Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

The effect of care plan based on the Roy adaptation model on General health and life Satisfaction in hemodialysis patients

Protocol summary

Summary

This study aimed to evaluate the effect of care plan based on the Roy adaptation model on General health and life Satisfaction in hemodialysis patients. The study is a randomized, non-blinded. The study population includes all patients under hemodialysis in Semnan Kowsar Hospital and Garmsar Emam Hospital affiliated to Semnan University of Medical Sciences. Inclusion criteria: consent for participation in study; age between 40-80 years; diagnosed as CRF; Treatment with hemodialysis at least 2-3 times weekly; history of hemodialysis at least 6 month. Exclusion Criteria: having physical or mental disability; addiction; patients with cancer; hearing or visual impairment; experience of stressful events in recent 6 month; renal transplantation during study; patient's unwillingness to cooperate; refusing for continuing study and participation in teaching sessions. Sample size includes 70 patients. After getting informed consent in test group, they will complete general health, life satisfaction questionnaires and assessment form of Roy adaptation model. Maladaptive behaviors and their stimuli extract and care-plan based on the Roy adaptation model will implement for them. Finally, aforementioned questionnaires will complete for patients again. Control group is similar to test group but for this group we will not implement care-plan based on Roy adaptation model.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201411198665N4**
Registration date: **2014-11-30, 1393/09/09**
Registration timing: **prospective**

Last update:
Update count: **0**

Registration date

2014-11-30, 1393/09/09

Registrant information

Name

Hassan Babamohamadi

Name of organization / entity

Semnan University of Medical Sciences

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Recruitment status

Recruitment complete

Funding source

Semnan University of Medical Sciences

Expected recruitment start date

2015-01-05, 1393/10/15

Expected recruitment end date

2015-10-07, 1394/07/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of care plan based on the Roy adaptation model on General health and life Satisfaction in hemodialysis patients

Public title

Effect of Roy adaptation model on general health and life satisfaction in hemodialysis patients

Purpose

Health service research

Inclusion/Exclusion criteria

Inclusion Criteria: consent for participation in study; age between 40-80 years; diagnosed as CRF; Treatment with hemodialysis at least 2-3 times weekly; history of hemodialysis at least 6 month. Exclusion Criteria: having physical or mental disability; addiction; patients with cancer; hearing or visual impairment; experience of stressful events in recent 6 month; renal transplantation during study; patient's unwillingness to cooperate; refusing for continuing study and participation in teaching sessions.

Age
From **40 years** old to **80 years** old

Gender
Both

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **70**

Randomization (investigator's opinion)
Randomized

Randomization description

Blinding (investigator's opinion)
Not blinded

Blinding description

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Semnan University of Medical Sciences

Street address
Semnan University of Medical Sciences, Vice Chancellor of Research and Technology, Basidj Blv, Semnan, Iran

City
Semnan

Postal code
3519899951

Approval date
2014-11-25, 1393/09/04

Ethics committee reference number
93/529209

Health conditions studied

1

Description of health condition studied
General Health

ICD-10 code
z10

ICD-10 code description
Routine general health check-up of defined subpopulation

2

Description of health condition studied
Life satisfaction

ICD-10 code
Y98

ICD-10 code description
Lifestyle-related condition

Primary outcomes

1

Description
General Health

Timepoint
At the first and end of study

Method of measurement
General Health Questionnaire (28 item)

2

Description
Life Satisfaction

Timepoint
At the first and end of study

Method of measurement
Satisfaction with Life scale questionnaire (SWLS)

Secondary outcomes

empty

Intervention groups

1

Description
After getting informed consent in control group, they will complete general health, life satisfaction questionnaires and assessment form of Roy adaptation model. But care-plan based on the Roy adaptation model will not implement for them and they will receive only routine nursing care during hemodialysis.

Category
Other

2

Description
After getting informed consent in test group, they will complete general health, life satisfaction and assessment form of Roy adaptation model questionnaires. Maladaptive behaviors and their stimuli extract and care-plan based on the Roy adaptation model will implemented for them. Finally, aforementioned

questionnaires will complete for patients again.

Category

Lifestyle

Recruitment centers

1

Recruitment center

Name of recruitment center

Semnan Kowsar Hospital

Full name of responsible person

Street address

Hemodialysis Department, Kowsar Hospital, Semnan

City

Semnan

2

Recruitment center

Name of recruitment center

Garmsar Emam Hospital

Full name of responsible person

Street address

Hemodialysis Department, Emam Hospital, Garmsar

City

Garmsar

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Semnan University of Medical Sciences

Full name of responsible person

Dr Ali Rashidypour

Street address

Semnan University of Medical Sciences, Vice Chancellor of Research and Technology, Basidj Blv, Semnan, Iran

City

Semnan

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Semnan 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

Semnan University of Medical Sciences

Full name of responsible person

Hassan Babamohamadi

Position

Assistant Professor

Other areas of specialty/work

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Web page address

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