DIAVERUM

Effectiveness of Nursing Educational Intervention on Vascular Access Self-Care in Hemodialysis

Study Protocol and Statistical Analysis Plan

NCT ID not yet assigned

13/06/2024

DIAVERUM STUDY PROPOSAL TEMPLATE

A. STUDY CHARACTERISTICS

A1. PRINCIPAL INVESTIGATOR

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A2. INSTITUTION

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A3. PROPOSAL TITLE

Effectiveness of Nursing Educational Intervention on Vascular Access Self-Care in Hemodialysis

A4. SUBJECT AREA

Transition process to self-care with vascular access

A5. STUDY DESIGN

Prospective, quantitative, cross-sectional study, employing a quasi-experimental methodology that involves an initial diagnostic assessment, a subsequent educational intervention to promote adherence to self-care, and an evaluation of outcomes after this intervention.

“Quasi-experimental studies fall within a positivist methodology, as they have a quantitative nature. The way in which the researcher controls the groups exposed to the study and the

manner in which interventions are carried out lead to expected outcomes, that is, an induction of results" (Soares, 2021).

B. BRIEF STUDY PROTOCOL SUMMARY

B1. SUMMARY

Background: Chronic Kidney Disease (CKD) is a condition that causes a slow, progressive, and irreversible loss of kidney function (Martins & Moura, 2023). The global incidence of this disease has been increasing and is currently a matter of great importance. At an advanced stage, renal replacement therapy is required, and Hemodialysis (HD) is the treatment of choice.

The therapeutic regimen of HD patients includes blood pressure control, glycemic control, anemia management, fluid and dietary restrictions, pharmacological regimen, vascular access care, and renal replacement techniques (Ordem dos Enfermeiros, 2016).

According to Barros (2020), "patients with CKD have educational needs for effective self-management of the therapeutic regimen." Self-management is defined by Shen et al. (2019) as the ability of an individual to manage symptoms, treatment, physical and psychosocial consequences, and lifestyle changes inherent to living with a chronic condition. In chronic disease self-management, "health promotion through encouragement of self-care" is considered fundamental, leading "nursing to provide interactive care, constructed jointly and empowering" (Rocha et al., 2020). Health literacy and the acquisition of knowledge for self-management of the health–disease transition process in CKD patients are essential for adherence to the therapeutic regimen and self-care.

Within active participation in their treatment, care of the Vascular Access (VA) is included. For HD treatment, there are three main types of VA: arteriovenous fistulas (AVF), arteriovenous grafts (AVG), and central venous catheters (CVC). According to Pinto et al. (2022), "the creation and maintenance of a functional vascular access is crucial for effective hemodialysis therapy" and "the importance of vascular access in patient care (...) is recognized by all health professionals and is a determining factor in the success of care and treatment effectiveness" (Ordem dos Enfermeiros, 2016). Arasu et al. (2022) add that in selecting the type of access, a "pragmatic and patient-centered approach" is required.

The AVF is the preferred access for HD, as it has the longest lifespan and lowest complication rates (Arasu et al., 2022) and is also associated with lower morbidity and mortality in CKD patients (Murea et al., 2019).

The nurse is primarily responsible for VA assessment and physical examination prior to treatment and plays a key role in identifying dysfunction. Thus, “the nurse should empower patients and guide them to recognize the necessary care for the vascular access, in order to facilitate adherence to the new routines imposed by treatment through teaching self-care” (Rocha et al., 2020).

Regarding VA care, Rocha et al. (2020) note that such care is not limited to treatment sessions but is also constant at home, where the patient “takes an even greater role, demonstrating commitment to the treatment through self-care.” Therefore, they must perform actions to ensure proper development and maintenance of the AVF. Martins and Moura (2023) add that self-care for VA “translates into spontaneous and purposeful behaviours by the patient aimed at promoting health and well-being and ensuring proper vascular access functioning.”

Given the complexity of these interventions and the considerable care needs, it is essential to develop differentiated care models that incorporate new nursing roles, in addition to those specific to HD treatment. In this context, the nurse acts as a promoter of patient self-management, actively contributing to improving the quality of life of individuals with chronic conditions (Ma et al., 2022; Mansoor & Khuwaja, 2020).

