

**Effectiveness of Skill Building Education on Arteriovenous Fistula Self-Care Behaviors and
Quality of Life of Patients on Hemodialysis:**

Randomized Controlled Trial

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Introduction

This chapter provides a succinct overview of the international and national prevalence of chronic kidney disease (CKD) and its associated treatments, especially hemodialysis. It will primarily focus on vascular access (VA) considerations for hemodialysis patients, specifically arteriovenous fistulas (AVF). It will compare AVF with the central venous catheter (CVC) and arteriovenous graft (AVG). Furthermore, it explores the relationships between hemodialysis, AVF, self-care behaviors, and quality of life. The chapter also highlights gaps in the existing literature regarding patient teaching and skill-based education, and addresses contextual issues that form the foundation of the study. Additionally, it outlines the problem statement, significance of the research, and purpose of the study, as well as presents the research question and hypothesis.

Chronic Kidney Disease and Hemodialysis

Chronic kidney disease (CKD) poses a significant global health challenge, leading to high mortality and healthcare expenses (Carney, 2020; Jager & Fraser, 2017; Neuen et al., 2017). CKD has emerged as the third fastest growing cause of death worldwide and the fifth most common cause of year of life lost by 2024 (Bikbov et al., 2020). Notably, a literature review of the epidemiology and prevalence of CKD indicated that the overall prevalence of CKD in Pakistan is substantial, reaching 21.2% (Imtiaz & Alam, 2023).

CKD exhibits a gradual progression, evolving from its early stages to eventual renal failure. According to Jager and Fraser (2017), 3.9 million individuals living with CKD worldwide were treated with renal replacement therapy. Hemodialysis is the most prevalent form of renal replacement therapy. Specifically, 89% of cases worldwide are attributed to hemodialysis while 11% to peritoneal dialysis (Bello et al., 2017, 2019; Pecoits-Filho et al., 2020). In Pakistan, the approach to hemodialysis becomes more difficult owing to its high cost (Shafi et al., 2018). However, hemodialysis is less costly than renal transplantation. Furthermore, it is the most easily available treatment in Pakistan (Imtiaz & Alam, 2021).

Hemodialysis is the preferred method to remove accumulated toxins and waste products from the body with the help of a machine (hemodialyzer) through diffusion and ultrafiltration (Lee, 2017). It is noteworthy that hemodialysis demands a VA in which the blood can quickly move between the patient's body and hemodialyzer. However, VA provides adequate blood flow, is easily accessible, cost-effective, has excellent long-term patency, and has a lower

complication rate (Santoro et al., 2014). Hemodialysis patients develop a range of complications related to vascular access. The complications arising in the VA lead to the critical role of patients in managing their VA. Patients should be educated and trained to maintain, monitor, and manage changes in their VA (Sousa et al., 2014, 2020). Patient care for VA significantly enhances the functionality and longevity of VA, as well as the quality of life, lowering the complication rates to ensure more efficient dialysis treatment (Lok et al., 2020).

Vascular Access for Hemodialysis Patients

Successful hemodialysis therapy necessitates patients to possess a VA. Effective dialysis depends on easy and repetitive cannulation, rapid blood flow, and excellent patency of the VA (Abo El-Fadl, 2020). Epidemiological data show that there is considerable variation in the establishment, use of VA, and patient preference in selection for VA among different countries worldwide (Asano et al., 2013; Balamuthusamy et al., 2020; Field et al., 2019; Pisoni et al., 2018). Additionally, it is essential to consider the functionality and impact of VA on a patient's overall health and quality of life (Gomes et al., 2013). Several VA options are available, including CVC, AVG, and AVF (Schmidli et al., 2018). The appropriate VA is selected based on various factors such as the patient's age, vascular anatomy, comorbidities, and personal preferences (Asano et al., 2013). An AVF is an anastomosis between an artery and a vein, allowing arterial blood to flow through a large-bore vein. The engorgement of the artery and enlargement of the vein facilitates swift arterial blood flow, which is required for hemodialysis treatment. Different types of AVF anastomosis are created, such as side-to-end of the vein to the artery, lateri-lateral, and terminalized side-to-side of the artery vein (Santoro et al., 2014). AVFs are named according to their placement in specific body parts. Upper extremities AVFs, such as radio cephalic, forearm basilic, and brachial cephalic AVFs, are more common than the lower extremities femoral and transverse femoral AVFs.

The AVG is similar to the AVF, connecting the artery and vein; however, it employs a plastic tube. However, CVC is a catheter inserted into the subclavian, jugular, or femoral veins. Hemodialysis starts soon after the insertion of the CVC and from two to four weeks after the creation of the AVG (Lin et al., 2021). However, AVF require more time for maturation; therefore, hemodialysis starts six weeks after AVF creation (Sabiu & Gallieni, 2023). The preferred site for AVF in Pakistan is the forearm, which matures within 42 days, and hemodialysis is initiated after AVF maturation.

AVF is considered the most effective and preferred vascular access method. National and international guidelines advocate the use of AVF for hemodialysis therapy in patients with CKD (Napalkov et al., 2013) for several reasons such as lower incidence of infection (9.5%) (Demiral, 2017) and increased patency rates (60-71%) compared to other VA (Al-Jaishi et al., 2017). In the case of AVF, unlike other VA, the vascular endothelium is maintained, reducing the risk of infection and hospitalization (Farrington et al., 2020). According to He and Liu (2023), CVC have more readmissions due to complications. Moreover, CVC is strongly associated with elevated mortality rates (35.6%) (Campos et al., 2024); hence, AVF is a better choice. Additionally, functional AVFs in hemodialysis patients minimize the risk of complications and improve well-being (Gomes et al., 2013). The preventable complications associated with AVFs, ranging from aneurysms to stenosis and infections, underscore the critical need to teach patients self-care (Sousa et al., 2014).

Patients Role in AVF Self-Care

The intricate nature of caring for AVF in hemodialysis patients highlights the role of patients' self-care behaviors. Hemodialysis patients who practice self-care for their AVFs experience notable benefits such as increased satisfaction, maintained fistula functionality, prevention of AVF complications, low hospitalization rate, and enhanced quality of life (Avanji et al., 2021; Pessoa & Linhares, 2015; Riegel et al., 2021). Self-care includes a range of activities, skills, and self-awareness intended to improve health and well-being (Johnsson et al., 2023; Marzband & Zakavi, 2015; Matarese et al., 2018). Self-care is a comprehensive concept encompassing a variety of behaviors such as self-care maintenance, self-care monitoring, and self-care management (Jaarsma et al., 2020). Self-care maintenance involves the activities required to maintain physical and mental health and prevent illness, such as exercising, taking prescribed medication, diet modification, and treatment adherence (Riegel et al., 2021). Self-care monitoring refers to the ongoing process of observing and noticing any changes in health status. Self-care management also includes the actions that individuals take to control and cope with changes in their health status.

The self-care maintenance of AVF involves actions to maintain functionality (Pessoa & Linhares, 2015). It includes preventive measures such as avoiding venous puncture for blood samples, medicine infusion, and measuring blood pressure on the AVF arm. Additionally, patients are suggested to refrain from wearing tight clothing, jewelry, and lying down or putting

pressure on the AVF arm (Adib-Hajbagheri et al., 2014; Ozen et al., 2017; Pessoa & Linhares, 2015; Roso et al., 2015). According to Kim and Cho (2021), patients quickly exhibit self-care maintenance behaviors regarding medication and fistula care. Moreover, a few experimental studies have revealed that patients adopt self-care maintenance behaviors related to AVF after educational interventions (Alsaqri et al., 2019; Sousa et al., 2021). Consistent self-care maintenance makes patients more attuned to their body and daily activities. Moreover, self-care maintenance helps patients to establish a standard baseline health indicator.

Understanding of the baseline is crucial for recognizing the changes in the body. In addition, it leads to monitoring of changes closely (Riegel et al., 2012). Self-care monitoring behaviors regarding AVF care include looking, listening, and feeling. This involves:

- The observation of the AVF in terms of its appearance
- Palpating over the AVF and feeling the thrill
- Listening to the bruits sound over the AVF.

These behaviors assist hemodialysis patients in maintaining the functionality of their fistulas and preventing complications (Pessoa & Linhares, 2015). However, the literature shows that 98% of hemodialysis patients lack knowledge of fistula care (Pessoa & Linhares, 2015). Furthermore, some studies have shown that patients cannot identify signs and symptoms of complications (Ozen et al., 2017; Pessoa & Linhares, 2015; Sousa et al., 2021). Monitoring AVF in hemodialysis patients enables the detection of potential changes. Since the fistula is visible on the patient's body, it can be visually inspected and cared for daily. This proactive approach facilitated timely intervention and management.

Self-care management involves the implementation and evaluation of treatments and interventions (Riegel et al., 2019). This ultimately improves the longevity and functionality of arteriovenous fistulas. According to Corbin and Strauss, patient education on self-care should address the adoption of meaningful behavioral changes and monitoring (Corbin & Strauss, 1988). When patients detect the signs and symptoms of their condition, they often seek to adopt a variety of interventions to address or manage changes. Self-care management of AVF depends on the symptoms that occur. For instance, cold or hot fomentation and elevation of the AVF arm can be applied in cases of swelling. Similarly, pressure should be applied directly to the bleeding site if bleeding occurs. Furthermore, the absence of thrill or bruit sounds indicates the need for

medical investigation and intervention. Notably, monitoring an AVF in response to any change is a crucial step in its management.

Proficiency and mastery in self-care behaviors related to AVF can result in effective monitoring and facilitation of better self-management (Martínez et al., 2021; Riegel et al., 2012). It requires intentional efforts from patients to assume responsibility for their health and effectively manage their condition (Blok, 2017; Ince et al., 2017; Jeffs et al., 2015; Kong et al., 2021). Developing self-care behavior in all components of maintenance, monitoring, and management enables patients to care for AVF effectively. By maintaining the AVF site, monitoring for potential complications, and managing it effectively, patients can ensure the functionality of AVF. This comprehensive approach not only preserves the AVF but also improves the clinical outcomes and quality of life of hemodialysis patients.

Arteriovenous Fistula and Quality of Life

Quality of life is an indicator of the effectiveness of the medical care provided to patients undergoing dialysis. Evidence suggests that all key domains (physical, social, role functioning, emotional, mental/psychological, general health, vitality, and spiritual) of quality of life are closely associated with patient survival (Peipert et al., 2019). Physical health is essential for overall well-being, reflecting normal functioning of the body in the absence of disease and illness. The factors associated with this domain include pain, discomfort, rest, sleep, and energy levels. Moreover, it is the ability to work and the extent to which a person can perform their roles in daily life activities to maintain their health status (Verberne et al., 2019). Social health encompasses personal relationships and interactions with others and impacts the quality of life. It is also considered a clinical outcome (Urquhart-Secord et al., 2016). With regard to emotional health, the key indicators of emotional health are emotional functioning, the experience of emotional pain, emotional distress, and any issue that interferes with daily life activities (Peipert et al., 2019). Likewise, the psychological aspect refers to the body image, self-esteem, memory, recognition, and concentration. Furthermore, the spiritual domain includes values, beliefs, and relationships with oneself and with superpowers. These factors influence the overall quality of life (Yang et al., 2015).

