⁶¹⁾ Brief therapy can help motivate an individual to change his high-risk behavior at a different stage of behavior change.⁽⁶²⁾ The stage of change model proposed by Prochaska & DiClemente, helps clinicians tailor a brief intervention to the stage of behavior change and the client's needs.⁽⁶³⁾

Brief interventions for tobacco use disorders aim to enhance motivation for change and provide

evidence-based resources to reduce usage or complete cessation of tobacco products. The 5A's approach (Ask, Advise, Assess, Assist, & Arrange) is an evidence-based approach that helps tobacco users in different settings with motivational strategies in a systematic fashion.⁽⁶⁴⁾ In addition, FLAGS-Feedback, Listen, Advice, Goals, Strategies and 'FRAMES'-Feedback, Responsibility, Advice, Menu of options, Empathy, and Self-efficacy, are other frameworks used to deliver brief interventions.⁽⁶⁵⁾

The brief intervention is effective in many ways, including cost-effectiveness in terms of time and money,⁽⁶⁶⁾ increased abstinence rate and days,^(35,67) and early days of discharge, and regular follow-ups⁽⁶⁸⁾. Similarly, a more intensive planned brief advice (>20 minutes) may augment the effect on quit rate and 6-months abstinence compared to minimal brief advice.⁽⁶⁹⁾ Additionally, the use of brief components in AWARD [Ask, Warn, Advice, Refer, Do-It Again] model, and cut down to quit: [CDTQ]), reported a higher quit rate in the former group.⁽³⁵⁾ Furthermore, brief advice in combination with tailored practice was highly effective on 7-days point prevalence and 7-days and 6-months abstinence rate among adult smokers.⁽³⁸⁾ Brief counseling also reported a significant reduction in quit rate, abstinence phenomenon, improved motivation, and self-efficacy in a regular follow-up in a group of nondaily smokers.^(36,39) Conversely, brief therapy showed no significant changes in abstinence rate among adults who underwent immediate and delayed intervention at the family health clinic U.S.-Mexico border,⁽⁴¹⁾ and hence, the efficacy of brief therapy has been questioned in recent years.⁽⁷⁰⁾

Further, brief treatment can be helpful for varied kinds of the population, including adolescents, older smokers, smokers with mental illness and co-morbidities, alcohol users, and pregnant women across different racial and ethnic groups.^(66,70) However, current or former tobacco smokers who were willing or unwilling to make quit attempts are the most eligible groups to attend the brief intervention.⁽⁶⁶⁾

Discussion

The use of tobacco has innumerable adverse effects on health. The present review aimed to assess the effectiveness of a brief intervention in reducing tobacco use among adults. The review findings indicate that brief intervention alone or combined with Motivational Interviews or Health Education was effective, supported by previous results.^(15,52) In contrast, an earlier systematic review documented that motivational interviewing was modestly successful in promoting smoking cessation compared with usual care or brief advice.⁽²⁵⁾ Conversely, motivation to quit was higher after Brief Advice than MI.⁽⁷¹⁾ Another recent systematic review conducted with 37 studies reported insufficient evidence to show whether MI helps people stop smoking compared with no intervention, as an addition to other types of behavioral support, or compared with different kinds of behavioral support for smoking cessation.⁽⁷²⁾

Modality and intensity of interventions with follow-up and primary outcomes were also determining factors for the effectiveness of the studies. In the current review, the intervention modality varied in face-to-face sessions or a combination of face-to-face and telephone sessions. Initial sessions were conducted face-to-face, and the follow-up was done over the telephone for most of the study, which is usual with much other previous work.⁽⁷²⁾ Brief intervention provided through telephone has great significance in the present scenario. Amid the COVID-19 pandemic, when individuals have restricted movement or limited resources available, virtual or phone delivered brief intervention can play a significant role in helping the adults quit smoking or reduce tobacco use. A previous study has documented moderate-certainty evidence of proactive telephone counseling in increasing the quit rates in smokers who seek help from quitlines.⁽⁷³⁾