In nursing practice, it becomes necessary to provide care with a positive impact on clinical and health/quality-of-life outcomes; to establish personalized care plans based on individual needs and vulnerabilities; to provide patients and their caregivers with sufficient knowledge about their situation—health literacy; and to empower patients to be as autonomous as possible, including promoting self-care with their VA.

To achieve this, “the nurse should use a systematic approach to assess and identify the nursing care needs of the patient. In particular, a careful assessment of their knowledge about the disease and treatment process (...) aiming at well-being and meeting their needs. The nurse should also identify diagnoses, define, and implement interventions to achieve nursing-sensitive outcomes” (Ordem dos Enfermeiros, 2016).

Considering this, it is essential to evaluate the impact of nursing interventions on promoting patient self-care, with one key area of study being the impact of nursing educational intervention on self-care adherence. To plan and tailor care appropriately, it is important to understand the “starting point,” i.e., to assess the self-care profile regarding VA in a group of HD patients, to define, implement, and evaluate the impact of an intervention plan.

Thus, the objectives of the present study are:

1. To assess the self-care profile regarding VA in a population of CKD outpatients in HD units;
2. To evaluate the impact of nursing educational interventions on the transition process to self-care with VA in this population.

To address these objectives, the following research question was formulated: What is the impact of nursing educational intervention on the transition process to self-care with vascular access in outpatients undergoing hemodialysis?

METHODS

Study type: Prospective, cross-sectional, quantitative study aimed at evaluating the effectiveness of nursing educational intervention on VA self-care. This study follows a quasi-experimental methodology, involving an initial diagnostic assessment, a set of health education sessions, and a subsequent evaluation of the results of this educational intervention.

Population and sample: The population will consist of individuals with CKD undergoing outpatient HD at two HD units in the central region of Portugal. The sample will be non-probabilistic and selected by convenience, including CKD patients in HD whose VA in use is an AVF, from the two aforementioned HD units.

Inclusion criteria:

- Individuals with CKD in HD;
- Independent in self-care;
- With VA – AVF.

Exclusion criteria:

- VA via CVC or AVG;
- Cognitive impairment (assessed using the Mini Mental State Examination – MMSE – developed by Folstein et al., 1975);
- Lack of fluency in Portuguese.

Data collection instrument: The study will use a data collection instrument consisting of three parts: sociodemographic characterization, clinical characterization of participants, and assessment of AVF self-care behaviours.

The first two parts will include:

- Sociodemographic variables: age (years), sex (male/female), household composition (number of members), education level (illiterate, primary, secondary,

higher education), and employment status (employed, unemployed, homemaker). Categorical variables will be assessed through closed-ended questions, and age will be a continuous variable (years).

- Clinical variables: CKD etiology (diabetes, hypertension, polycystic kidney disease, glomerulonephritis, hypoplasia/dysplasia, unknown, or other causes), HD duration (years), duration of HD with AVF, AVF location/type (cubitocubital, radiocephalic, humerobasilic, humerocephalic, humerohumeral), and previous VA complications (thrombosis and infection episodes). Clinical data will be obtained from patient medical records.

Self-care behaviours will be assessed using the **Scale for Assessment of Self-Care Behaviours with AVF in HD** developed by Sousa et al. (2015), consisting of 16 items, structured into two dimensions:

1. *Prevention of complications* – 10 items assessing behaviours related to preventing AV thrombosis and infection;
2. *Management of signs and symptoms* – 6 items assessing self-care behaviours related to detecting VA complications.

In its original study, this scale showed good reliability (Cronbach's alpha: global 0.80; prevention subscale 0.72; management subscale 0.80).

A pilot test will be conducted with 4 patients to assess applicability, clarity, and completion time.

Data collection procedure: Participants will be recruited by designated study liaisons from each HD unit, in close collaboration with the principal investigator, according to inclusion/exclusion criteria. Eligible patients will be invited to participate and given full study information. Those who agree will provide written informed consent.

First phase: sociodemographic and clinical data collection and administration of the AVF self-care scale. Data will be collected by the principal investigator, in person, with manual completion of the scale. Duration: ~1 month.

Intervention phase: Based on the first assessment results, patients with suboptimal behaviours will receive a tailored nursing educational intervention—a series of health education sessions integrated into HD sessions—each lasting approximately 30 minutes.