Reflecting the complexity of the disease itself, VA is viewed as affecting health-related quality of life and symptoms, both directly and indirectly (Robert & Petersen, 2013). Health-related quality of life (HRQOL) is significantly different among patients undergoing dialysis via

CVC and AVF (Maguire et al., 2022). In addition, the degree of access drastically affects patients' quality of life (Nordyke et al., 2020). A study on different hemodialysis access types revealed that patients with AVF were more satisfied with their vascular access than those with CVC. This satisfaction improves patients' overall QoL (Maguire et al., 2022; Robert & Petersen, 2013). Moreover, a study examined HRQOL among various AV access types, and the findings revealed that the AVF group's mean scores were higher in the physical composite summary, social functioning, mental composite summary, physical functioning, role functioning, role emotional, and general health domains of HRQOL than CVC after three months. Similarly, the average score in all HRQOL domains increased after one year compared with AVG and CVC. Moreover, patients with AVF were more satisfied with their lives (Kim, 2020). In contrast, patients showed higher dissatisfaction with CVC care (Browne et al., 2022). CVC interferes with normal routine activities, such as bathing, and is challenging to care for compared to AVF. In contrast, the current management practice for the access type is to keep the access area dry and clean. However, pain is less likely to be associated with CVC (Maguire et al., 2022). In contrast, patients with AVF are more concerned about bleeding, bruises, pain, edema, and swelling, which adversely affect the physical domain of QOL (Maguire et al., 2022). Hence, AVF care is more bothersome than catheter access, and AVF requires more significant consideration than the symptoms attributed to the physical domain.

Skill Building Educational Interventions for Self-Care Behaviors

Patients can significantly enhance the functionality of AVF by adopting self-care behaviors. AVF self-care behaviors can easily be incorporated into daily routines, allowing patients to perform consistently (Sousa et al., 2017). Effective AVF self-care behaviors can be achieved through educational sessions and training. Moreover, education enhances health literacy, helps patients maintain their AVF in good condition, preserves patency, prevents complications, makes informed decisions, and actively engages in health care (Kukita et al., 2015). However, it is essential to consider how educational sessions are delivered to the patients. Learning strategies must be tailored to the patient's level of understanding and involvement.

Teach-back is a highly effective teaching-learning strategy to improve self-care behaviors. The effectiveness of the teach-back mechanism is evaluated in different circumstances, such as in enhancing knowledge and skills while utilizing self-care skills training skills in adult patients. It encourages patient engagement and involvement, ensuring they

comprehend information, identifies mistakes and misunderstandings, and corrects them as needed (Pessoa & Linhares, 2015; Şahan et al., 2023). Moreover, the teach-back method was found to be effective in providing discharge teaching and satisfaction in emergency patients, improving hemodialysis patients' self-care, reducing anxiety in C-section patients, and improving self-care status in post-menopausal women. Furthermore, it improves patients' quality of life (Abbasi Abianeh et al., 2020; Bahri et al., 2018; Ghiasvand et al., 2017; Griffey et al., 2015; Katrachanca & Koleske, 2017; Shen et al., 2023).

To develop self-care behaviors for AVFs, patients require skills-building education to manage themselves at home. Skill-building education emphasizes the practical abilities and competencies of patients in managing themselves at home. This skills intervention starts by assessing current knowledge and recognizing it as a foundation. Then, individuals need tactical skills, such as "how to," as well as situational skills, such as "what to do and when" (Dickson et al., 2014; Dickson et al., 2014). Skill-building education has been effective in focusing skills deficits and improving heart failure patients' self-care and quality of life (Dickson et al., 2014). Hemodialysis patients require skills to learn self-care maintenance, monitoring, and management of AVF. Health education, along with skill building, works as a comprehensive approach to improving patients' overall well-being. With skills-building education through the utilization of the teach-back strategy, hemodialysis patients address their self-care maintenance, monitoring, and management of their AVF, improving their overall self-care management and abilities.

Current Practices related to AVF Care in Pakistan

In Pakistan, in current practice, patients need to receive education regarding self-care for AVF. They have limited information, such as avoiding blood pressure measurement on the affected arm and avoiding heavy lifting and shifting with the AVF arm, as well as sleep over the AVF arm. In addition, they did not avoid tight jewelry and clothing on the AVF arms (Iqbal et al., 2018; Rashid et al., 2018). Moreover, when the patients were asked about the assessment of their fistula, the majority responded that they knew that there was increased pulsation over the fistula, but they did not assess their fistula daily (Sultan et al., 2023; Rashid et al., 2018). In addition, only some self-care actions were performed by the patients, despite knowing about it. For instance, the majority of patients responded that they had knowledge about thrill palpation, disinfection of AVF, and washing of AVF before dialysis, but only a few patients performed these actions. However, only some aspects of self-care for AVF were performed by the patients,

and they demonstrated good knowledge, attitude, and practice. For instance, they knew why they needed AVF, felt the need to take care of their AVF, avoid cannulation on the AVF arm, and avoid weight lifting (Iqbal et al., 2018; Rashid et al., 2018). When they were asked about how often they received information on self-care of AVF from health care providers, they responded that the health care staff told them only about pressure application at the AVF site and the time to remove the dressing over the AVF after dialysis. Information related to AVF self-care should be included. Similarly, they must receive written information on AVF self-care (Sultan et al., 2023). Consistently, no significant correlation was found in knowledge regarding dialysis duration because of the need for more repetition of relevant information on AVF self-care by healthcare staff (Rashid et al., 2018).

Gap in the Literature

Self-care of AVF in hemodialysis patients is an important consideration. The literature shows that educational interventions effectively enhance AVF self-care behaviors in hemodialysis patients. Health care providers can design an educational program or protocols to develop AVF self-care behavior in hemodialysis patients (Ibeas et al., 2017; Sousa et al., 2017; Trask et al., 2016). Moreover, several guidelines recommend educating hemodialysis patients to take care of their AVF (Ibeas et al., 2017; Kukita et al., 2015; Schmidli et al., 2018). The existing literature indicates that numerous educational interventions have influenced treatment adherence among hemodialysis patients across various aspects, including medication adherence, dietary modification, adjustment of fluid and electrolyte balance, and management of interdialytic weight gain, except for AVF care (Cho & Kang, 2021; Sultan & Froelicher, 2023; Tao et al., 2020; Yangöz et al., 2021). Moreover, limited literature is available on the self-care behavior of patients with AVF; few studies suggest the theoretical aspects of AVF self-care of hemodialysis patients that address only the self-care maintenance of AVF. Minimal information is provided on interventions that should be included in the educational program to empower patients for their fistula care (Pessoa & Linhares, 2015a; Sousa et al., 2021). Only one study highlighted self-care maintenance and self-care monitoring of AVF by integrating the theoretical and practical aspects of their educational intervention (Sousa et al., 2021). Therefore, designing more effective and structured interventions are required to guide and train the hemodialysis patients for adopting AVF self-care behaviors while considering the all the component of self-care (Self-care

maintenance, self-care monitoring and self-care management). Thus, this study will focus on adopting the self-care behavior of AVF via skills building education.

Problem Statement

AVF plays a crucial role in hemodialysis therapy, yet its care is often overlooked leading to compromised functionality (Pessoa & Linhares, 2015). A dysfunctional fistula poses significant health risks, contributing to higher morbidity in terms of complications such as infection, bleeding, stenosis, thrombosis, and aneurysm. These complications can lead to medical and surgical treatment and, ultimately, a higher mortality rate. Self-care of the AVFs allows the patient to determine whether their fistula is functioning correctly. In Pakistan, the primary researcher has observed that patients often only become aware of their AVF dysfunction when they come for a hemodialysis session. This lack of awareness is due to not knowing how to properly maintain, monitor, and manage their AVF at home, which prevents them from effectively managing it. The dysfunction of their AVF necessitates the radiological evaluation. Based on the radiology findings, an alternative route may be required for hemodialysis (Sultan, et al., 2023). This condition not only becomes painful but also places patients at risk of complications and inadequate dialysis. Furthermore, it leads to a financial burden due to additional medical intervention and unplanned treatment. Therefore, a functional AVF is a significant requirement for hemodialysis treatment. Effective self-care behaviors, including all components (maintenance, monitoring, and management) is crucial for AVF functionality. To mitigate the issues related to AVF and develop self-care behaviors in hemodialysis patients, education and training are essential. These efforts are likely to empower patients to identify abnormalities promptly and seek timely intervention, reduce complications, ultimately enhancing dialysis efficiency, and improving their overall quality of life.

Significance of the Study

Skill building educational intervention plays a crucial role in influencing the self-care behaviors of patients. Providing patient education and imparting skills on how to care for their AVF can foster a positive change in the health of patients. Patients are more likely to engage in proactive health care behavior when equipped with the knowledge and necessary skills. Moreover, it encourages a sense of ownership in their health care journey. Knowledge acquisition and behavior modification through skill building are essential for improving the health-related outcomes and quality of life (Liu et al., 2016). Practicing proper hygiene and self-

care monitoring and self-care maintenance can empower patients and their families to identify the potential issues in their AVF. Early recognition of issue in the functionality of AVF might allow for prompt intervention, reducing the risk of serious complications. Educating patients and their families about AVF care can contribute to the longevity and functionality of AVF. Moreover, it improves the hemodialysis treatment and positively impacts their quality of life. Furthermore, financial, physical, emotional, and psychological burden may be reduced. This educational and skills building intervention has the potential to be integrated into the protocol of dialysis units. Moreover, it can ensure structured training for the health care provider, fostering expertise in AVF care, and improving the clinical practices.

Purpose of the Study

This study will assess the effectiveness of skill building educational interventions in improving the self-care behaviors and quality of life of AVF in hemodialysis patients.

Research Question

What is the effect of skill building education on the self-care behaviors of AVF care in patients undergoing hemodialysis treatment?

What is the effect of skill building education on the quality of life in patients with AVF undergoing hemodialysis treatment?

Hypothesis

Ho 1. Skill building education interventions will have no effect on the self-care behaviors of AVF in patients undergoing hemodialysis treatment.

Ha 1. Skill building education interventions will have a significant effect on the self-care behaviors of arteriovenous fistula in patient undergoing hemodialysis treatment.

Ho 2. Skill building education interventions will have no effect on the quality of life in patients with arteriovenous fistula undergoing hemodialysis treatment.

Ha 2. Skill building education interventions will have a significant effect on the quality of life in patients with arteriovenous fistula undergoing hemodialysis treatment.

Patient education is a paramount strategy, often considered as the most practical approach to augmenting patient knowledge and promoting self-care (Sousa et al., 2020). Moreover, patients should be taught to assess and monitor their AVF for signs and symptoms nonfunctional AVF (Alsaqri et al., 2019). The literature reports that patients' education regarding the AVF self-care positively affect self-care behaviors (Sousa et al., 2020). Consequently, there is pressing

need to implement intervention aimed at fostering self-care behaviors of hemodialysis patients related to AVF.

Theoretical Framework

Self-care embodies a proactive approach directed toward sustaining health through the adoption of health promoting behaviors and the management of illness. This concept transcends the mere treatment of illness and incorporates a broad spectrum of daily activities engaged to preserve their wellbeing (Riegel et al., 2012). For instance, activities such as tooth brushing, bathing, and food consumption exemplify the practical application of self-care. This concept has been elucidated by numerous theorists in their theories and models. The middle-range theory of self-care for chronic illness focuses on the self-care behaviors associated with the diagnosis of chronic illness. Moreover, it emphasizes that the healthcare provider needs to understand where patients having difficulties in adopting and maintaining self-care behaviors (Riegel et al., 2012). Healthcare providers can play a crucial role in promoting the self-care of the patients. Moreover, individuals prioritizing self-care predominantly emphasize self-improvement (Marzband & Zakavi, 2015). The middle-range theory of self-care for chronic illness guided the organization and conceptualization of the study variables. The middle-range theory of self-care for chronic illness possesses three components: self-care maintenance, self-care monitoring and self-care management (Riegel et al., 2012). Initially, patients will be introduced to the basic principles of self-care maintenance, followed by monitoring techniques and training in management strategies. This hierarchical approach may facilitate systematic skills acquisition and knowledge advancement for ensuring patients develop a comprehensive understanding and proficiency in AVF self-care behaviors.