The included studies had intervention sessions as little as one brief session⁽³⁷⁾ to four sessions based

on Motivational Interviews.⁽³⁰⁾ Prior literature suggests that multiple sessions might increase the likelihood of quitting over single-session treatment, but positive outcomes were reported in both cases.⁽²⁵⁾ However, there is no specific evidence on the duration and number of MI sessions on quitting the behavior.⁽⁷²⁾ The current review found that the included studies had a follow-up of the intervention ranging from 3 months to 12 months. However, face-to-face or telephone counseling follow-up did not show a significant effect of an intervention. However, reduction of smoking behavior or abstinence was not sustained over time. These findings were supported by a previous work where smoking abstinence averaged 10% at 1 month and around 2% at 3, 6, and 12 months.⁽⁷¹⁾ At present, evidence is unclear on the optimal number of follow-up calls.^(25,43)

The primary outcomes of the studies were smoking abstinence, reduction in smoking rates, and an increase in motivation to quit. However, outcomes other than cessation may be essential to assess when determining the effects of brief interventions for tobacco use. Hence, different outcomes were self-efficacy, motivation, and changes in depression over the studies. Biological tests to confirm tobacco abstinence provided more reliable findings than self-reported abstinence.

Intervention programs on Smoking cessation, such as brief advice, motivational interviews, or the 5A approach (Ask, Advise, Assess, Assist, and Arrange), are effective among specific populations or specialized clinical settings.^(45,74) Professional support and cessation interventions or medications significantly increase the chance of successfully quitting.⁽³⁾ A systematic review and meta-synthesis explored smokers' perspectives regarding smoking cessation and reported that lack of motivation to quit was one of the significant issues they felt for tobacco cessation.⁽⁷⁵⁾ Nonetheless, these non-pharmacological interventions had shown efficacy similar to the pharmacological intervention⁽⁷⁴⁾ with additional benefits of cost-effectiveness, competency of the provider, and accessibility to the treatment center.

Tobacco-related deaths and disabilities are increasing around the globe because of the continued use of different kinds of tobacco products. Many earlier studies confirmed the beneficial effect of a brief intervention based on motivational principles to reduce tobacco use. Nurses' role is precise in tobacco cessation to endorse the International Council of Nurses statement to integrate tobacco use prevention and cessation as part of their regular nursing practice.⁽⁷⁶⁾ This systematic review indicates the potential benefits of brief intervention, which can be a breakthrough for nurses in tobacco reduction around the globe. However, nursing policymakers should incorporate smoking cessation interventions as a part of standard practice for all the patients. Hence, brief intervention or motivational interviews provide promising results in cessation or reduction of tobacco use which needs to be further supported by evidence.

The present review should be appraised under its many limitations and strengths. Among its strengths is that it provides coverage of randomized controlled trials that included brief intervention and motivational interviewing on smoking and other tobacco use among adults. This review included samples of those with clinical and non-clinical samples using tobacco. The major strength of this review lies in the inclusion of RCT studies that give a clear description of participants' characteristics, methodology, and implemented intervention. Secondly, the risk of bias assessment showed that most studies had low to moderate risk. This review highlights several opportunities for future research, such as brief intervention or motivational interview combined with other adjuncts to improve outcomes and

further research integration of these interventions with combination therapies of psychotherapeutic and pharmacological interventions.

In terms of limitations, the heterogeneity of the selected studies did not allow to reach a specific conclusion. Studies included in this review used different brief intervention and motivational interview forms, making it challenging to synthesize the results and suggest a potential use of these interventions in day-to-day practice. Heterogeneity in population also made it challenging to generalize the findings across all people around the globe. Further, studies involved in the review only investigated tobacco cessation among healthy adults may confer unique limitations on the generalizability of results. The authors suggest interpreting and using review findings cautiously due to variations in treatment fidelity and the inclusion of a limited number of studies.

Conclusion. Over time there have been changes in treatment modalities for tobacco cessation. Preference for non-pharmacological intervention over pharmacological has led the researchers to find supportive evidence. The present review highlights the effectiveness of a brief intervention and motivational interviewing in reducing tobacco use among adults. It also demonstrates that the effects are far-reaching. However, it remains inconclusive which intervention is more effective than the other. Future longitudinal studies or RCTs with direct comparison of different interventions may further refine the evidence-based practice on tobacco cessation among adults.

Funding Sources: None declared.

Table 2. Characteristics of included studies in the review

Reference 15: Catley D, Goggin K, Harris KJ, Richter KP, Williams K, Patten C, et al. A randomized trial of motivational interviewing: Cessation induction among smokers with low desire to quit. *Am. J. Prev. Med.* 2016; 50(5):573–83.