Second phase: Three months later, the scale will be re-administered to all initial participants, regardless of the need for intervention. Data collection will again be by the principal investigator, in person, with manual completion. Duration: ~1 month.

Each participant will be assigned an alphanumeric code for pairing pre- and post-intervention data. The code–name key will be accessible only to the principal investigator.
Nursing educational intervention: A set of individual health education sessions, delivered using expository methods and an informational leaflet, focusing on:

- Prevention of thrombosis and infection (recognition of complications during and between HD sessions, hemostasis care, limb protection from trauma, avoidance of non-HD punctures);
- Correct assessment of signs/symptoms suggestive of AVF complications (AVF functionality assessment via thrill palpation, detection of thrombosis by absence of thrill, changes in colour/sensation of the limb, limb pain).

The sessions will be conducted by the principal investigator.

ETHICAL PROCEDURES

This research will comply with applicable ethical principles throughout its course.
Regarding the principles of beneficence and non-maleficence, it is considered that patients undergoing the intervention will experience health gains and therefore the study will "do good for the participant" (Nunes, 2020) and will not cause harm.
The principle of veracity will also be ensured by informing patients about the risks and benefits of their participation, as stated in the informed consent provided in advance.
Confidentiality will be guaranteed by protecting any personal information collected, ensuring that such data will only be known to the principal investigator and will be deleted upon completion of the research.

Under these principles, participants' rights will be safeguarded, including: the right to avoid harm, the right to full knowledge about the study, the right to self-determination, the right to anonymity and confidentiality (Nunes, 2020).
The study will be approved by the Ethics Committee of Diaverum – Investimentos e Serviços, Lda., where it will be conducted. Authorization will also be obtained from the clinical directors and nurse managers of the participating units.
Use of the Scale for Assessment of Self-Care Behaviours with AVF in HD has been authorized by its authors.
All paper documentation will be stored in a restricted-access location accessible only to the principal investigator. After data entry into a database and pseudonymization, paper

questionnaires will be destroyed. Digital files will be stored in a password-protected folder accessible only to the principal investigator and supervisor.
All paper and digital files will be destroyed when the study ends.

DATA ANALYSIS

Data analysis will be organized in two parts:

Part 1 – Sociodemographic and clinical variables:

- Mean and median for quantitative variables (age);
- Absolute frequencies and percentages for categorical variables.

Part 2 – Scale results:

- Results presented as percentage of responses, as recommended by the scale's author.

Impact assessment:

Inferential statistics will be used to compare VA self-care behaviours between the two data collection moments (pre- and post-intervention).

TIMELINE:

Atividades	04/2024	05/2024	06/2024	07/2024	08/2024	09/2024	10/2024	11/2024	12/2024	01/2025	02/2025	03/2025	04/2025	05/2025
Literature Review														
Participant identification														
Data Collection (moment 1)														
Data analysis														
Intervention preparation														
Intervention														
Data Collection (moment 2)														
Data analysis														
Interpretative results analysis														
Final report and submission														

EXPECTED RESULTS

At a higher level of abstraction, the primary expected outcome of this study is an improvement in VA self-care capacity among CKD outpatients undergoing HD.

It is also relevant to reflect on possible health gains for patients and contributions to nursing professional development.

From the analysis of behaviours related to AVF complication prevention and management, it is expected that patients will demonstrate knowledge of the necessary self-care behaviours to recognize changes in AVF function and to adopt behaviours that prevent and/or detect complication signs.

It is considered essential to implement health education programs promoting VA self-care behaviours, as Sousa et al. (2020) observed that patients targeted by structured nursing interventions show better general self-care behaviours and improved AVF maintenance practices.

Nursing practice in the follow-up and monitoring of CKD patients on regular HD is extremely important. In addition to providing treatment-specific care, the nurse should establish a therapeutic relationship with the patient. One of this study's objectives is to empower patients for self-care and promote their involvement in treatment, negotiating and adapting strategies, facilitating the transition process, and fostering self-care—always aiming to address real patient needs.

Developing nursing care conceptualization that ensures high-quality standards is essential for professional practice, representing another expected result and, ultimately, this project's contribution to nursing practice in CKD patient care.

B2. KEY REFERENCES

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C. BUDGET

Not applicable.

