

Clinical Trial Protocol

Iranian Registry of Clinical Trials

14 Jul 2026

The effect of comfort based nursing cares among hemodialysis patients on their quality of life and comfort level

Protocol summary

Summary

This study is a randomised clinical trial (no blind) . the aim of the present study is to determine the effect of comfort-oriented nursing care on comfort level and quality of life in hemodialysis patients. The study population is all hemodialysis patients who referred to hemodialysis center of Ferdows Chamran doctor hospital. 40 patients were randomly divided into control and intervention groups. Randomization in this study was conducted using a throw coins. This study will implement in Chamran doctor Hospital Dialysis Center. The main inclusion criteria include: receiving haemodialysis three times per week and at least 6 months of dialysis. At first, questionnaire of hospice comfort and questionnaire for quality of life of patients in both intervention and control groups will be recorded. Patients problems are categorised in 4 groups as: physical, psychological, social and environmental discomfort, described in kolkaba table 3 in 4; in which, back massage for 5 to 15 minutes in the last hour of dialysis session. Massage of male patients will be done by male nurse and massage of female patients will be done by female nurse. is used to relieve physical discomfort; and having a company and educating patient through face to face consultation and pamphlet, is considered as psychological support. Intervention is applied for 6 consecutive sessions and control group will receive no specific intervention. assessment of comfort will be measure refilled after the final session, and quality of life will takes place after 2 months. Comfort and quality of life scores before and after intervention will be compared between 2 groups and in each group.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2016103130607N1**

Registration date: **2017-03-15, 1395/12/25**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2017-03-15, 1395/12/25

Registrant information

Name

Akram Momeni

Name of organization / entity

Birjand University of Medical Sciences

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Recruitment status

Recruitment complete

Funding source

Vice Chancellor for Research Birjand University of Medical Sciences

Expected recruitment start date

2016-11-15, 1395/08/25

Expected recruitment end date

2017-01-14, 1395/10/25

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of comfort based nursing cares among hemodialysis patients on their quality of life and comfort level

Public title

The effect of the comfort-oriented nursing care on comfort and quality of life

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria: have an arteriovenous fistula or graft; receiving haemodialysis three times per week; Having at least 6 months of dialysis; perfect alertness and having willingness to cooperate in the study; age between 18 to 70; Lack of acute illnesses; ability to communicate verbally; intact skin at the massage. Exclusion Criteria: Severe complications of hemodialysis; Guest of patients for dialysis; The reluctance of patients to continue working during the study; Communication Failure and disturbance of consciousness; any changes in the treatment planning; Death of patient.

Age

From **18 years** old to **70 years** old

Gender

Both

Phase

2

Groups that have been masked

No information

Sample size

Target sample size: **40**

Randomization (investigator's opinion)

Randomized

Randomization description**Blinding (investigator's opinion)**

Not blinded

Blinding description**Placebo**

Not used

Assignment

Parallel

Other design features

Randomization in this study was conducted using a throw coins

Secondary Ids

empty

Ethics committees

1

Ethics committee**Name of ethics committee**

Ethics committee of Birjand University of Medical Sciences

Street address

Birjand University of Medical Sciences, Ayatollah Ghaffari Street

City

Birjand

Postal code

9717853577

Approval date

2016-10-16, 1395/07/25

Ethics committee reference number

ir.bums.1395.108

Health conditions studied

1

Description of health condition studied

Chronic renal failure

ICD-10 code

N17, N18,

ICD-10 code description

Renal failure

Primary outcomes

1

Description

Comfort

Timepoint

Before and 2 weeks after intervention

Method of measurement

Questionnaire Hospitalized Comfort

Secondary outcomes

1

Description

Quality of Life

Timepoint

Before intervention and 2 months after the intervention

Method of measurement

Questionnaire Kidney Disease Quality of Life

Intervention groups

1

Description

Intervention group: In this group 1- back massage will be done for 5 to 15 minutes in the last hour of dialysis session, during six consecutive sessions of dialysis by trained colleagues. Massage of male patients will be done by male nurse and massage of female patients will be done by female nurse. 2- Family involvement in the treatment process as an accompaniment during six consecutive sessions of dialysis 3. Educating the patient and family through face to face consultation and pamphlet during six consecutive sessions of dialysis patients will be conducted as required

Category

Treatment - Other

2

Description

Control group: There is no intervention in this group.

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Dialysis center of Chamran doctor hospital

Full name of responsible person

Reyhaneh Amozi, nursing expert

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Dialysis center of Chamran doctor hospital, Motahari street

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice chancellor for research of Birjand University of Medical Sciences

Full name of responsible person

Gholamreza Sharifzade

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Birjand University of Medical Sciences, Ayatollah Ghaffari Street

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Birjand

Grant name**Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

Title of funding source

Vice chancellor for research of Birjand University of Medical Sciences

Proportion provided by this source

100

Public or private sector

empty

Domestic or foreign origin

empty

Category of foreign source of funding

empty

Country of origin**Type of organization providing the funding**

empty

Person responsible for general inquiries

Contact**Name of organization / entity**

Birjand University of Medical Sciences

Full name of responsible person

Akram Momeni

Position

Nursing expert, Master's students

Other areas of specialty/work**Street address**

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

empty

Study Protocol

empty

Statistical Analysis Plan

empty

Informed Consent Form

empty

Clinical Study Report

empty

Analytic Code

empty

Data Dictionary

empty