Population and sample size: Setting: Midwestern city, Kansas, USA. Sample: Adult smokers. Sample size: 255. Age (Mean, SD): 45.8 [SD = 10.9]. Design: Single site, parallel-group RCT design. Randomization: Computer-generated random assignment, Imbalanced allocation (2:2:1) for three interventions

Inclusion criteria: Adult age 18 years & currently smoking one or more cigarettes per day, able to speak English, have stable reachability, no intention to get pregnant in the next 6 months, not using any medication for smoking cessation, have no cessation plan in the next 7 days and confirm tobacco use on CO \geq 7 ppm. **Exclusion criteria:** N/A

Intervention and comparators: Motivational interview (MI, $n=102$) Versus Health education (HE, $n =102$) Versus Brief advise (BA, $n =52$)

Primary outcomes: The health education group significantly shows a higher abstinence rate at 6-month follow-up, Motivational interviews and health education groups showed a more significant increase in reduced medication use, motivation, and confidence to quit over the brief advice group, Health advice was relatively found better to improve motivation than motivational interviewing.

Others: Strengths: Biochemical verification of 7-day smoking point prevalence by saliva testing, use of intensity match comparison design to test the exact effect of MI over health education. **Limitations:** Self-reported measures to test motivation, desire to quit, quit attempts, and point

prevalence, the study was limited to willing to quit smokers, and findings may not be generalizable to unmotivated smokers.

Any other Notes: Follow-up for all three interventions at 3 months and 6 months. Missing data handling using appropriate measures to avoid bias in the study.

Reference 30: Mujika A, Forbes A, Canga N, de Irala J, Serrano I, Gascó P, et al. Motivational interviewing as a smoking cessation strategy with nurses: an exploratory randomised controlled trial. *Int. J. Nurs. Stud.* 2014; 51(8):1074–82.

Population and sample size: Setting: Clinical Universidad de Navarra (CUN) in Pamplona (Navarra), teaching hospital, North Spain. Sample: Nurses. Sample size: 30. Age (Mean, SD): 40.15[SD = 9.45]. Design: Two groups parallel experimental design. Randomization: Computer generated random allocation method, and seal the opaque envelope for location concealment.

Inclusion criteria: Nurses who smoke and are ready to participate in the study and nurses work in the hospital irrespective of thinking of quit or not.] **Exclusion criteria:** N/A.

Intervention and comparators: Motivational interview ($n =15$)/ brief advices ($n =15$)

Primary outcomes: More nurses in the intervention arm had quit smoking with an absolute difference of 33.3% 95% CI (2.6-58.2). Progress in the stage of changes was more significant in nurses who attended a motivational interview.

Others: Strengths: Biochemical verification of urine cotinine level for recent smoking detection and Micro+Smokerlyzer use for expired Carbon Monoxide (CO) detection for enrollment of the subjects. Detection of self-report of abstinence by biochemically urine cotinine measurement. Intention-to-treat analysis to control bias. **Limitations:** Use of self-reported measures to report nicotine dependence, desire, and readiness to quit. Very low small size to study the effectiveness of the intervention. No follow-up to measure smoking cessation. No sample size analysis; small sample size.

Any other Notes: Collection of data at baseline, end of the intervention, and 3 months after the intervention to cross-check adherence. High satisfaction with the acceptability and feasibility of the intervention indicates the genuine interest of the participants. Use of one-to-one sessions with each participant.

Reference 32. Virtanen SE, Zeebari Z, Rohyo I, Galanti MR. Evaluation of a brief counseling for tobacco cessation in dental clinics among Swedish smokers and snus users. A cluster randomized controlled trial (the FRITT study). *Prev. Med.* 2015; 70:26-32.

Table 2. Characteristics of included studies in the review. (Cont.)

Population and sample size: Setting: Gavleborg and Sodermanland county, Sweden. Sample: Patients currently using tobacco daily. Sample size: 467. Age (Mean, SD): 45.57 [SD = 14.91]. Design: Randomized Cluster design. Randomization: Setting randomization with a 1:1 computer-generated random number.

