

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

18 Sep 2026

### The effect of educational intervention based on social support theory on quality of life in hemodialysis Patients

#### Protocol summary

##### Summary

The aim of this randomized controlled clinical trial is to determine the effect of an educational intervention based on the theory of social support on improving the quality of life in hemodialysis patients. It will be done on 100 hemodialysis patients in Fatemeh Zahra hospital in Sari. First, in coordination with the hospital authorities to provide a list of patients and then from two different shifts randomly selected patients were divided into two experimental and control groups (each group, n=50). Data gathering tools are Sherborne and Stewart social support questionnaire and the World Health Organization questionnaire about quality of life. First The questionnaires are completed by both groups. Based on the analysis of the results of this stage, the intervention is designed. Educational intervention consisted of 5 sessions. The duration of each session lasting 45 minutes, and the educational methods are short lecture, group discussion, questions and answers, advice and the use of materials including booklets. Intervention take place only in the experimental group in the dialysis ward in groups of 10 runs. One month and three months after intervention in both groups questionnaires will be completed and the results will be analyzed and compared. Inclusion criteria is at least three months after initiation of dialysis patients and exclusion criteria are kidney transplant, transfer to other wards and death. The primary outcome measure is quality of life and social support is a secondary consequence.

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT2015122615650N6**

Registration date: **2016-02-02, 1394/11/13**

Registration timing: **prospective**

Last update:

Update count: **0**

##### Registration date

2016-02-02, 1394/11/13

##### Registrant information

###### Name

Mahnaz Solhi

###### Name of organization / entity

Iran University of Medical Sciences

###### Country

Iran (Islamic Republic of)

###### Phone

+98 21 8877 9928

###### Email address

solhi.m@iums.ac.ir

##### Recruitment status

###### Recruitment complete

##### Funding source

Vice chancellor for research and technology, Iran University of Medical Sciences

##### Expected recruitment start date

2016-02-20, 1394/12/01

##### Expected recruitment end date

2016-03-19, 1394/12/29

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

The effect of educational intervention based on social support theory on quality of life in hemodialysis Patients

##### Public title

The effect of social support on quality of life

##### Purpose

Other

## Inclusion/Exclusion criteria

Inclusion criteria: at least 3 month after hemodialysis  
Exclusion criteria: implant; transfer to other centers;  
death

## Age

No age limit

## Gender

Both

## Phase

N/A

## Groups that have been masked

No information

## Sample size

Target sample size: 100

## Randomization (investigator's opinion)

Randomized

## Randomization description

## Blinding (investigator's opinion)

Single blinded

## Blinding description

## Placebo

Not used

## Assignment

Parallel

## Other design features

Closed envelope

## Secondary Ids

### 1

#### Registry name

-

#### Secondary trial Id

-

#### Registration date

empty

## Ethics committees

### 1

#### Ethics committee

##### Name of ethics committee

Ethics committee of Iran University of Medical  
Sciences

##### Street address

Vice-chancellor for Research and Technology, Iran  
University of Medical Sciences, Hemmat Highway,  
near Milad Hospital

##### City

Tehran

##### Postal code

1449614535

#### Approval date

2015-12-07, 1394/09/16

#### Ethics committee reference number

IR.IUMS.REC.1394.27105

## Health conditions studied

### 1

#### Description of health condition studied

Hemodialysis patients

#### ICD-10 code

N17-N19

#### ICD-10 code description

renal failure

## Primary outcomes

### 1

#### Description

Quality of life

#### Timepoint

1 and 3 month after intervention

#### Method of measurement

standard questionnaire for quality of life from WHO with  
26 questions

## Secondary outcomes

### 1

#### Description

Social support

#### Timepoint

1 and 3 month after intervention

#### Method of measurement

standard questionnaire for social support from Sherborn  
and Stuart

## Intervention groups

### 1

#### Description

Then educational intervention is going to be done just for  
case group by short lecture - group discussion and  
booklet during 5 sessions(each of 45 min)

#### Category

Other

### 2

#### Description

There is no intervention for control group.

#### Category

N/A

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

Fatemeh Zahra Hospital

##### Full name of responsible person

Laila Zhianfar

**Street address**

NO.14, Rahahan Building, Artesh Blvd

**City**

Sari

## Sponsors / Funding sources

### 1

**Sponsor**

**Name of organization / entity**

Vice-chancellor for Research and Technology, Iran university of medical sciences

**Full name of responsible person**

Dr. Seyed Ali Javad MooOsavi

**Street address**

Shahid Hemmat highway, near Milad Hospital

**City**

Tehran

**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 and Technology, Iran 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**

Iran University of Medical Sciences

**Full name of responsible person**

Dr. Mahnaz Solhi

**Position**

Associate Prof.

**Other areas of specialty/work**

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## Person responsible for scientific inquiries

**Contact**

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**Full name of responsible person**

Leila Zhianfar

**Position**

MS student

**Other areas of specialty/work**

**Street address**

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## Person responsible for updating data

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PhD/Associate Prof.

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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*

