Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

The effect of empowerment program based on the Trans Theoretical Model (TTM) on health literacy of peoples undergoing haemodialysis

Protocol summary

Summary

The aim of this study is to improve health literacy in hemodialysis patients. inclusion criteria:;Get three dialysis sessions per week;One-year history of dialysis;Lack of mental disorders and diseases based wide area file;Being patient is pre-contemplation and contemplation based on a questionnaire in accordance with the framework Transtheoretical. Exclusion criteria:unwillingness to continue the study;Dialysis interrupted for any reason, including kidney transplantation. The study population of dialysis patients referred to hospitals but age is Borujen and Hajar. Of the patients on hemodialysis days of referral on the basis of the proposed formulas are divided into two groups of 33. Empowerment program based on the structures of TTM for seven 45-minute sessions will run for the intervention group and So after the intervention, one month, three months and six months later health literacy questionnaire will be completed by the researcher.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201606112861N12**
Registration date: **2016-07-29, 1395/05/08**
Registration timing: **registered_while_recruiting**

Last update:
Update count: **0**

Registration date

2016-07-29, 1395/05/08

Registrant information

Name

Reza Masoodi

Name of organization / entity

Nursing department, Shahrekord University of Medical Science,

Country

Iran (Islamic Republic of)

Phone

+98 38 1333 5654

Email address

masoodi@skums.ac.ir

Recruitment status

Recruitment complete

Funding source

Sharekord University of Medical Sciences

Expected recruitment start date

2016-07-22, 1395/05/01

Expected recruitment end date

2016-08-20, 1395/05/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of empowerment program based on the Trans Theoretical Model (TTM) on health literacy of peoples undergoing haemodialysis

Public title

The impact of the empowerment program on health literacy in hemodialysis patients

Purpose

Other

Inclusion/Exclusion criteria

inclusion criteria:Age over 18 years;ability to read and write;Get three dialysis sessions per week;One-year history of dialysis;Lack of mental disorders and diseases based wide area file;Lack of medical science-related college education;Maximum age 60 years;Being patient is pre-contemplation and contemplation based on a questionnaire in accordance with the framework

Transtheoretical Exclusion criteria:unwillingness to continue the study;Dialysis interrupted for any reason, including kidney transplantation

Age
From **18 years** old to **65 years** old

Gender
Both

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **66**

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
Shahrekord University of Medical Sciences

Street address
Kashani Bld. Shahrekord. IRAN

City
Shahrekord

Postal code
8815713471

Approval date
2010-09-23, 1389/07/01

Ethics committee reference number
IR.SKUMS.REC.1395.82

Health conditions studied

1

Description of health condition studied
Hemodialysis

ICD-10 code
Z49.0

ICD-10 code description
Preparatory care for dialysis

Primary outcomes

1

Description
Health Literacy

Timepoint
Before the intervention, after intervention, one month, three months and six months later

Method of measurement
Health literacy questionnaire TOFHLA

Secondary outcomes

1

Description
no

Timepoint
no

Method of measurement
no

Intervention groups

1

Description
In the intervention group empowerment program based on meta-theory framework for 7 sessions of 45 minutes is performed.The control group doing routine

Category
Behavior

2

Description
The control group doing routine.

Category
Behavior

Recruitment centers

1

Recruitment center

Name of recruitment center
The Hajar Hospital ShahreKord

Full name of responsible person
Dr Reza Masoodi

Street address
The Hajar Hospital ShahreKord- Hemodialysis Department

City
ShareKord

2

Recruitment center

Name of recruitment center
Borujen Vali-Asr Hospital

Full name of responsible person
Dr Reza Masoodi

Street address

Borujen Vali-Asr Hospital Dialysis unit

City

Borujen

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Sharekord University of Medical Sciences and Health Services

Full name of responsible person

Dr Kamal Solati

Street address

Shahrekord Kashani Blvd.

City

Sharekord

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Sharekord University of Medical Sciences and Health Services

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

Sharekord University of Medical Sciences and Health Services

Full name of responsible person

Dr Reza Masoodi

Position

Assistant Professor Faculty

Other areas of specialty/work

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Person responsible for scientific inquiries

Contact

Name of organization / entity

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University of Medical Sciences Graduate Student

Full name of responsible person

Rahmat o Allah Kord Yazdi

Position

Graduate Student

Other areas of specialty/work

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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