Inclusion criteria: Patient's age 18-75 years, Daily tobacco users since last 1 year, able to converse in the Swedish language. **Exclusion criteria:** Patients with acute dental illness, severe psychiatric disease, alcohol problems, or use illicit drugs and are currently involved in other cessation programs.

Intervention and comparators: Brief advice based on 5A's principles ($n=225$) Versus usual care ($n=242$).

Primary outcomes: Reduction of tobacco consumption & changes in the expected direction for all outcomes were more frequent in the intervention arm.

Others: Strengths: The study used brief advice as per standard 5 A's approach. Selection of big sample size to make the findings generalizable to a similar population. **Limitations:** Lack of randomization for patients, use of computer randomized random sequence for only clinics used; lack of blindness and self-report data; failure to screen all eligible patients at some clinics.

Any other Notes: Sub-groups analysis to differentiate the impact of the intervention on snus and smoke users; Demonstration of counseling using interactive teaching techniques; Follow-ups visits after 6- months.

Reference 33: Cook JW, Collins LM, Fiore MC, Smith SS, Fraser D, Bolt DM, et al. Comparative effectiveness of motivation phase intervention components for use with smokers unwilling to quit: a factorial screening experiment. *Addiction*. 2016; 111(1):117–28.

Population and sample size: Setting: Southern Wisconsin, USA. Sample: Adult smokers. Sample size: 517. Age (Mean, SD): 47.0 ([SD = 14.4]). Design: Balanced four-factor randomized factorial design. Randomization: Stratified permuted, computer-generated block randomization (block size 16) based on gender and clinic.

Inclusion criteria: Adult aged ≥ 18 years; smoked ≥ 5 cigarettes/day for the previous 6months, adult not interested in quitting in the next 30 days but willing to cut down, able to read, write and speak the English language, agreed to complete assessment, planned to remain in the area for next 6 months, not currently using Bupropion and Varenicline, consented to use only study smoking medication during the study if reported current NRT use; nonmedical contraindications to Nicotine Replacement Therapy (NRT) use, women of potential childbearing agree to use birth control pills. **Exclusion criteria: N/A.**

Intervention and comparators: Motivational interviewing vs. none x Nicotine patch vs. none, x Nicotine gum vs. none x Behavioral reduction vs. no intervention ($n=253$) or usual care ($n=264$).

Primary outcomes: Smoking reduction was higher in nicotine gum combined with behavioral reduction counseling group and behavioral reduction counseling combined with motivational interviewing.

Others: Strengths: Use factorial design to test multiple interventions compared to usual care and stratified permuted random sampling. Follow-ups at 12- and 26-weeks following study enrollment.

Limitations: Self-reported response for outcomes measures and limited blinding for staff and participants.

Any other Notes: Use of phase base model of smoking intervention, the use of multiple treatment strategies using factorial design will help to test multiple hypotheses at one time.

Reference 34: Steinberg ML, Rosen RL, Versella M V, Borges A, Leyro TM. A Pilot Randomized Clinical Trial of Brief Interventions to Encourage Quit Attempts in Smokers From Socioeconomic Disadvantage. *Nicotine Tob. Res.* 2020; 22(9):1500–8.

Population and sample size: Setting: Local community soup kitchen, Northeastern US State. Sample: Daily smokers. Sample size: 64. Age (Mean, SD): ($M_{age} = 47.4$ years [SD = 10.7]). Design: Pilot Randomized Clinical Trial. Randomization: Block randomization.

Table 2. Characteristics of included studies in the review. (Cont.)

Inclusion criteria: Patient's age 19-65 years, daily tobacco users, able to read and speak the English language, and Carbon Monoxide (CO) reading greater than 5 ppm. **Exclusion criteria:** Patients on U.S FDA approved smoking cessation aids, patients with severe psychiatric disease, alcohol problems, illicit drug use, and are currently involved in other cessation programs, patients on antipsychotics medications, self-reported current medical problems potential concern to nicotine replacement, pending legal issues with the potential to result in incarceration and women should be on effective birth control and could not be nursing or pregnant or planning to become pregnant in the next 2 months.

Intervention and comparators: Brief (e.g., 30 m) Motivational Interviewing (19), Nicotine Replacement Therapy (NRT) ($n=19$), or a Referral-Only intervention ($n=20$).