Self-care Maintenance

Self-care maintenance pertains to conscientious behaviors to sustain overall wellbeing, promote optimal health, and preserve both physical and emotional equilibrium (Riegel et al., 2012). Hemodialysis patients are expected to actively participate in their care, including maintaining the health and functionality of their AVF. The most common AVF self-care instructions include refraining from applying pressure on the AVF, avoiding blood pressure monitoring and blood sampling from the AVF arm, avoiding tight clothing and jewelry on the AVF arm, and abstaining from exerting force or carrying heavy weights with the AVF arm (Pessoa & Linhares, 2015). Furthermore, Costa Pessoa et al., (2020) identified three themes for

functional AVF. These themes are: self-care actions for preserving AVF, self-care actions for prevention and monitoring of AVF complications, and self-care action at perioperative AVF construction. Self-care actions aimed at AVF preservation including actions that are necessary for the self-care maintenance of AVF. Furthermore, these self-care maintenance actions were examined across eight studies (Costa Pessoa et al., 2020). According to Riegel (2012), self-care behaviors build on the foundation of self-care maintenance. When patients master self-care maintenance, they can easily adopt self-care monitoring actions.

Self-care Monitoring

Self-care monitoring entails vigilant observation or attentive listening to one's body. The primary objective of self-care monitoring is to differentiate the normal anatomy and physiology from abnormal condition or changes in the body (Riegel et al., 2012). In chronic illness, self-care monitoring includes measuring blood pressure, sugar level, height and weight and observing wound condition. Adopting self-care monitoring allows patients to notice the change in their physical health. According to Costa Pessoa (2020) the second theme is prevention and monitoring of complications of AVF, indicates that action must be taken to identify or prevent the complications. Among these complications were thrombosis, bleeding, infection, hematoma, and steal syndrome. Therefore, the AVF limb must be examined regularly to determine its appearance and presence of thrill. Recognizing the physical changes initiates the decision-making process regarding the necessary course of action. Consequently, it becomes imperative for individuals to be aware of their symptoms and proficient in self-care monitoring (Riegel et al., 2019). Implementing self-care monitoring of AVF among hemodialysis patients is readily achievable. Furthermore, a systematic review and meta-analysis (Almasri et al., 2016) focusing on outcomes for vascular access for hemodialysis underscores the necessity for regular limb examination. This examination should enable patients to visually inspect, palpate, and auscultate their AVF. Routine monitoring of AVF blood flow can be accomplished by palpating the AVF site with the palm to detect the presence of a thrill. This tactile observation enables patients to discern between the normal and abnormal conditions of the AVF. Additionally, the identification of bruit can be detected by auscultating/using a stethoscope. This auscultation is relatively straightforward and can be conveniently conducted at home by the patients themselves (Sousa et al., 2017).

Self-care Management

The monitoring of any change or identification of symptoms leads to self-care management. When patient monitored their symptoms, then they are prompted to take action or make decisions regarding their care or interventions (Riegel et al., 2012). In self-care management, the patients can evaluate the treatment implementation. Patients who manage their self-care can improve their health status, and overall well-being, and enhance their quality of life (Riegel et al., 2012). They can decide what further actions could be required to positively change/manage their health and overall wellbeing. For instance, when patients notice that medication for the blood pressure is not controlling the blood pressure. So, they consult with the physician to change the medication so that they can have better control over their blood pressure. Self-care management depends upon the presence of symptoms. Monitoring of the arteriovenous fistula in hemodialysis patients enables the detection of potential changes and facilitates timely intervention. For instance, patients can perform self-care management actions such as cold compression within 24 hours in case of a puncture to the AVF area or in the presence of any redness, swelling, or pain (Pessoa & Linhares, 2015). Likewise, report to the health care providers in case of absence of thrill or bruit sound. Proficiency and mastery in maintaining health behaviors related to AVF can result in effective monitoring and management. Likewise, effective monitoring leads to effective management (Martínez et al., 2021; Riegel et al., 2012). However, different factors affect the patient's self-care behaviors AVF. such as motivation, knowledge, skills, abilities to understand and implement the process, cognitive impairment, culture, and norms (Arnault, 2018; Cocchieri et al., 2015).

Study Design

The randomize control trial (RCT) parallel design with the allocation ratio 1:1 will be employed to assess the effectiveness of a skill-building educational intervention on the self-care behaviors and quality of life of AVF in hemodialysis patients. An RCT is considered the gold standard for evaluating the impact of an intervention on outcomes. In a parallel RCT design, one group receives the intervention while the other group receives routine care. In this study, one group will receive a skill building educational intervention focused on AVF self-care behaviors while the other group will receive routine care information.

Participants

This study will involve participants meeting the eligibility criteria. Specifying inclusion and exclusion criteria enhances the likelihood of obtaining reliable and reproducible results and protects valuable individuals from exploitation (Nikolopoulou, 2023). A set of defined inclusion and exclusion criteria has been established to ensure that participants are appropriately selected to address the study's objectives.

Inclusion Criteria

The study will include patients:

1. diagnosed with end-stage renal disease on hemodialysis through an arteriovenous fistula
2. aged 18 years or above.
3. who can read and understand the Urdu language.

Exclusion Criteria

The study will exclude patients:

1. having any physical or mental disabilities that can interfere with their capacity to perform daily life activities.
2. with any visual and hearing impairment.

Recruitment

Patients will be recruited from two dialysis units. Effective recruitment and advertisements play a vital role in reaching and engaging potential participants. Annexure 1 includes information that will be shared with unit managers and staff at these two units about the study.

Screening

Medical Record Screening. The PI will obtain hospital approvals to review patients' medical records at the two hemodialysis units. The process will include creating a detailed checklist based on the study inclusion and exclusion criteria to guide the review of each medical record. The PI will take any necessary measures to ensure that medical records are anonymized and patient confidentiality is protected by pseudonymization (replacing their medical record number or ID with the private identifier). The PI will review the medical records and document each potential participant's eligibility based on the inclusion and exclusion criteria (Annexure 2).

Contacting Eligible Participants. A data analyst will be hired who will contact and brief the potential patients in the dialysis units during their dialysis procedure in all shifts on daily basis until the sample size achieved. A brief contact with patients will include sharing the study

purpose, what participation would involve, and why they were selected (Annexure 3). Patients will be allowed time to ask questions. If the patients express interest in participating, a meeting will be scheduled to go through the informed consent form in detail. Consenting will take place in a private room in the dialysis unit after dialysis procedure.

Study Setting

This proposed study will be conducted at two dialysis units within a private tertiary-level hospital in Islamabad, Pakistan. These units are located in different buildings of the hospital. Unit one is within the main premises of the hospital, whereas unit two is in a medical centre managed by the hospital. This medical unit is located six kilometers distance from the main hospital. Unit one accommodates up to 100 hemodialysis patients on a daily basis, divided across three shifts: morning, afternoon, and evening. Similarly, unit two, accommodates up to 70 hemodialysis patients on a daily basis, following the same shift schedule. Each hospital units consists of several rooms, 4-6 beds in each room.

The study is planned to be conducted between January-2024, to December 2026 upon the approval of the study from the relevant ethical review boards.

Group Assignment

Control Group

The control group will receive the routine care information at the hemodialysis units. The health care staff provide the usual routine care to patients during their regular dialysis procedures. There is no predetermined schedule for the routine care at these units but it consists of the application of dressing on the AVF and health care staff providing the following information to patients verbally:

- Refraining from pulling or pushing objects with the arm having a fistula
- Avoid measuring B.P. on the AVF arm
- Do not apply pressure on the fistula area
- Do not provide a sample from the affected side
- Wash the fistula with soap and water
- Remove the bandage upon return home following dialysis

All the research process in the control group will be conducted in the same manner as those in the intervention group, with the exception of intervention itself.

Intervention Group

The intervention group will receive skill-building education as developed by Sousa (2021) to enhance self-care behaviors in hemodialysis patients with AVF. Sousa's educational model is based on the middle-range theory of self-care for chronic illness and includes both didactic and practical components (Riegel et al., 2012). The didactic part provides knowledge base about AVF self-care. The practical part promotes skills acquisition to promote healthy access to AVF. This study will replicate Sousa's educational model with slight modification to align with the local context. While Sousa (2021) implemented the educational model for AVF self-care behaviors in a group format, in the current study the educational model will be delivered on a one-on-one basis. This modification is sought to accommodate the cultural difference, language proficiency, literacy level and individual patient need. Furthermore, individualized approach is tailored to ensure the clear and effective communication while respecting cultural norm.

Timing of the intervention will set based on the overall health status of patients. Patient will be given the option of rescheduling if not feeling well at given time. Each participant will receive individualized didactic instruction and personalized practical training before the dialysis procedure start (Annexure 9,11). These two sessions will be delivered on separate days within the same week. The primary investigator will be responsible for the intervention delivery. The sessions will take place in a private conference room at each dialysis unit.

The didactic session. The purpose of this session is to educate patients on AVF self-care maintenance. Participants will explore the AVF concept, their perceptions of AVF, their current care practices, and the individual responsible for their AVF care at home. Next, patients will be educated on fistula, its functionality, its significance in dialysis patients, and its impact on social, emotional and mental health. Any concerns about self-care behaviors will be addressed. The session will conclude within a total duration of 25-30 minutes before the dialysis. Teaching methods that will be utilized in this session are oral presentations and discussions. The didactic sessions will be scheduled when patients are in hemodynamically stable condition and can engage in discussions.

The practical session. The purpose of the practical session is to build skills that promote AVF self-care assessment and monitoring. The session will conclude within 20 to 25 minutes. In this session, participants will be shown how to assess and monitor AVF skill using a checklist

(Annexure 8). The checklist will serve dual purposes: first, as a teaching guide to teach the skill to the participants and second, for patients to demonstrate their understanding through return demonstration. The assessment will be step-wise process starting with inspection, palpation and auscultation. The details step-wise process is:

1-Inspection serves the purpose of identifying any situation that may compromise the AVF functioning, such as skin color changes, temperature changes at the AV fistula site indicative of signs of infection (signs of drainage, redness, fever or tenderness at the incision site) etc.

2- Palpation serves the purpose of training the participants to identify the thrill of their fistula. A continuous purring or vibration should be present, diminishing in strength when further from anastomosis.

3-Auscultation serves the purpose of training the participants to listen the bruits sounds of their AVFs. The participants will be encouraged to listen to their bruit sounds (a sound which is heard over AVF) with a stethoscope. A continuous low-pitched bruit should be audible. A teaching stethoscope will be utilized for auscultation. Participants will be encouraged to talk about the difficulties at any point of the session in the last five minutes. At the end of this session, participants will have a return demonstration of skill, verbalizing potential changes in the appearance, thrill and bruit sound of AVF. Moreover, they will articulate the significance of monitoring AVF in their daily life activities and outline their plan of action to detect any changes in the AVF. The primary investigator will observe and mark the checklist during the participants' return demonstration. If the participants are unable to redemonstrate accurately, they will be given time to practice the skill according to their feasibility and have redemonstration. This observation and marking aim to ensure that the participants comprehend and follow the technique. The practical session will be offered before dialysis. Patients will be instructed to follow this assessment daily at home for their AVF assessment utilizing the provided checklist. The checklist will be provided to the patients in the Urdu language, facilitating their ability to memorize and refer to the steps when performing their AVF assessment at home.

Teaching methods utilized in the session will include teach-back, demonstration and back demonstration techniques.

Assessment Checklist for AVF

The primary investigator developed the assessment checklist after reviewing the literature. This assessment checklist will be utilized in the teaching-learning and assessment process of the intervention's practical part (session two). This checklist includes the steps of inspection, palpation and auscultation. The checklist consists of 27 items, with the yes/ no responses. The maximum score on the checklist is 27 and the minimum is 0. The first draft of the checklist (Annexure 8) will be sent to the experts (Two educationists, one senior nurse manager and two nephrologists) for evaluation on clarity and relevance. Educationist must have five years' experience of classroom and clinical teaching. Nurse manager and nephrologist must have experience of working in dialysis units. Experts will be informed to delete the irrelevant items and add new ones, justifying additions and deletions. Moreover, they will be requested to review the weightage of each item. Feedback will be integrated, and this checklist will undergo pilot testing after consensus development. Subsequently, reliability will be calculated. The bilingual translator will then translate the checklist into Urdu. The CVI will be calculated.

