Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 2026

Comparison the effect of training using short massage services, face to face and booklet on knowledge and quality of life of patients under hemodialysis

Protocol summary

Summary

In this randomized controlled trial the knowledge and quality of life of patients under hemodialysis will be assessed by Chronic Hemodialysis Knowledge Survey and Kidney Disease Quality of Life-Short Form. This study will conduct by three groups, two intervention groups include face to face, short massage services training (SMS) and a control group with booklet, which will be chosen based on inclusion criteria, then will be allocated to groups randomly using random table counting. The participants with be selected among eligible patients (18-70 years) referring to hemodialysis of Sina Medical Educational Center of Tabriz in 2016. During first session, the aims of study will be explained. After getting informed consent, the researcher will complete knowledge and quality of life questionnaires of patients, by interview. For the face to face training group, four sessions in 10-15 minutes will be done one by one with a week interval, under hemodialysis. Also for tele-educational group an educational objective in the form of 3 SMS every day, totally 108 SMS will be sent within 36 days with the same educational content of face to face group in Persian with maximum of 160 characters per text message. The control group will receive common booklet training. For prevention of contact with other ones, the groups will be chosen from different shifts of hemodialysis. Six weeks after the intervention, all three groups will complete the questionnaire again. Finally, for blinding, the data will be collected then analyzed by a person unaware of training methods.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201508045665N6**
Registration date: **2016-02-08, 1394/11/19**
Registration timing: **registered_while_recruiting**

Last update:
Update count: **0**

Registration date

2016-02-08, 1394/11/19

Registrant information

Name
Sima Lakdizaji
Name of organization / entity
Tabriz University of Medical Sciences, Nursing and Midwifery Faculty
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Iran (Islamic Republic of)
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Recruitment status

Recruitment complete

Funding source

Vice chancellor for research, Tabriz University of Medical Sciences

Expected recruitment start date

2016-02-04, 1394/11/15

Expected recruitment end date

2016-05-04, 1395/02/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison the effect of training using short massage

services, face to face and booklet on knowledge and quality of life of patients under hemodialysis

Public title
Comparison the effect of training with short massage services, face to face and booklet on knowledge and quality of life of patients under hemodialysis
Purpose
Prevention
Inclusion/Exclusion criteria
Inclusion criteria: Patients with chronic renal failure undergoing hemodialysis; age between 18-70 years; history of at least 6 months of hemodialysis (4 hours) two or three times a week; literacy to read SMS; having a mobile phone for personal and necessary information on how to use it; lack of psychiatric disorders according to the patient's medical records; lack of vision problems in tele-educational group. Exclusion Criteria: to change the center of hemodialysis or living location; unwilling to continue at any time of the study; Kidney transplant surgery and termination of hemodialysis.
Age
From **18 years** old to **70 years** old
Gender
Both

Phase
N/A
Groups that have been masked
No information
Sample size
Target sample size: **60**
Randomization (investigator's opinion)
Randomized
Randomization description
Blinding (investigator's opinion)
Single blinded
Blinding description
Placebo
Not used
Assignment
Parallel
Other design features
For prevention of contact with ones, each group will be chosen from different shifts of dialysis. As well as for blinding, data will be collected and analyzed by a person unaware of each groups training method. Also similar envelopes will be used for randomized allocation.

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics Committee of Tabriz University of Medical Sciences
Street address
Ethics committee, Vice chancellor for research, Central building 2, Tabriz University of Medical Sciences, Golgasht Ave.
City
Tabriz
Postal code
Approval date
2015-10-26, 1394/08/04
Ethics committee reference number
TBZMED. REC.1394. 853

Health conditions studied

1

Description of health condition studied
Dialysis
ICD-10 code
Z49
ICD-10 code description
care involving dialysis

Primary outcomes

1

Description
Knowledge of patients
Timepoint
before intervention and six weeks after final intervention
Method of measurement
CHEKS (Chronic Hemodialysis Knowledge Survey)

Secondary outcomes

1

Description
Quality of life
Timepoint
before intervention and six weeks after intervention
Method of measurement
Kidney Disease Quality of Life-SF

Intervention groups

1

Description
During the first session, the aims of study will be explained to the patients. After informed consent form, the researcher will complete knowledge and quality of life questionnaires for hemodialysis patients, by interview. For the face to face training group, four sessions in 10-15 minutes will be done one by one with a week interval, under hemodialysis.
Category
Prevention

2

Description

The control group will receive the common dialysis ward training using booklet. After the intervention, all three groups will complete the questionnaire again. Finally, the questionnaires will be collected and the data will be analyzed using SPSS 22 software by a person unaware of training groups.

Category

Prevention

3

Description

For tele-educational group an educational objective in the form of 3 SMS every day, totally 108 SMS will be sent within 36 days with the same educational content of face to face group. Text messages will be in Persian and a maximum of 160 characters per message.

Category

Prevention

Recruitment centers

1

Recruitment center

Name of recruitment center

Hemodialysis of Sina Medical Educational Center of Tabriz

Full name of responsible person

Pooia Tarverdizadeh Asl

Street address

Hemodialysis of Sina Medical Educational Center, Azadi Ave.

City

Tabriz

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice chancellor for research, Tabriz University of Medical Sciences

Full name of responsible person

Dr Mohammad Reza Rashidi

Street address

Vice Chancellor for research, Central Building 2, Tabriz University of Medical Sciences, Golgasht Ave.

City

Tabriz

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, Tabriz 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

Tabriz University of Medical Sciences

Full name of responsible person

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Position

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Other areas of specialty/work

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Person responsible for updating data

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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