Primary outcomes: 40% of the sample reported making a serious quit attempt at follow-up, significant self-reported reduction in smoking and more use of NRT and lozenge in NRT group at 6 months' follow-up.

Others: Strengths: Unique population (socio-economically disadvantaged smokers), follow-up (30 days) the cases to measure self-reported quit rate/attempt and comparison of three interventions simultaneously in one design. **Limitation:** Study included a small sample size ($n=57$).

Any other Notes: Follow-up at 1 month, unique population; socio-economically disadvantaged smokers, use of Post hoc analysis to find financial strain as a significant moderator of the effect of the intervention on smoking behavior

Reference 35: Ho KY, Li WHC, Wang MP, Lam KKW, Lam TH, Chan SSC. Comparison of two approaches in achieving smoking abstinence among patients in an outpatient clinic: A Phase 2 randomized controlled trial. Patient Educ. Couns. 2018; 101(5):885–93.

Population and sample size: Setting: Hong Kong –outpatient clinic. Sample: Chinese smokers- medical follow-up. Sample size: 100. Age (Mean, SD): ($M_{age} = 55.6$ years [SD = NA]). Design: A Phase 2 RCT. Randomization: Computer generated

Inclusion criteria: 18- years or older and smoked at least five cigarettes per day **Exclusion criteria:** Unstable medical conditions, poor cognitive function, mental illness, currently participating in other smoking cessation programs or services.

Intervention and comparators: (Quit immediately: [QI]- received a booklet about smoking cessation and brief intervention using the AWARD [ask, Warn, Advice, Refer, Do-It Again] model, and cut down to quit: [CDTQ]), to quit progressively.

Primary outcomes: QI group had a significantly higher self-reported quit rate than those in the CDTQ group at the 6-month follow-up (18.0% vs. 4.0%, adjusted OR = 0.190, 95% CI = 0.039–0.929). Not significant at the 12-month follow-up (12.0% vs. 4.0%, adjusted OR = 0.306, 95% CI = 0.059–1.594).

Others: Strengths: 4 follow-ups (1,3,6,12 months) to measures outcomes, use of allocation concealment to blind randomization and intention-to-treat analysis to control bias in the analysis. **Limitations:** A pilot approach to select all subjects from the same setting may infuse participant selection bias and only 6 and 12 months follow up with 73 % retention rate.

Any other Notes: 50 years and over half had received education at the lower secondary school level or below CDTQ methods are relatively more complicated than QI methods, which require an understanding of smoking education strategies and close monitoring of the number of cigarettes consumed and reduced.

Reference 36: Cabriaes JA, Suro Maldonado B, Cooper T V. Smoking transitions in a sample of Hispanic daily light and intermittent smokers. Addict Behav. 2016; 62:42–6.

Population and sample size: Setting: Health clinic, hospital, or university on the U.S/México border. Sample: Hispanic (DLS/ITS) daily light (DLS; ≤ 10 cigarettes per day) and intermittent (ITS; nondaily) smokers. Sample size: 190, a subset of 390 follow-up samples. Age (Mean, SD): ($M_{age} = 38.6$ years [SD = 15.1]) Design: Randomized controlled trial. Randomization: Randomly assigned to either an immediate or delayed intervention group at baseline using an online random number generator

Inclusion criteria: Age of at least 18 years and smoking between one cigarette a month to 10 cigarettes per day (CPD). **Exclusion criteria:** N/A

Table 2. Characteristics of included studies in the review. (Cont.)

Intervention and comparators: Immediate brief cessation intervention versus delayed intervention (control) group.

Primary outcomes: Smoking categories to control group (DLS/ITS) remains stable, with no significant group difference. DLS group at both points showed higher nicotine dependence levels. 8.95% went from daily light smokers (DLS) to quitting, and 5.26% went from intermittent smokers to quitting at 3-month follow-up.

Others: Strengths: Specific population; Hispanic, an underrepresented population in smoking cessation studies, use of multi-component intervention in one study. The first study to discuss light and intermittent smoking to compare efficacy of brief smoking cessation intervention. 3-month follow-up to measure to measures outcomes in both groups. **Limitations:** High attrition rate (48%); “contact-information mobility” - challenges to maintain communication with participants; participant work schedules; prioritization of “personal and family safety” over health-related behaviors; “the study was brief and perhaps not intensive enough to cause cessation.” The self-report method at baseline and follow-up for smoking status rather than biochemical process.