Follow-up. The purpose of the follow-up is to assess the effectiveness of intervention and sustainability in the self-care behaviors of participants. There will be two follow-up assessments: the 2nd, and 6th week post-intervention. Follow-up sessions will be completed during patients' routine dialysis schedules in the dialysis units. Each patient will complete the ASBHD-AVF and HARQ. Each follow-up time will be approximately 15-20 minutes. If patients do not come for their routine dialysis for three scheduled days during the follow-up weeks, they will receive a phone call to inquire about their status by primary investigator. Throughout the intervention and follow-up periods, the usual questions will be addressed by PI. Patients will be advised to complete the checklist daily after assessing their AVF. Daily assessment of the AVF using the checklist will serve to reinforce their behaviors. Patients will also be instructed to promptly report any observed changes in their AVF to health care providers. A reminder for the assessment of AVF and marking on the checklist will be provided through WhatsApp message to the patient. Participants will not be allowed to communicate through WhatsApp.

Pilot Testing of Intervention

Before the actual research begins, the PI will conduct pilot testing of the intervention on 10% of the sample in the same setting and population where the actual study is planned to take place. Based on the findings of the pilot testing, modifications may be made in the intervention.

Fidelity of the Intervention

Intervention fidelity is referred to how accurately intervention is implemented according to its original design. Moreover, it also ensures that the intervention is applied consistently across all participants (Horner, 2012). Horner (2012) outline five key areas that will be focused on to enhance the fidelity of intervention.

Standardized intervention dose: To ensure consistent intervention dose for all the participants, primary investigator will strictly follow a detailed manual of operation (Annexure 10). Moreover, adherence to the lesson plan (Annexure 9) for both didactic and practical sessions will be ensured uphold consistency.

Standardized interventionist training: The practice and implementation of the intervention on simulated patients will enhance the investigator's proficiency.

Monitoring intervention delivery: Each session will follow a standardized format based on a predetermined lesson plan (Annexure 9). Additionally, a randomly selected intervention session will be audio-taped for quality assurance.

Evaluating participant understanding of information provided: A teach-back strategy will be employed to reinforce understanding. This will allow the investigator to determine the level of comprehension among participants.

Ensuring participant's use the skill taught. Participants will be required to demonstrate their newly acquired AVF skill at the end of the session will help to ensure the learning has taken place. To further verify, the correct application of skill, a checklist will be used by patients during assessment of AVF at their homes.

Outcome measures:

Primary outcome of this study will be self-care behaviors related to AVF and secondary outcome will be AVF quality of life. Primary and secondary outcome will be compared by using the independent T test.

Sampling

Participants will initially be recruited using consecutive sampling techniques. This method involves enrolling the eligible participants in a specific order, allowing for the calculation of response rates, and using clinical information until the desired sample size is achieved (Bujang et al., 2022; Thewes et al., 2018). Hemodialysis patients who meet the inclusion criteria will be invited to participate in the study.

Sample size

The sample size was calculated by using G* power (Faul et al., 2009). The parameters used for sample size calculation were: $\alpha=0.05$, $\beta=0.15$; power $1-\beta=0.85$, with an allocation ratio of 1:1 and effect size $=0.4$. Effect size is determined by reviewing the previous RCTs or the meta-analysis, pilot testing and taking the expert feedback (opinion seeking) (Rothwell, 2018). However, only one RCT is found on the relevant topic with small sample size, therefore effect size is determined by opinion seeking method. Hence the calculated sample size is 228, with 114 participants in each group. However, attrition rates can significantly affect the later stages of the study, so factoring them into the initial sample size calculation can enhance the validity and reliability of the study (Hui et al., 2013). In behavioral and educational interventions, the most common reasons for attrition are patients' withdrawal and clinical deterioration. Hence, after adjusting the anticipated 20% attrition rate, the final calculated sample size will be 274 participants, with 137 in each group. To minimize the loss to follow-up in this RCT multiple strategies will be implemented. First, the researcher will recruit a larger sample to overcome potential loss to follow-up, incorporating a 20% attrition rate into the sample size calculation.

Second, the research assistant contacted the participants at follow-up points via phone calls. Third, an intention to treat analysis will be applied when analyzing the results. The intention-to-treat analysis method ensures that data from all randomized patients are included in the analysis, regardless of their dropout from the study at any stage (Andrade, 2022).

Random Allocation

Consented patients will be randomized into a control group and experimental group, within each hemodialysis unit. Randomization is an optimal approach utilized in RCTs, to minimize the influence of extraneous variables and the risk of biases (Baghbaninaghadehi, 2016).

Data analyst will assist with permuted block randomization procedure will be used to separate random scheme in both setting (A) and (B). The sealed envelopes will be prepared by data analyst, shuffled, numbered serial, and placed in a locked drawer in both units (A and B), and only research assistant can access it. After consenting and completing baseline assessment, the research assistant will open a sealed envelope to reveal the patient's group assignment. The patient will then be assigned to specific group accordingly. Research assistant will ensure that

intervention and control groups' patients will have dialysis in separate rooms or wards to prevent contamination in intervention.

Blinding

Blinding is a methodological indicator in RCTs to minimize biases (Monaghan et al., 2021). Blinding will be implemented at two levels. First, baseline data will be collected before randomization to prevent bias in data collection and maintain patient blinding regarding their group assignment. Second, the PI will not be involved in the data collection process to ensure objectivity. A research assistant will be responsible for data collection process and an independent data analyst will perform the data analysis to further minimize potential biases.

Data Collection Tools

Demographic and Socioeconomical

Information will be collected on demographic and socioeconomical status using a form developed for this purpose (Annexure 5).

Clinical History. Data will be collected on current health conditions, hemodialysis frequency, dialysis duration, AVF duration and on Charlton's Comorbidity Index. Charlton comorbidity index predicts the survival rates in 10 years in patients with multiple comorbidities. The use of this index enables to identification of comorbidities in hemodialysis patients and assess their impact on the study outcomes (Brusselaers, & Lagergren, 2017).

Assessment of Self-care Behaviors with AVF in Hemodialysis Patients

The primary outcome of this study is AVF self-care behaviors. This outcome will be assessed using the Self-care Behaviors Scale with Arteriovenous Fistula in Hemodialysis patients (ASBHD-AVF) (Annexure 6a). The ASBHD-AVF is a 16 items self- assessment scale developed by Sousa et al (2015) to assess the self-care behaviors of AVF of hemodialysis patients. The scale consists of two subscales: 1) management of signs and symptoms (6 items) and 2) prevention from complications (10 items). Response options consist of a five-point Likert scale ranging from 1 (never develop the self-care) to 5 (always develop the self-care). The minimum score is 16 and a maximum score is 80. A higher score reflects a higher frequency of self-care behaviors. The overall reported reliability of this tool is 0.72 and CVI is 1 (Sousa, 2015). Permission to use the tool was obtained from author (Annexure 6b). This tool had been used in different countries such as Portugal, Iraq, China and Turkey. The tool will be translated

and administered in Urdu language. The process of translation of tools ASBHD-AVF and Hemodialysis Access-related Quality of Life is described in the below section.

Hemodialysis Access related Quality of Life

The secondary outcome of this study is Quality of Life related to AVF. This outcome will be assessed using the Hemodialysis Access-related Quality of Life (HARQ) (Annexure 7a) which is a self-administered tool developed by (Nordyke, 2020). This tool includes six domains and specific scales are used to assess various domains that impact a patient's quality of life. In symptoms domain two numerical rating scale is used, that is (0-10) to measure the severity of pain related to the hemodialysis access, and Likert-type scale (0= not at all bothered, 1= sometime bothered, 2= moderately bothered, 3=very much bothered, 4= extremely bothered) for bleeding, bruises, needle-stick pain, swelling, and numbness. Likewise, the emotional domain is assessed using a same Likert-type scale and evaluates how the hemodialysis access affects emotional aspect of the patients. The physical functioning domain evaluates how the hemodialysis access affects daily physical activities and overall mobility levels using a Likert-type scale 0 to 4 (0=cannot do, 1= quite a lot, 2= somewhat, 3= very little, 4= not at all). The social and role functioning domain evaluates how the hemodialysis VA affects patients' social activity using a Likert-type scale 0 to 4 (0=never, 1= rarely, 2= sometime, 3=often, 4=always). In addition, the sleep domain evaluates how the hemodialysis access affects sleep of the patients using a Likert-type scale (0= none of the time 1= a little of the time, 2= some of the time, 3= most of the time, 4= all of the time). Lastly, care related burden domain is assessed using a Likert-type scale 0 to 4 (0=never, 1= rarely, 2= sometime, 3=often, 4=always). However, the psychometric properties of this are not reported. Permission to use the tool is obtained from the author (Annexure 7b). The tool will be translated and administered in Urdu.

Translation Process. The ASBHD-AVF and the HARQ tools will be translated into Urdu and validated to ensure they are appropriately adapted to the local context according to the Sousa & Rojjanasrirat, (2011) guideline. The translation is a seven steps process. First five steps of translation will be implemented. Steps 6 and 7 will not be implemented as it requires bilingual experts and large sample size which is beyond the scope of this study. Step-1 is translation of original instrument from English to Urdu, step-2: comparison of the two translated version, step 3: blind back translation to English, Step-4: comparison of two back translated version, step-5: pilot testing of the Urdu version tool. Two independent bilingual translators, fluent in both

languages (English, Urdu) with the understanding of both cultures will translate the tools into Urdu language. Both translators will have distinct background. Translator 1 must have understanding of medical terminologies and the content area of the instrument. And second translator will be familiar with colloquial phrases, slang, jargon, and idiomatic and emotional expression. Translators will be brief about tool and translation process by primary investigator before starting the process. Translations done by both translators will be compared. Next, an independent bilingual translator will translate these Urdu translated tools back into the English language. The research team and translators will compare the translation and back translation copies of the tools. Moreover, the tools will be pilot-tested on 10% of the population of the same setting and Cronbach alpha will be calculated.

Data Collection

The primary and secondary outcomes will be assessed at: baseline, after the completion of the intervention, and follow-up data will be collected at the second and sixth weeks after intervention is completed. The research assistant (RA) will receive training on study procedures.

Training of Research Assistant

A manual of operation (Annexure 10) is developed by primary researcher and will be used to train the research assistant. The research assistant will be trained about the baseline assessment, randomization, and assignment allocation and pilot testing. Initially, time will be given to read and understand the tools, its possible responses, scoring method. Then primary researcher will perform a role play while considering all the elements of study. Research assistant will practice it multiple times on a simulated patients until she/he become proficient. Concern and questions will be addressed.

Data Management and Analysis

Double data entry will be employed to ensure the accuracy of the data. The data will be checked for missing values, outliers, and logical inconsistencies. Data will be analyzed using the Statistical Package of Social Science (SPSS) version 25. Descriptive statistics, means and standard deviations will be used for the continuous variables, (age, income, dialysis duration, AVF Duration) while frequencies and percentages will be utilized for categorical demographic data (gender, educational level, hemodialysis frequency, items of self-care behavior scale, QOL). Important demographic data will be presented in the table to confirm randomization and assess the equal distribution of the groups. The normality of the data will be checked. An Independent t-

test will be applied to compare the differences between the groups. In case normality not achieve then Mann-witney U test will be applied. Mean scores and frequencies will be calculated for overall, each dimension, and for each item for both the outcomes.