D. PARTICIPATING CENTERS

HD Unit of Águeda and HD Unit of Aveiro (DIAVERUM).

E. DISCLOSURE OF INTEREST

This research project was developed within the Curricular Unit “Internship in Nursing for the Person with Chronic Conditions” (1st year, 2nd semester) of the Master’s Degree in Medical-Surgical Nursing (MEMC) – chronic condition area – at the School of Health Sciences of Aveiro (ESSUA) during the 2023–2024 academic year, under the supervision of Professor João Lindo Simões.

The research will be conducted in the 3rd semester of the MEMC – chronic condition area – and will be disseminated at ESSUA, in the participating centres, and at relevant congresses in Medical-Surgical Nursing and Nephrology. Publication in scientific journals in the field is also intended.

Effectiveness of Nursing Educational Intervention on Vascular Access Self-Care in Hemodialysis

Informed Consent Form
NCT ID not yet assigned
13/06/2024

Informed Consent Statement for Research Study Participants

Considering the "Declaration of Helsinki" of the World Medical Association and the Oviedo Convention

Within the scope of the Master's in Medical-Surgical Nursing (MEMC) at the School of Health Sciences of the University of Aveiro (ESSUA), Nurse Ana Catarina Silva, a collaborator at the Aveiro and Vouga Dialysis Units of Diaverum – Investimentos e Serviços, Lda., under the supervision of Professor João Lindo Simões, is conducting a research project entitled "Effectiveness of Nursing Educational Intervention on Vascular Access Self-Care in Hemodialysis", whose objective is to assess the effectiveness of nursing educational intervention on vascular access self-care.

For this study, it is necessary to collect sociodemographic and clinical data from participants. The required sociodemographic variables are: age, sex, household composition, education level, and employment status. The clinical variables are: etiology of kidney disease, duration of hemodialysis (in years), type of fistula, and previous vascular access complications.

You will also be asked to complete the Scale for Assessment of Self-Care Behaviors with Arteriovenous Fistula in Hemodialysis developed by Sousa et al. (2015), which consists of 16 items.

After analyzing the results of this assessment, you may receive a nursing intervention to help improve your vascular access care for hemodialysis. All participants will undergo a new evaluation, regardless of the first evaluation's results, and will again be asked to complete the above-mentioned scale.

Participation is voluntary, and your decision to participate or not will have no effect on the care you receive. No risks are anticipated from your participation in this research.

This study has received a favourable opinion from the DIAVERUM Ethics Committee and has been duly authorized by the General Management of DIAVERUM – Portugal.

For ethical purposes, it will be ensured that:

- All data that could identify you will be shared only with persons directly involved in the research;
- No identifying information will be included in any report or publication;

- When the study ends, all questionnaires will be destroyed;
- At the end of the study, you may access the results and the final report if you wish.

All data will be collected in accordance with the General Data Protection Regulation (GDPR), in effect since May 25, 2018, and respecting the privacy policy of DIAVERUM. Data will be used exclusively for this study. All documentation will be collected and coded so as to make identification impossible. Thus, your confidentiality will be ensured, and no personal identifying information will be included. If the results of this study are published, your identity and that of your family will always remain confidential.

You have the right to access, portability, rectification, deletion, restriction, and to withdraw consent while the data are still non-anonymized. To do so, you may contact the principal investigator using the contact details below.

If you require any further clarification, you may contact us at:

Phone: +351 910 616 059

E-mail: catarinabsilva1993@gmail.com

If you agree to participate in this nominal group, and considering the Declaration of Helsinki of the World Medical Association and the Oviedo Convention, you declare that you understand the explanation provided to you about the research in which you will be included. You have had the opportunity to ask any questions you deemed necessary to decide to participate and have received satisfactory answers.

You also acknowledge that, according to the recommendations of the Declaration of Helsinki, the information provided to you covered the objectives, methods, anticipated benefits, potential risks, and possible discomfort.

Furthermore, you have been assured that you have the right to refuse or withdraw from the study at any time, without any prejudice to you. For this purpose, you should contact the principal investigator of this study using the contact information provided above.

Therefore, you agree to participate in this study.

Date: _____

Signature of participant: _____

Signature of person obtaining informed consent: _____

Best regards,

Ana Catarina Silva