

Clinical Trial Protocol

Iranian Registry of Clinical Trials

06 Jun 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

Country

Iran (Islamic Republic of)

Phone

+98 23 3365 4190

Email address

babamohamadi@sem-ums.ac.ir

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

Street address

Nursing and Allied Health Faculty, Semnan University
of Medical Sciences, 5 Kilometers of Damghan Road,
Semnan, Iran

City

Semnan

Postal code

3513138111

Phone

+98 23 3365 4192

Fax

+98 23 3365 4299

Email

babamohamadi@semums.ac.ir

Web page address

Person responsible for scientific 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

Street address

Nursing and Allied Health Faculty, Semnan University
of Medical Sciences, 5 Kilometers of Damghan Road,
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Person responsible for updating data

Contact

Name of organization / entity

Semnan University of Medical Sciences

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Email

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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