Ethical Consideration

Approval to conduct the study will be obtained from the institutional review board (IRB) and the Ethical Committee of the institution (Shifa International Hospital). Furthermore, permission to collect patient data will be obtained from the head of hemodialysis units. Permission for using the tools already have been taken from the authors. The purpose of the study will be shared with study participants before collecting data. Informed consent will be obtained from eligible and patients interested in the study (Annexure 2). The participants' autonomy will be ensured by using informed consent. No known risks are involved in this research, and the benefits of the study will be explained. However, patients may feel overwhelmed during the data collection process. Data collection process will be scheduled and divided into two slots according to participant's ease. Patients will be allowed to ask any questions related to the study. A serial code instead of the participant's name will be assigned to participants' data sheets. Participants' names and ID numbers will be kept confidential. Contact information will be kept with primary investigator during the intervention and follow-up duration which will not be shared with anyone. On a personal laptop, a data folder will be created and secured with a password. Only the research team will have access to the data. The participants have a right to withdraw from the study at any time of data collection. The intervention will be implemented in the control group after the data collection.

Summary

This chapter outlines the primary methodology of the study. Moreover, the didactic approach underpinning the intervention, the intervention plan, follow-up procedures, and the intervention's fidelity are discussed.

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Annexures

Annexure 1

Information Sheet for Head of Departments

I am Bushra Sultan student of Doctor of Philosophy of Nursing (Ph. D) at Shifa Tameer-e- Millat. The research study is the academic requirement of my Ph.D. degree. The study will be supervised by Dr. Khairunnisa Dhamani. The purpose of this study is to assess the Effectiveness of Skill Building Education on Arteriovenous Fistula Self-care Behavior and quality of life among Patients on Hemodialysis. I will invite all the hemodialysis patient who have AVF came in the hemodialysis units to participate in this research.

This research will involve the skill building educational intervention which mean that patients will be trained to assess and care their own AVF at home. Participants will be instructed to perform that assessment on daily basis. There are no potential risks associated with this study. Participants will have the following benefits

1. They will get more knowledge and information to care your AVF at home
2. They will be able to learn AVF assessment skill. They can apply that skill at home on AVF on regular basis. This activity will help them to prevent from AVF complication and indirectly improve the quality of life
3. Their participation will allow us to test this intervention on real hemodialysis patients and include it as a protocol in hemodialysis units for the future patients.

Thank you for your cooperation. If you have any concerns or questions about the study, please feel free to contact

Bushra Sultan (primary investigator)

Mobile Number: 03315116190

Email address: bushra.scn@stmu.edu.pk

Annexure 2

Medical Record Screening Form

Date of Screening: _____ Screen by: _____

Participant ID or Medical record (M.R) number: _____

Reviewed by (Name/ID): _____

Eligibility Criteria:

1. **Age:** aged 18 years or above.

___ Eligible

___ Not Eligible

___ Not Applicable
2. **Diagnosis:** diagnosed with end-stage renal disease___

___ Eligible (Specify: _____)

___ Not Eligible

___ Not Applicable
3. Hemodialysis: on hemodialysis through an arteriovenous fistula

a. ___ Eligible (Specify: _____)

b. ___ Not Eligible

c. ___ Not Applicable
3. Can read and understand the Urdu language.

a. ___ Eligible

b. ___ Not Eligible (Specify condition: _____)

c. ___ Not Applicable

Overall Eligibility Status:

- a. ___ Eligible
- b. ___ Not Eligible (Specify reason: _____)

Notes/Comments:

Annexure 3

Participants Needed for Research Study on AVF Self-Care and Quality of Life!

I am Bushra Sultan student of Ph. D at Shifa Tameer-e- Millat

I am conducting a study as a requirement of my Ph.D. degree

What's the study about? We are conducting a study to explore how educational interventions focused on AVF self-care can impact overall health and well-being. The study aims to empower patients with the knowledge and skills needed to better manage their AVF and improve their quality of life.

The study will be supervised by Dr. Khairunnisa Dhamani. The study is approved by IRB

Who can participate?

- Adults 18 years or older
- Currently receiving hemodialysis with an AVF
- Willing to participate in a brief educational program
- Able to provide informed consent

What's involved?

- A skill-building educational session focused on AVF self-care
- Routine care information for patients
- Follow-up assessments to monitor health and well-being

Thank you for your cooperation. If you have any concerns or questions about the study, please feel free to contact Bushra Sultan (primary investigator) at the below-given details. Ph.D student, Shifa College of Nursing, and Islamabad, Pakistan

Mobile Number: 03315116190

Email address: bushra.scn@stmu.edu.pk

Annexure 4

Consent form for Participants

Study Title: Effectiveness of Skill Building Education on Arteriovenous Fistula Self-care

Behaviour and quality of life among Patients on Haemodialysis

Principal Investigator (PI): Bushra Sultan

Supervisor: Prof. Khairunnisa Dhamani

Co-supervisor: **Prof. Kawkab Shishani**

Committee member: **Muhammad Ishtiaq**

Organization: Shifa College of Nursing, Shifa Tameer e Millat, Islamabad.

Introduction

I am **Bushra Sultan** student of Doctor of Philosophy of Nursing (Ph. D) at Shifa Tameer e Millat. The research study is the academic requirement of my Ph.D degree. The study will be supervised by **Dr. Khairunnisa Dhamani**. I am inviting you to participate in this research. This research will be related to the arteriovenous fistula care in hemodialysis patients. Before taking decision of participation in this study you can seek clarification.

Do not be concerned by the length of this template. It is long only because it contains guidance and explanations which are for you to participants in your research.

Purpose of the Study

AVF is a common and lifelong vascular access for the hemodialysis patients. It is created via surgery and become a part of patient body. Every time for hemodialysis you required a functional AVF. However, its functionality could be compromise due to lack of awareness and carelessness. Therefore, I am doing this research to train hemodialysis patients to take care their fistula at home. This study aims to assess the Effectiveness of Skill Building Education on Arteriovenous Fistula Self-care Behavior and quality of life among Patients on Hemodialysis.

Right to withdrawal

I will invite all the hemodialysis patient who have AVF came in the hemodialysis units to participate in this research. Your participation in this research will be entirely voluntary.

Whether you want to participate or not, your services in the dialysis units will continue and will not be change. If you participate, and withdraw from study on any phase of this research, you can.

Procedure

If you are interested to participate in this study, following procedure will be completed in the research process. A data (two survey form) related to self-care and quality of life of your AVF will be taken after you give consent for participation. The time duration for data collection (survey form) will be approximately 30 minutes. Afterward you will assign to either intervention group or the control group by selecting a sealed envelope. Participants in one group will receive the routine care of dialysis and other group will receive the skill building educational intervention. Neither you, nor I will know, you are in which group. Your record will be saved in the files but that file will not be open until the intervention completed.

Type of intervention This research will involve the skill building educational intervention which mean that patients will be trained to assess and care their own AVF at home. The intervention of this study will be divided into two teaching sessions. In session one, you will be asked to explain your experience of caring AVF at home and then information will be provided to you regarding your AVF care. Session one will be completed in 25min. In the next session, AVF assessment skill will be taught by demonstration and then you will have return demonstration which will be completed in 20 min. During intervention implementation phase there may be some word that you do not understand. Please ask me to stop, I will take time to explain and clarifies you. Moreover, you will be instructed to perform that assessment on daily basis. Data will be collected on the same form after intervention, then after 2, 4 weeks of intervention implementation. During the time frame of intervention and follow-up you can ask any question, queries on daily basis.

Possible Discomfort and Risk

There are no potential risks associated with this study. If you do not feel comfortable you can refuse without any hesitation. The data collection will be instantly halted and resumed with your permission when you feel comfortable. As the data will be collected on two survey forms that may cause minimal discomfort or burden to you.

Benefits

If you participate in this research, you will have the following benefits

1. You will get more knowledge and information to care your AVF at home
2. You will be able to learn AVF assessment skill. You can apply that skill at home on your AVF on regular basis. This activity will help to prevent yourself form AVF complication and indirectly improve the quality of life

3. Your participation will allow us to test this intervention on real hemodialysis patients and include it as a protocol in hemodialysis units for the future patients.

Confidentiality

To maintain anonymity, codes will be used for each individual. A password-protected copy on the personal laptop will be used to save data and keep hard copies of the data under lock and key. The information you provide will be accessible only to the thesis committee. Your name will not be reflected anywhere during transcribing the data, thesis writing, and publication

Contact Information

Thank you for your cooperation. If you have any concerns or questions about the study, please feel free to contact Bushra Sultan (primary investigator) at the below-given details. Ph.D student, Shifa College of Nursing, and Islamabad, Pakistan

Mobile Number: 03315116190

Email address: bushra.scn@stmu.edu.pk

Agreement to Participation

I have read and understood the information provided in the form for the study participants. I agree to participate in the study. I had an opportunity to ask any question. I have a right to withdraw from the study at any stage. I agree that the study's findings may be published but will not show my identity.

Participant Name: _____

Participant's Signature or thumb impression: _____

Email: _____

Mobile Number _____

Date: _____

Annexure 5

Personal and Clinical Information Sheet

Name

Phone number

Address

Email

address

Family member name, Email address,

Phone number,

Patient age Gender, Educational

level Employment, Income

Any other earning source, total income)

and

Clinical characteristic

Current disease, Hemodialysis frequency

Dialysis duration,

When dialysis treatment was started:

Time of Dialysis start from AVF

Charlton's Comorbidity Index

Annexure 6a

Assessment of Self-care Behaviors with AVF in Hemodialysis Patients

S		1	2	3	4	5
1.	I address the nurse when I have cramps during hemodialysis					
2.	I do compression of puncture sites with the fingers.					
3.	I address the nurse when I get a headache and chest during hemodialysis.					
4.	I apply ointment when hematoma occurs.					
5.	I feel the thrill at the site of the fistula twice a day					
6.	I do compression at home at puncture site if bleeding occurs.					
7.	I check every day if the hand of the fistula arm cools.					
8.	I observe signs of redness and swelling at the puncture sites.					
9	I protect the fistula arm from scratches, cuts and wounds.					
10.	I check every day if the color of the hand from the fistula arm changes.					
11.	I protect the fistula arm from bumps and shocks					
12.	I allow blood sampling in the fistula arm*					
13.	I address the nurse if the hand of the fistula arm starts to hurt.					
14.	I avoid getting into places with different temperatures					
15	I immediately go to hospital or a clinic if fistula has not thrill.					
16	I address nurses if the hand of the fistula arm appears with wounds					

- 1= “Never develop this self-care”
2= Rarely
3=Sometime
4=Often
5= Always develop this self-care”

Annexure 6b:

Permission for Self-care Behaviors tool

B

Bushra Sultan

Respected Author Greetings of the day. I am a PhD student interested in working on Arteriovenous Fistula care. While reviewing the liter...

Apr 20, 2024, 11:01 PM

☆

B

Bushra Sultan

Reminder Kindly response --

Apr 26, 2024, 8:17 PM

☆

C

Clemente Sousa <clementesousa@esenf.pt>

to me ▼

Dear Bushra,

I am very happy with your interest in the scale of assessment of self-care behaviors with arteriovenous fistula in hemodialysis.
I give the authorization for the validation the scale if:
- I am following the scale validation process
- You write an article about the validation process in journal with impact factor
- I have to integrate the article as co-author

Best regards,

Clemente
Clemente Neves Sousa | PhD, MSc, RN

CINTESIS@RISE, Nursing School of Porto (ESEP), Porto, Portugal

Apr 29, 2024, 10:38 AM

☆

↩

⋮

Annexure 7a:

Hemodialysis Access Related Quality of Life Tool

Va

Hemodialysis Access-Related Quality of Life
Draft v. 5.1

Vascular access includes a fistula (AVF), graft (AVG), or catheter (CVC). This survey asks about how your vascular access affects your life. When you answer the questions, please think of how your vascular access affects your life.

Please respond to each question or statement by marking one box in each row.