Any other Notes: All-Hispanic, predominantly Mexican/Mexican American community sample potentially limits generalizability.

Reference 37: Krigel SW, Grobe JE, Goggin K, Harris KJ, Moreno JL, Catley D. Motivational interviewing and the decisional balance procedure for cessation induction in smokers not intending to quit. *Addict Behav.* 2017; 64:171–8.

Population and sample size: Setting: Urban University using the psychology department research pool, USA. Sample: University students. Sample size: 82 Age (Mean, SD): ($M_{age} = 26.9$ years [SD = 9.6]) Design: Not Specified [Random assignment of the subjects in two groups]. Randomization: Computer-generated random number assignment in a sealed envelope.

Inclusion criteria: Smoking at least one cigarette during the last 7 days, having no intentions to quit in the next 30 days, age at least 18, college enrollment, and reachability via phone & email. **Exclusion criteria:** N/A.

Intervention and comparators: Motivational Interviewing using only the decisional balance component (MIDB)/ health education around smoking cessation (HE).

Primary outcomes: Both groups showed significant reductions in smoking rates and increases in motivation to quit, quit attempts, and self-reported abstinence, with no significant group differences.

Others: Strengths: Cost & time efficient interventions, use of intention-to-treat analysis and maximum-likelihood estimation to accommodate missing data. **Limitations:** Population of interest is a small/limited group; “college students who were generally light smokers”. The use of a small sample size may hinder generalizability. Outcomes measures were self-reported without control group with no biochemical verification of abstinence.

Any other Notes: Recruitment materials made no mention of quitting smoking, and participants were informed they would receive up to \$20 for study completion. Only one session of MIDB or HE was performed per participant. Each session was, on average <20 minutes.

Reference 38: Meyer C, Ulbricht S, Gross B, Kästel L, Wittrien S, Klein G, et al. Adoption, reach and effectiveness of computer-based, practitioner delivered and combined smoking interventions in general medical practices: a three-arm cluster randomized trial. *Drug Alcohol Depend.* 2012; 121(1–2):124–32.

Population and sample size: Setting: Northern Eastern, Germany. Sample: Adult smoker patients. Sample size: 263. Age (Mean, SD): 41.17 years [SD = 15.2]). Design: Three-arm clustered randomized controlled design. Randomization: Cluster randomization of the medical practices ($n=151$).

Inclusion criteria: Patients aged more than 18 years or older reported any tobacco smoking use in the last 6 months.

Exclusion criteria: Practices registered for another facility apart from general practice.

Intervention and comparators: Brief advice (practice $n=50$; patients $n=618$)/Tailored letter (practice $n=50$; patients $n=1484$) / Combination (practice $n=51$; patients $n=1113$).

Table 2. Characteristics of included studies in the review. (Cont.)

Primary outcomes: The seven-day point prevalence was higher in the combination group compared to brief advice or tailored intervention. The rate of 6-month prolonged was higher in the combination group than the brief advice and tailored letters group. 7-days and 6-month prolonged abstinence were statistically significant between the combination group and the other two groups. Tailored letters group shows significantly higher abstinence within past 7-days at 12-month follow-up in contrast to combination and brief advice. The number of abstinent patients was significantly higher in a tailored letter or combination group followed by brief advice.

Others: Strengths: Recruiting a large sample size for a three-arm clustered randomized design. Use of advanced imputations to find best results for 'missing at random' cases. **Limitations:** Self-reported abstinence and lost to follow-up of one-quarter of patients at 12-months.

Any other Notes: 12 months' follow-ups for all registered patients. Comparison of three interventions in different arms at a time to determine the efficacy of three different interventions.

Reference 39: Schane RE, Prochaska JJ, Glantz SA. Counseling nondaily smokers about secondhand smoke as a cessation message: a pilot randomized trial. *Nicotine Tob. Res.* 2013; 15(2):334–42.

Population and sample size: Setting: San Francisco Bay Area, U.S. Sample: Nondaily smokers. Sample size: 52 Age (Mean, SD): 32.66 years [SD = 11.11]. Design: A randomized pilot trial. Randomization: Random sequence created by SAG using the random number generator in Minitab 14.

