Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

Comparison the effect of care centered group discussion and workshops on the caregiver burden of patients undergoing hemodialysis

Protocol summary

Summary

The aim of this study is to determine the effect of care centered group discussion and workshops on the caregiver burden of patients undergoing hemodialysis. This study is a randomized clinical trial. Participant of this study contain 105 caregivers of patients undergoing hemodialysis in educational therapeutic centers in Urmia. They are their family member and they have primary responsibility of patient care at home. Caregivers are selected and allocated randomly in three groups of intervention (group discussion and workshops) and control groups. Demographic and caregiver burden questionnaire will be completed by caregiver before the intervention. The program consist of 6 sessions of group discussion (2 hour) and 4 sessions of workshops (4 hour) during 6 weeks. Topics of the program include learning about end stage renal disease, principle of self care, personal health, role planing and delegating tasks, promote of care skills, ways of increase confidence, reduce stress, time management, education to increase communication skills with friends and acquaintances. Those who don't attend in two training sessions will be excluded. One week after the intervention the caregiver burden questionnaire will be completed by caregivers in intervention and control groups. After intervention, educational booklet will be given to the control group. The data will be analyzed using descriptive and analytic statistics.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2016062823779N2**
Registration date: **2016-08-07, 1395/05/17**
Registration timing: **retrospective**

Last update:
Update count: **0**

Registration date

2016-08-07, 1395/05/17

Registrant information

Name
Mehdi Torabi
Name of organization / entity
Urmia University of Medical Science
Country
Iran (Islamic Republic of)
Phone
+98 81 3682 4179
Email address
torabi.m@umsu.ac.ir

Recruitment status

Recruitment complete

Funding source

Urmia University of Medical Sciences and Health Services

Expected recruitment start date

2016-06-30, 1395/04/10

Expected recruitment end date

2016-07-20, 1395/04/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison the effect of care centered group discussion and workshops on the caregiver burden of patients undergoing hemodialysis

Public title

Comparison the effect of care centered group discussion and workshops on the caregiver burden

Purpose

Supportive

Inclusion/Exclusion criteria
Include criteria: Age between 18-60 years; Can read and right; Lack of mental illness and chronic physical and cognitive disorders, hearing and vision; Lack of use drugs and psychotropic substances; The care of patients have at least 6 months; Is not a member of the medical team; With the patient in one place to live; Are main caregivers; Orientation to Persian language; Access to cell phone or telephone; Be able to participate in training sessions; Don't Participate in other educational classes. Exclude criteria: Don't attend two training sessions; Death of the patient in during of this study; Don't want to attend classes.

Age
From **18 years** old to **60 years** old

Gender
Both

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **105**

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
Urmia University of Medical Sciences and Health Services

Street address
Emergency district, Resalat Blvd, Urmia

City
Urmia

Postal code
5714783734

Approval date
2015-09-09, 1394/06/18

Ethics committee reference number
ir.umsu.rec.1394.184

Health conditions studied

1

Description of health condition studied
hemodialysis

ICD-10 code
Z49.1

ICD-10 code description
Extracorporeal dialysis

Primary outcomes

1

Description
burnout severity

Timepoint
before intervention and 1 week after intervention

Method of measurement
Zarit caregiver burden scale

Secondary outcomes

empty

Intervention groups

1

Description
Group discussion: This program consist of 6 sessions of group discussion (2 hour) during 6 weeks. To facilitate the work, as well as increase performance classes, their intervention groups will be divided into smaller groups. So that the group discussion divided into third groups. The topics of the program include learning more about end stage renal disease, principle of self care, personal health, role planning and delegating tasks, promote of care skills, ways of increase confidence, reduce stress, time management, education to increase communication skills with friends and acquaintances.

Category
Behavior

2

Description
Workshops: This program consist of 4 sessions of workshops (4 hour) during 4 weeks To facilitate the work, as well as increase performance classes, their intervention groups will be divided into smaller groups. So that workshop will be divided into 2 groups. The topics of the program include learning more about end stage renal disease, principle of self care, personal health, role planning and delegating tasks, promote of care skills, ways of increase confidence, reduce stress, time management, education to increase communication skills with friends and acquaintances.

Category
Behavior

3

Description

Control group: Routine training will be conducted in the control group. After intervention, educational booklet will be given to the control group.

Category

Behavior

Recruitment centers

1

Recruitment center

Name of recruitment center

Imam Khomeini Hospital

Full name of responsible person

Mehdi Torabi

Street address

Imam Khomeini Hospital, Ershad Street, Ayatollah Modarres Blvd, Urmia.

City

Urmia

2

Recruitment center

Name of recruitment center

Ayatollah Taleghani Hospital

Full name of responsible person

MehdiTorabi

Street address

Ayatollah Taleghani hospital, Opposite the Takhti sports complex, Kashani street, Urmia

City

Urmia

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Research Council of Urmia University of Medical Sciences

Full name of responsible person

Dr Iraj Mohebbi

Street address

Staff of Urmia University of Medical Sciences, Emergency district, Resalat Blvd, Urmia

City

Urmia

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Research Council of Urmia 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

School of Nursing and Midwifery

Full name of responsible person

Mehdi Torabi

Position

Master or Science in Nursing

Other areas of specialty/work

Street address

School of Nursing and Midwifery, University of Medical Sciences, Cero road, Urmia

City

Urmia

Postal code

Phone

+98 44 3275 4961

Fax

Email

torabi.m@umsu.ac.irmehditorabi90@yahoo.com

Web page address

Person responsible for scientific inquiries

Contact

Name of organization / entity

School of Nursing and Midwifery

Full name of responsible person

Masomeh Hemmati Maslak Pak

Position

Associate Professor

Other areas of specialty/work

Street address

School of Nursing and Midwifery, Nazloo College , km 11 Cero Road, Urmia

City

Urmia

Postal code

Phone

+98 44 3275 4961

Fax

Email

hemmatma@yahoo.com

Web page address

Person responsible for updating data

Contact

Name of organization / entity

School of Nursing and Midwifery

Full name of responsible person

Mehdi Torabi

Position

Master of Nursing

Other areas of specialty/work

Street address

School of Nursing and Midwifery, , Urmia University of Medical Sciences, Cero road, Urmia

City

Urmia

Postal code

Phone

Fax

Email

torabi.m@umsu.ac.ir

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