1	In THE LAST 7 DAYS, my ability to....	Never	Rarely	Sometimes	Often	Always
	...keep up with my family responsibilities was limited by <i>my access</i>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
	...do all my regular family activities was limited by <i>my access</i>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
	...socialize with my friends was limited by <i>my access</i>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
	... do hobbies and leisure activities was limited by <i>my access</i>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
	...perform my daily routine was limited by <i>my access</i>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
	...keep up with my work responsibilities (including work at home) was limited by <i>my access</i>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

Please respond to each question or statement by marking one box in each row.

2	In THE LAST 7 DAYS...	No pain 0	1	2	3	4	5	6	7	8	9	Worst imaginable pain 10
	...how would you rate the pain because of <i>your access</i> on average?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
	...how would you rate your <u>needle stick</u> pain on average?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

3	During the LAST 4 WEEKS, how much were you bothered by each of the following?	Not at all bothered	Somewhat bothered	Moderately bothered	Very much bothered	Extremely bothered
	<i>Your access</i> interfering with your work or other regular daily activities?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
	Worrying about being hospitalized because of problems with <i>your access</i> ?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
	Worrying about how long <i>your access</i> will last?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
	Needing to be careful to clean or protect <i>your access</i> ?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
	Being limited in working around the house because of <i>your access</i> ?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

Please respond to each question or statement by marking one box in each row.

4

How much of the time during the
LAST 4 WEEKS did you feel...

Never

Rarely

Sometimes

Often

Always

...worried about getting an infection because of <i>your access</i> ?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
...afraid or anxious that <i>your access</i> might be blocked or clotted?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
...that it was a burden to take care of <i>your access</i> ?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

5

How much were you
bothered in THE LAST 4
WEEKS by the following
vascular access-related
problems?

Not at all
bothered

Somewhat
bothered

Moderately
bothered

Very
much
bothered

Extremely
bothered

Bleeding around <i>your access</i>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Bruising because of <i>your access</i>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Swelling around <i>your access</i>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Numbness or tingling because of <i>your access</i>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Needle-stick pain	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Problems sleeping because of <i>your access</i>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

Please respond to each question or statement by marking one box in each row.

6	How often during THE LAST 4 WEEKS did you...	All of the time	Most of the time	Some of the time	A Little of the time	None of the time
	...get too little sleep at night because of <i>your access</i> ?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
	...have a poor night's sleep because of <i>your access</i> ?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
	...wake up during the night because of <i>your access</i> ?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

7	During THE LAST 4 WEEKS, how bothered were you by...	Not at all bothered	Somewhat bothered	Moderately bothered	Very much bothered	Extremely bothered
	...the way you look because of <i>your access</i> ?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
	...the clothes you are able to wear because of <i>your access</i> ?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
	...the appearance of <i>your access</i> ?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

Please respond to each question or statement by marking one box in each row.

8	during THE LAST 4 WEEKS...	Never	Rarely	Sometimes	Often	Always
	...how often did you avoid social situations because of the way <i>your access</i> looks?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
	...some people avoided me because of <i>my access</i> .	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
	...people avoided looking at me because of <i>my access</i> .	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
	...I felt embarrassed about <i>my access</i> .	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
	...some people were uncomfortable with me because of <i>my access</i> .	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

9	While in the dialysis clinic over THE LAST 4 WEEKS...	Never	Rarely	Sometimes	Often	Always
	...how often were you concerned for the safety of <i>your access</i> (for example, having to keep track of what happens in the clinic)?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
		Not at all bothered	Somewhat bothered	Moderately bothered	Very much bothered	Extremely bothered
	...how bothered were you by having to talk to nurses or technicians to make sure they took care of <i>your access</i> ?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

Please respond to each question or statement by marking one box in each row.

10		Not at all bothered	Somewhat bothered	Moderately bothered	Very much bothered	Extremely bothered
	How much does <i>your access</i> bother you in your sex life?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
	<i>Have you had any sexual activity in the last 4 weeks? If "no" please skip to Question 11 below.</i>				<input type="checkbox"/> Yes	<input type="checkbox"/> No
	In the last 4 weeks, how much did <i>your access</i> bother you in enjoying sex?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

11	How true or false is each of the following statements for you?	Definitely false	Mostly false	Don't know	Mostly true	Definitely true
	Too much of my time is spent dealing with <i>my access</i>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
	My <i>vascular access</i> interferes too much with my life	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

Please respond to each question or statement by marking one box in each row.

12	How much is your ability to...	Not at all	Very little	Somewhat	Quite a lot	Cannot do
	...do difficult activities such as running, lifting heavy objects, or sports limited by <i>your access</i> ?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
	...lift or carry groceries limited by <i>your access</i> ?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
	...wash and dry your body limited by <i>your access</i> ?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
	...shampoo or wash your hair limited by <i>your access</i> ?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
	... lift your arm above head limited by <i>your access</i> ?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
	...reach into a high cupboard limited by <i>your access</i> ?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
	...dry your back with a towel limited by <i>your access</i> ?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
	...put on a shirt or blouse limited by <i>your access</i> ?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

END OF QUESTIONNAIRE – Thank you!

Annexure 7b:

Permission for HARQ Tool

R

Robert Nordyke

<bob@beta6consulting.com>

Apr 25, 2024, 7:18 AM

☆

↶

⋮

to me ▾

Bushra: Yes, please, you're welcome to use the HARQ and adapt as needed. The draft measure is attached to this email. Note that it is referred to as "draft" because it has not been psychometrically validated. We believe that doing so would require a study with about 400 patients and I don't believe that anyone has conducted that study.

Best,

Bob

On Sat, Apr 20, 2024 at 11:15 PM Bushra Sultan <bushra.scn@stmu.edu.pk> wrote:

Dear Author.

Greetings of the day. I am a PhD student interested in working on Arteriovenous Fistula care. My Dissertation topic is 'Effects of Skill Building Education on the AVF Self-care Behaviors and Quality of Life in Hemodialysis Patients'. I wanted to utilize your tool Hemodialysis Access-related Quality of Life. Kindly provide me with your tool so that I can use it for my study. I also require your permission to translate this tool into Urdu language.

Regards

Bushra Sultan

MSN & BSN

Assistant Professor

Annexure 8

Checklist for Assessment of Arteriovenous Fistula

	Items	Yes (1)	No (0)
1	Have you felt any changes in your fistula		
	LOOK		
2	Inspection Observe for fistula for the following		
3	Location of fistula <ul style="list-style-type: none">• Radio cephalic• Brachiocephalic• Upper arm transpose basilic		
	Infection/ Inflammation		
4	Do you observe any swelling around or on fistula?		
4.1	If yes from how long this swelling is _____		
4.2	Have you performed any intervention for swelling		
4.3	What intervention you perform any of these intervention		
	4.3.1 Hot fomentation (1)		
	4.3.2 Cold fomentation (2)		
	4.3.3 Bandage (3)		
	4.3.4 Arm elevation (4)		
	4.3.5 Other (5)		
5	Do you observe redness around or on fistula?		
6	Are you feeling pain at fistula side?		
	If yes then		
6.1	• What is the intensity of the pain? Scoring will be on pain scale		
6.2	• What intervention you perform to relieve the pain		
	6.2.1 Hot fomentation (1)		
	6.2.2 Cold fomentation (2)		
	6.2.3 Bandage (3)		
	6.2.4 Arm elevation (4)		
	6.2.5 Ointment painkiller (5)		
	6.2.6 Oral analgesic (6)		
6.3	• Has it impacted your daily life activities?		
	Steal syndrome		

7	Do you feel any change in the temperature at fistula side or at that hand?		
8	Do you feel any numbness or change in sensation at fistula side or at hand		
9	Do you feel tingling sensation at hand		
10	Do you feel any changes in the strength of your hand or arm		
11	Do you feel any difficult in performing the daily activities with the fistula arm or hand		
12	Do you feel any discoloration at fistula side?		
13	Dou you have ischemia of finger and nail		
14	Is there any change in the skin integrity at fistula side <ul style="list-style-type: none">• Skin rash		
15	Is there any scar at fistula side		
16	Is there any formation of clot		
17	Observe for aneurysm		
18	Is there any hematoma		
19	Perform Arm elevation test Is your fistula being collapse on arm elevation? If No, report to doctor Ask the patient to raise or elevate the fistula arm above the level of the heart. <i>Normal finding: The fistula should collapse or become flat on elevation of arm and return back to normal when arm at horizontal or lower to the body.</i> Note: In the presence of a significant stenosis, blood drainage is hampered and the AVF may not collapse and usually becomes hyper pulsatile.		
20	Inspect for central vein stenosis Have you compared both arm(extremities)		
20.1	Are your both arms being of equal size		
20.2	Is the fistula arm is swollen		
20.3	Have you observed colla lateral vein in the fistula arm.		
21	Aneurysm and pseudoaneurysm <ul style="list-style-type: none">• Observe for aneurysm		
22	Palpation (feel) Palpate the pulses (Radial, ulnar, brachial)		
23	Perform Allen test		

24	Check the capillary refill Is the capillary refill less than 3sec.		
25	Perform Augmentation test Is the augmentation test normal? The augmentation test is done by occluding the access completely by palpation several centimeters beyond the arterial anastomosis. <i>The test is normal when the portion of the access upstream from the palpation (occlusion) demonstrates augmentation of the pulse.</i> <i>Pulse is expected to increase in intensity and thrill should disappear after AVF occlusion.</i>		
26	Feel for Accessory veins Do you feel the accessory veins on palpation? <i>Normally on examination the thrill that is palpable over the arterial anastomosis disappear completely when the downstream or the outflow of the fistula is manually occluded.</i> If the thrill does not disappear with manual occlusion of the outflow, then one should suspect an extra channel or extra outflow channel that we call an accessory vein which may be present between anastomosis and the points of occlusion. In presence to accessory vein despite occlusion the thrill persists especially if the accessory vein is large.		
27 27.1 27.2	Auscultation Is the bruits sound being normal over the fistula and along the entire length of the arm? Is the sound is same along on the fistula and on the entire length of the arm Have you listened sound other than bruits If yes Report to doctor <i>Bruits is sound or the murmur is heard over the fistula</i> Listen along the entire length of the arm.		

Assessment after hemodialysis (After 2-3hrs)

S	Items	Yes (1)	No (0)
1	Do you feel erythema, swelling at fistula site		
2	Do you feel tenderness at a fistula site		
3	Do you feel a persistent extremity swelling		

4	Do you feel a prolonged bleeding after needle withdrawal		
5	Do you feel an altered pulse or thrill in the fistula		
6	Do you feel an altered bruit in the fistula		
7	Do you feel an absence of bruits in the fistula		
8	Do you feel an absence of thrills in the fistula		
	I confirm that the fistula or graft is officially abandoned for further use and is not safely salvageable (by Health care professional)		

Note: This assessment can be performed by the patient him/herself or by the caregiver.

Annexure 9

Teaching Plan

Sessions	Time	Content	Strategy	Facilitator
1	25min	<p>This session will focus on the self- care maintenance of AVF:</p> <p>1. Patients will be inquired about their AVF concept, their subjective feelings about AVF, care practices at home, their pattern of dialysis, and who is responsible for their AVF care at home</p> <p>2. Information related to the general concept of fistula maintenance, its functionality, its significance in dialysis patients, specific instruction needs to be considered in daily life activities, and its impact on social, emotion and mental health will be covered. Patients' concerns and quarries about their self-care behaviors will be clarified in this session.</p>	Teach-back, PPT,	Primary Investigator
Plan for practical session				
2	20min	<p>Demonstration of Skill</p> <p>This session will focus on the self- care monitoring of AVF, the importance of self-care monitoring in daily routines, and assessment of AVF. The skill will be demonstrated by following three steps: inspection, palpation and auscultation following a skill checklist.</p>	Demonstration Re-demonstration	

Annexure 10

Manual of Operation Introduction

The purpose of this Manual of operation is to provide a guideline for the principal investigator and member of research team. It serves as an extensive document that outline the fundamental processes, procedures, and guideline to conduct the study. It provides a clear instruction for the implementation of the intervention.