Inclusion criteria: Respondents smoked at least 100 cigarettes in their lifetime, smoked at least once in the past seven days but not every day, age 18 years or older and speak the English language. **Exclusion criteria:** Participants had an exhaled carbon monoxide (CO) exceeding 10ppm.

Intervention and comparators: Brief counseling on Harm to Self-group (HTS, $n = 26$) provided information on tobacco use and its risk on developing different medical conditions along with chemical ingredients of tobacco by a nurse/Harm to Others (HTO, $n = 26$) informed about tobacco use and its risk on friends and family members similar to the HTS group.

Primary outcomes: A significant difference in abstinence between harm to others (HTO) (36.8%) and harm to self (HTS) (9.5%) groups. A significant change in contemplation ladder score between participants who completed follow-ups than who lost to follow-up. Trying to reduce or quit smoking is higher in the HTO group (not significant, $p=0.607$). Comparable smoking reduction at 3 months follows in both groups. No difference in intervention acceptability in both the groups. Improved motivation and self-efficacy from baseline to 3-month follow-up in both groups.

Others: Strengths: Bio confirmed tobacco abstinence at the 3-month follow-up. **Limitations:** The sample size was small for testing efficacy and limited to self-reported smoking cessation at 3-month follow-up.

Any other Notes: 3-month follow-up for smoking cessation. Bio confirmed tobacco abstinence at the 3 months and use of urinary cotinine test to cross-check the abstinence.

Reference 40: Leavens ELS, Meier E, Tackett AP, Miller MB, Tahirkheli NN, Brett EI, et al. The impact of a brief cessation induction intervention for waterpipe tobacco smoking: A pilot randomized clinical trial. *Addict Behav.* 2018; 78:94–100.

Population and sample size: Setting: Water pipe (WP) lounges in urban and suburban areas in the Midwest U.S. Sample: Water pipe smokers. Sample size: 109. Age (Mean, SD): 21.1 [SD = 5.08]. Design: Pilot randomized control trial. Randomization: Cluster randomization (block of 4).

Inclusion criteria: Participant age ≥ 18 years. **Exclusion criteria:** N/A.

Intervention and comparators: Brief motivational interview ($n=53$) /No intervention ($n=55$).

Primary outcomes: No Significant difference in WP (number of days WP used and number of WP used). Increase awareness on risk perceptions, commitment to quit, and confidence to quit WP smoking.

Others: Strengths: Cluster randomization to avoid bias in sample selection. Carbon monoxide exposure detection by eCO (exhaled carbon monoxide) detector. Multiple outcome measurement. **Limitations:** No eCO detection at 3 months' follow-up.

Table 2. Characteristics of included studies in the review. (Cont.)

Any other Notes: Use of eCO detector at baseline, immediately before entering to lounge and post-session gave more reliable findings. Follow-up survey at 3 months of post-session.

Reference 41: Cabriaes JA, Cooper T V., Salgado-Garcia F, Naylor N, Gonzalez E. A randomized trial of a brief smoking cessation intervention in a light and intermittent Hispanic sample. *Exp. Clin. Psychopharmacol.* 2012; 20(5):410–9.

Population and sample size: Setting: StopLite smoking cessation intervention at a family health clinical (primarily) or university on the U.S. Mexico border. Sample: Hispanic smokers. Sample size: 214. Age (Mean, SD): 38.62 years [SD = 15.08]. Design: Pretest–posttest randomized control-group design with replacement of control group with delayed intervention. Randomization: Online random number generator.

Inclusion criteria: Hispanic at least 18 years of age and smoking between one cigarette a month to 10 cigarettes per day. **Exclusion criteria:** Non-Hispanic

Intervention and comparators: Carbon Monoxide (CO) feedback, ME, trigger management, and HE (Immediate versus delayed intervention group).

Primary outcomes: No significant differences in abstinence rates between the immediate and delayed intervention conditions. Significant increases in motivation to quit in the immediate intervention compared to the delayed intervention group.

Others: Strengths: 3-month follow-up by telephone, mail, or in person. Participants in a delayed intervention (control group) received the brief intervention after the end of the study. **Limitations:** Self-reported nicotine status as outcome measures and limited to the Hispanic population only.

Any other Notes: The brief intervention included self-efficacy, motivational enhancement, trigger management, and health education components. Non-eligible participants were offered QuitLine & Quintet resources.

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