Manual of operation content and organization

Research team responsibilities

- Responsibilities of primary investigator are the development of protocol, initial plan and intervention of the study.
- Implementation of feedback and refinement of protocol
- Taking the IRB approval
- Meeting with HOD and staff of dialysis units, translators.
- Facilitation of translators
- Training of research assistant
- Pilot test the tool and intervention
- Actual implementation of intervention
- Provision of data to data analyst
- Finalization of study finding

Responsibilities of supervisor, co-supervisor and team

Provision of feedback and guidance ongoing basis

Study Protocol

Study protocol will be attached as an appendix

Meeting with dialysis head and staff

A meeting will be held with the head of dialysis units. The purpose of this meeting will be to share the information related to the research process, intervention and pilot testing. An information sheet is developed to share with them (Annexure). Moreover, a permission will be taken to conduct research in the dialysis unit. That letter of permission will be attached as an annexure to show to institution review board.

Tools Translation and validation

Written in protocol

Ethical Approval

Ethical approval will be taken from institution review board. After ethical approval tools and intervention will be pilot tested.

Psychometric properties of Tools

Tools will be sent to 5 experts for review. Content validity index will be calculated. Feedback will be incorporated and tool will be finalized. The primary investigator will pilot test the tool in 10% of population of same setting (dialysis units) where the actual study will be conducted.

Reliability of tool will be calculated.

Eligibility criteria of 10% population

4. Patients diagnosed with end-stage renal disease on hemodialysis through an arteriovenous fistula
5. Have aged 18 years or above
6. Who can read and understand the Urdu language.

Meeting with dialysis staff

A meeting will be held at the time of pilot testing with the dialysis unit team leader. The purpose of this meeting is to not only discuss the research process, intervention but also taking the permission of using their room for the purpose of education session for patients. Moreover, having a setting of dialysis treatment of interventional and control group in a separate rooms or wards.

Training of research assistant

A research assistant will be trained for the data collection process. The research assistant will be briefed about the pilot testing, consent form, baseline assessment, randomization, and sealed envelope. Both the tools in Urdu language, and consent form will be share with research assistant. Time will be given to read and understand the tools, its possible responses, scoring method. Concern and questions will be entertained. First, the research assistant will take a consent from the participant, then base line assessment will be done. Later on, a sealed envelope will be handed over to participants and assign in a particular group.

Intervention pilot testing

Intervention will be pilot tested at the same time with the tools by the primary investigator.

Results will be finalized and modification made according to the finding of pilot testing.

Communication Plan

Ongoing communication will be required among the primary investigator, research assistant, dialysis unit team leader/staff and other member of the research team to ensure that the study progress and other emerging issues deal properly.

Intervention

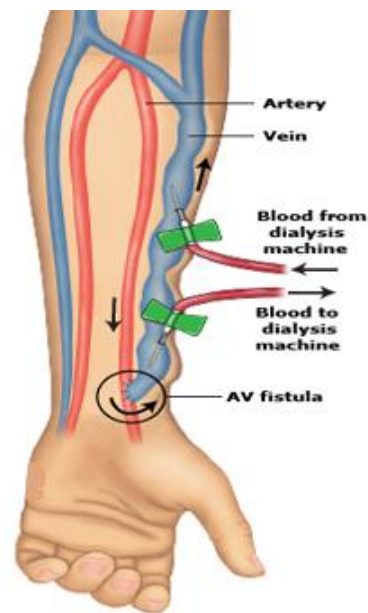
Intervention of the study will be implemented by primary investigator. Each patient will receive two educational sessions individually. The detail of intervention is explained in protocol.

Data Analysis

Data will be analyzed by data analyst. However, the final writing and explanation of finding will be done by the primary investigator.

Annexure 11

Assessment Guide
Empowering patients and Caregivers: A guide for AVF assessment



Purpose

This guide or manual will serve a comprehensive resource for the hemodialysis patients and their caregiver to manage the arteriovenous fistula. This guideline typically provides information, and instruction to ensure the proper care and handling of AVF. Moreover, it guides the patients and caregiver to ensure the normal functioning of AVF and identify the abnormality or changes in the normal functioning of AVF.



Table of Content

Content	Page No
AVF concepts	4
AVF examination	
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Palpation	13-15
Auscultation	16
Checklist for AVF assessment	17-19
Checklist for AVF assessment after dialysis	19
General points for consideration	20

Arteriovenous Fistula

Arteriovenous fistula (AVF) can be surgically created by vascular specialist for the hemodialysis access. Arteriovenous fistula is the abnormal connection between the artery and vein (Abreo et al., 2019). The AVF blood flow from the artery directly into the vein, increasing the blood pressure and amount of blood flow through the vein. The increase flow and pressure cause the vein to enlarge because increase blood flow and pressure is required for the hemodialysis treatment.

Arteriovenous fistula depends on the location in the body. Typically, it is created in the extremities, upper extremities are most prefer than lower extremities.

Fistula		Arteries and veins
Upper extremity	Radio cephalic,	Radial artery and cephalic vein at the wrist
	Forearm-Basilic	Radial or ulnar artery and basilic vein at the wrist
		Radial artery and antecubital vein
		Radial artery and median antebrachial vein
	Brachial-cephalic	Brachial artery and cephalic vein the proximal forearm
	Brachial-basilic	Brachial artery and basilic vein in the upper arm
Lower Extremity	Femoral	Femoral artery or femoral vein
	Transpose femoral	Femoral artery and saphenous vein superficial artery and saphenous with femoral or popliteal vein

AVF become a part of patient body. Having fistula is a visual reminder of their disease. The experience and anticipation of complication with their access can a key source of stress and interruption to the routine of hemodialysis patients. Therefore, daily care is required to keep the fistula functional. The first step in the fistula care is the assessment of fistula and act according to the changes in the normal functioning. When the patients able to know the normal functionality of the fistula they better able to detect the any changes in the normal functioning and prevent them from complication.

Arteriovenous Fistula examination

AVF require daily inspection and care.

Physical examination of the arteriovenous access is an accurate diagnostic tool that can be quickly performed by the patient. It can provide valuable information to detect or rule out normal or abnormal functioning of AVFs

Arteriovenous fistula examination involve LOOK, LISTEN and FEEL.

How to Examine AVF?



LOOK

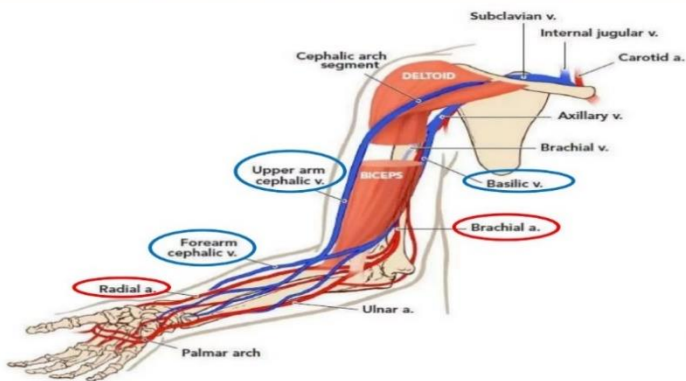
Inspection

Location of Fistula

Inspection

1- Vascular Access Scar

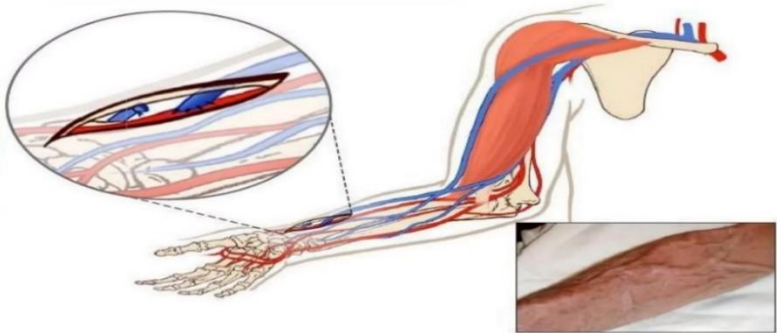
Anatomy of Upper Extremity Vessels



Inspection

1- Vascular Access Scar

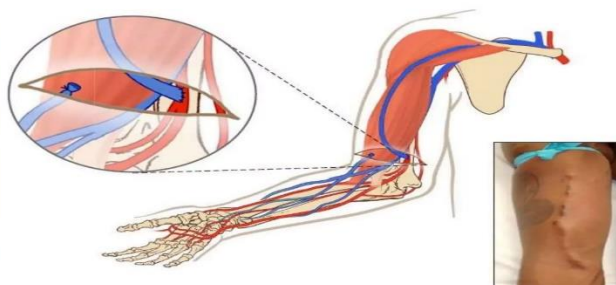
Radiocephalic AVF



Inspection

1- Vascular Access Scar

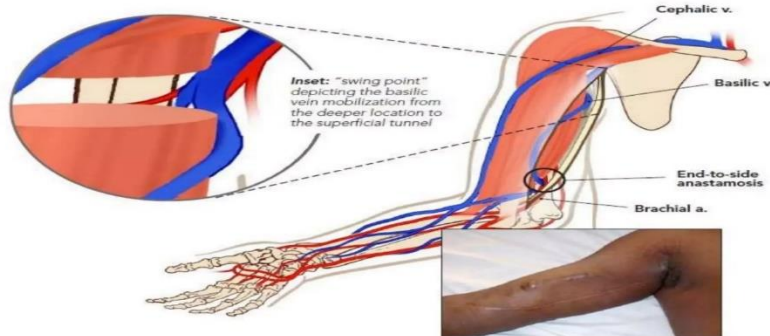
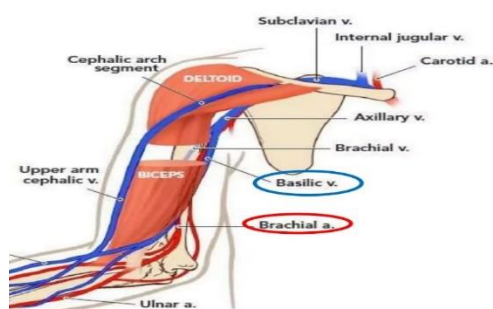
Brachiocephalic AVF



Inspection

1- Vascular Access Scar

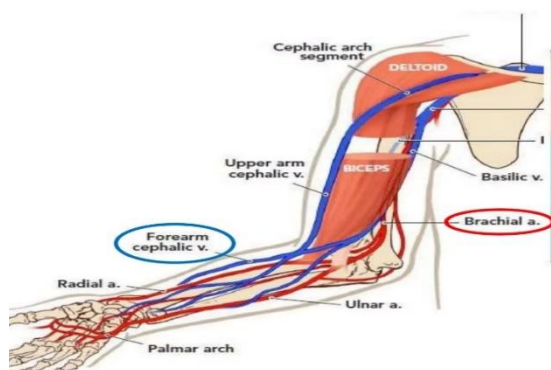
Transposed Basilic Vein AVF



Inspection

1- Vascular Access Scar

Transposed Forearm Cephalic Vein AVF



Observe for fistula for the following

1. Sign of infection and inflammation. If sign of infection and inflammation is present then then observe for cardinal symptom. Pain, redness, swelling, loss of function, increase in temperature.
 - Assess Pain scale
 - What is a location of pain?
 - What is the intensity of the pain?

- Is it rotating?
- Is it associated with any other symptom?
- How it relieves?
- How this impacts your daily life activities?
- Redness & swelling is local or it in whole arm
- Does the patient is able move AVF arm?
- Compare temperature of AVF side with area of AVF arm

2. Rule out for the Steal syndrome in inspection:

- Evaluate for any discoloration at fistula, (discoloration of the hand, the hand may appear dusky, and have bluish tinge or pale in color).
- Evaluate for ischemia of finger and nail
- Check the temperature at fistula side or at that hand
- Check for numbness or change in sensation at AVF side or at hand
- Presence of tingling sensation at hand
- Check for any changes in the strength of your hand or arm
- Evaluate for any difficulty in performing the daily activities with the fistula arm or hand
- Check the skin integrity at fistula side
- Evaluate for the presence of scars at fistula side

3. Observe for aneurysm

4. Observe for hematoma

Inspection

4- Signs of Ischemia (Steal Syndrome)

LOOK



Fingers are blue and cold
Hand pain rest/exercise
Paresthesia



Inspection

4- Signs of Ischemia (Steal Syndrome)

LOOK



Ulcers



Perform arm elevation test

Arm elevation test

It is a simple noninvasive test that can easily be performed to rule out the stenosis. It is low cost, convenient and quick test that can help to save patients from the unwarranted invasive procedures. This test is performed by elevating the patient access arm above the level of heart. Normally, the elevation leads to the collapse of fistula. Gravity causes the blood within the AVF to drain, thus, causing the fistula to collapse. In case of stenosis the fistula will not collapse and become hyper pulsatile.



Arm elevation test. (A) Left forearm (radial artery to cephalic vein) arteriovenous fistula (AVF) in a patient on hemodialysis. The AVF is visibly raised, well distended, and aneurysmal. (B) Elevation of the arm above the heart level leads to the collapse of the AVF. Full collapse of the most distal aneurysm is clearly seen while the proximal aneurysms partially collapse.

Inspect for central vein stenosis

In case of central venous stenosis, the access arm will be swollen. Presence of collateral vein are also sign of central venous stenosis. Patient arm will be compared for the inspection of central venous stenosis.



Collateral Vein

Inspection
7- Central vein stenosis



A: Massively swollen right upper extremity from completely occluded right subclavian vein. The transposed basilic vein arteriovenous fistula is patent.



B: Extensive network of collateral veins over the right shoulder and chest area.



Inspect for Aneurysm

Aneurysms – come in all sizes and shapes



Palpation (Feel)

Palpation involves the assessment of Inflow (augmentation test), out flow (hyper pulsatile pulse and absence of thrill) and feel for accessory vein

The normal AVF is soft and compressible. AVF should be palpated from the area of anastomosis to the subclavian vein. In doing so, the character of the pulse and quality of thrill could be evaluated.

Pulse

Normally the pulse is soft and compressible. As a rule of thumb, having pulse is bad, indicating downstream stenosis. The degree of hyperpulsatility is proportional to the severity of the stenosis.

Juxta-anastomosis vein stenosis is the most common site for stenosis. Juxta-anastomosis mean close to the anastomosis. Juxta-anastomosis is site where there is a surgical mobilization of the vein and this mobilization leads to small trauma or ischemia of the vein. Early diagnosis by palpation of the anastomosis and the distal outflow vein help in the stenotic lesion. Normally the AVF is soft and compressible. With juxta anastomosis, the water hammer pulse is felt at the anastomosis.

Water hammer pulse is very forceful pulse that is felt at the anastomosis. The pulse goes away rather abruptly as the side of stenosis encountered, about this level the pulse is very week and the vein is poorly developed. An unusually weak pulse (hypopulsatile access) or "flat access" suggests the presence of a stenotic lesion located in the inflow side of the access.

Palpation

1-AVF Pulse Character

Soft Compressible

Hyperpulsatile, Water-hammer

Outflow Stenosis

Hypopulsatile, Feeble, Flat

Inflow Stenosis

FEEL

Soft and compressible

Hyperpulsatile

Stenosis

Thrill

A thrill is a palpable vibration indicating the blood flow within the AVF. It could be checked by using the palm of the hand. A Normal thrill is diffuse, continuous and machinery like vibration of sensation with a systolic and diastolic component. A thrill is most obvious at the arterial anastomosis, but it can be palpable over the course of AVF.

The absence of a thrill indicates a lack of flow, which along with the absence of any pulse is characteristic of a thrombosed access.

Check the Augmentation of the fistula

Augmentation test is performed to assess the adequacy of inflow pressure. It is the assessment of arterial flow or arterial inflow. The outflow vein is manually occluded few centimeters proximal to the anastomosis. The segment between the arterial anastomosis and the occlusion becomes hyper pulsatile because of the arterial pressure is transmitted across patent anastomosis.

In inflow stenosis the arterial pressure is not adequately transmitted and the segment between the occlusion and the anastomosis remains weakly pulsatile.

Pulse is expected to increase in intensity and thrill should disappear after AVF occlusion.

Absence of thrill distal to outflow stenosis

With outflow stenosis the fistula becomes pulsatile firm and loses the thrill. Absence of thrill distal to stenosis this distal segment becomes firm does not collapse with the arm elevation and there is no thrill. Distal to the stenosis the segment is hyper pulsatile.

Feel for Accessory veins

Accessory vein sometime prevents the maturation of the fistula. The accessory vein especially in the juxta-anastomosis segment that is a segment closer to the anastomosis in the outflow track can lead to loss of pressure head into the main channel that is useful for cannulation. Normally on examination the thrill that is palpable over the arterial anastomosis disappears completely when the downstream or the outflow of the fistula is manually occluded.

If the thrill does not disappear with manual occlusion of the outflow, then one should suspect an extra channel or extra outflow channel that we call an accessory vein which may be present between anastomosis and the points of occlusion. In presence of accessory vein despite occlusion the thrill persists especially if the accessory vein is large.

Normally the thrill that is palpable over the arterial anastomosis disappears completely when the downstream fistula is manually occluded.

Capillary refill

Check the capillary refill of the hand and finger. It should be less than 3sec.

Palpation
2-AVF Thrill



Normally:
Continues Thrill

Systolic & Diastolic
Soft background

Abnormally: Discontinues Thrill (Systolic only)

Strong, Localized

Weak, not localized

Stenosis

Outflow Stenosis

Inflow Stenosis

Auscultation

Auscultation is the last step of AVF examination. On auscultation the bruit are sound or the murmur is heard over the fistula. It should be listened along the entire length of the arm.

Auscultation
1-Bruit



Normally:
Continues Thrill

Systolic & Diastolic
Low pitched
Background

Abnormally: Discontinues Thrill (Systolic only)

High Pitched, Loud

Low Pitched, Quiet

Outflow Stenosis

Inflow Stenosis

Checklist for Assessment of Arteriovenous Fistula

	Items	Yes (1)	No (0)
1	Have you felt any changes in your fistula		
	LOOK		
2	Inspection Observe for fistula for the following		
3	Location of fistula <ul style="list-style-type: none">• Radio cephalic• Brachiocephalic• Upper arm transpose basilic		
	Infection/ Inflammation		
4	Do you observe any swelling around or on fistula?		
4.1	If yes from how long this swelling is _____		
4.2	Have you performed any intervention for swelling		
4.3	What intervention you perform any of these intervention		
	4.3.1 Hot fomentation (1)		
	4.3.2 Cold fomentation (2)		
	4.3.3 Bandage (3)		
	4.3.4 Arm elevation (4)		
	4.3.5 Other (5)		
5	Do you observe redness around or on fistula?		
6	Are you feeling pain at fistula side?		
	If yes then		
6.1	• What is the intensity of the pain? Scoring will be on pain scale		
6.2	• What intervention you perform to relieve the pain		
	6.2.1 Hot fomentation (1)		
	6.2.2 Cold fomentation (2)		
	6.2.3 Bandage (3)		
	6.2.4 Arm elevation (4)		
	6.2.5 Ointment painkiller (5)		
	6.2.6 Oral analgesic (6)		
6.3	• Has it impacted your daily life activities?		
	Steal syndrome		
7	Do you feel any change in the temperature at fistula side or at that hand?		

8	Do you feel any numbness or change in sensation at fistula side or at hand		
9	Do you feel tingling sensation at hand		
10	Do you feel any changes in the strength of your hand or arm		
11	Do you feel any difficult in performing the daily activities with the fistula arm or hand		
12	Do you feel any discoloration at fistula side?		
13	Dou you have ischemia of finger and nail		
14	Is there any change in the skin integrity at fistula side <ul style="list-style-type: none">• Skin rash		
15	Is there any scar at fistula side		
16	Is there any formation of clot		
17	Observe for aneurysm		
18	Is there any hematoma		
19	Perform Arm elevation test Is your fistula being collapse on arm elevation? If No, report to doctor Ask the patient to raise or elevate the fistula arm above the level of the heart. <i>Normal finding: The fistula should collapse or become flat on elevation of arm and return back to normal when arm at horizontal or lower to the body.</i> Note: In the presence of a significant stenosis, blood drainage is hampered and the AVF may not collapse and usually becomes hyper pulsatile.		
20	Inspect for central vein stenosis		
	Have you compared both arm(extremities)		
20.1	Are your both arms being of equal size		
20.2	Is the fistula arm is swollen		
20.3	Have you observed colla lateral vein in the fistula arm.		
21	Aneurysm and pseudoaneurysm <ul style="list-style-type: none">• Observe for aneurysm		
22	Palpation (feel) Palpate the pulses (Radial, ulnar, brachial)		
23	Perform Allen test		
	Check the capillary refill		

24	Is the capillary refill less than 3sec.		
25	<p>Perform Augmentation test</p> <p>Is the augmentation test normal?</p> <p>The augmentation test is done by occluding the access completely by palpation several centimeters beyond the arterial anastomosis.</p> <p><i>The test is normal when the portion of the access upstream from the palpation (occlusion) demonstrates augmentation of the pulse.</i></p> <p><i>Pulse is expected to increase in intensity and thrill should disappear after AVF occlusion.</i></p>		
26	<p>Feel for Accessory veins</p> <p>Do you feel the accessory veins on palpation?</p> <p><i>Normally on examination the thrill that is palpable over the arterial anastomosis disappear completely when the downstream or the outflow of the fistula is manually occluded.</i></p> <p>If the thrill does not disappear with manual occlusion of the outflow, then one should suspect an extra channel or extra outflow channel that we call an accessory vein which may be present between anastomosis and the points of occlusion. In presence to accessory vein despite occlusion the thrill persists especially if the accessory vein is large.</p>		
27	<p>Auscultation</p> <p>Is the bruits sound being normal over the fistula and along the entire length of the arm?</p> <p>Is the sound is same along on the fistula and on the entire length of the arm</p> <p>Have you listened sound other than bruits</p> <p>If yes Report to doctor</p> <p><i>Bruits is sound or the murmur is heard over the fistula</i></p> <p>Listen along the entire length of the arm.</p>		
27.1			
27.2			

Assessment after hemodialysis (After 2-3hrs)

S	Items	Yes (1)	No (0)
1	Do you feel erythema, swelling at fistula site		
2	Do you feel tenderness at a fistula site		
3	Do you feel a persistent extremity swelling		
4	Do you feel a prolonged bleeding after needle withdrawal		

5	Do you feel an altered pulse or thrill in the fistula		
6	Do you feel an altered bruit in the fistula		
7	Do you feel an absence of bruits in the fistula		
8	Do you feel an absence of thrills in the fistula		
	I confirm that the fistula or graft is officially abandoned for further use and is not safely salvageable (by Health care professional)		

Note: This assessment can be perform by the patient him/herself or by the caregiver.

DOs and DON'T OF Fistula Care

Cleanliness is important to keep the fistula uninfected. Wash it with soap and water daily.

Any restriction in the blood flow can lead to clotting or fistula blockage.

Avoid tight clothing

Avoid tight jewelry over the access area

Do not carry heavy item with the access arm

Do not sleep over access arm

Do not check your blood pressure form the access arm.

Do not give sample from the access arm.

Attend regular follow-up appointment Engage in gentle exercise as recommended by the health care provider. This can help promote blood flow and overall vascular health.

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