

Clinical Trial Protocol

Iranian Registry of Clinical Trials

15 Jul 2026

Study of interactive multimedia education impact on fatigue in hemodialysis patients referred to Urmia hospitals, 2017

Protocol summary

Study aim

The effect of interactive multimedia education impact on fatigue in hemodialysis patients referred to Urmia hospitals, 2017

Design

Clinical trial with control group, with parallel groups, without blinding

Settings and conduct

This study will be carried out on hemodialysis patients in diaysis unit of Ayatollah Taleghani hospital of Urmia in 2018 with convenience sampling according to inclusion and exclusion criteria. The participants were divided into two random groups of intervention and the control group consist of 40 subjects for each group and there is no blinding. A interactive multimedia education program this education is provided by the researcher with a tablet and consist of film, audio, video, animation, text summaries and then fatigue severity of them evaluated.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Lack of other diseases, at least three sessions of dialysis per week Exclusion criteria: Unwillingness to cooperate.

Intervention groups

Patients in the intervention group acquainted to interactive multimedia education, individually by a tablet, underwent a 45-minute training session in eight sessions that were in line with their dialysis program. Control group: just received routine care.

Main outcome variables

Fatigue

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20160220026662N4**

Registration date: **2018-10-03, 1397/07/11**

Registration timing: **retrospective**

Last update: **2018-10-03, 1397/07/11**

Update count: **0**

Registration date

2018-10-03, 1397/07/11

Registrant information

Name

Nader Aghakhani

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 44 3275 4816

Email address

nader1453@umsu.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-01-21, 1396/11/01

Expected recruitment end date

2018-07-21, 1397/04/30

Actual recruitment start date

2018-02-09, 1396/11/20

Actual recruitment end date

2018-08-18, 1397/05/27

Trial completion date

2018-08-18, 1397/05/27

Scientific title

Study of interactive multimedia education impact on fatigue in hemodialysis patients referred to Urmia hospitals, 2017

Public title

Study of interactive multimedia education impact on fatigue in hemodialysis patients

Purpose

Education/Guidance

Inclusion/Exclusion criteria

Inclusion criteria:

Lack of another disease based on documented medical records such as cancer and heart failure not attending in similar educational or massage courses Having dialysis sessions at least 3 times a week

Exclusion criteria:

Refusal to participate in the study and dissatisfaction for any reason

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: **80**

Actual sample size reached: **80**

Randomization (investigator's opinion)

Randomized

Randomization description

In this study, for assigning participants in control or intervention groups, block randomization will be used. Thus, blocks will be created based on personal information and inside of each block will divide two equal parts, half of them will consider as intervention group and another part will be control group.

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**

Ethics committee of Urmia University of Medical Sciences

Street address

Orjhans Street, Resalat Blvd

City

Urmia

Province

West Azarbaijan

Postal code

5714783734

Approval date

2017-11-08, 1396/08/17

Ethics committee reference number

lr.umsu.rec.1396.277

Health conditions studied**1****Description of health condition studied**

Patients' fatigue under hemodialysis

ICD-10 code**ICD-10 code description****Primary outcomes****1****Description**

Fatigue severity in hemodialysis patients

Timepoint

Before intervention, after intervention and 4 weeks after intervention

Method of measurement

Krupp fatigue severity questionnaire

Secondary outcomes

empty

Intervention groups**1****Description**

Intervention group: After the randomization, the fatigue severity questionnaire was completed by patients before the intervention. The education done by 8 sessions of film, audio, video, animation and brochure in which it is provided by the researcher. After that, the questionnaire was completed again by the patient. Four weeks after educational course, the questionnaire was given to patients and completed again.

Category

Other

2**Description**

Control group: No intervention was done in the control group and this group only received routine care.

Category

Other

Recruitment centers**1****Recruitment center****Name of recruitment center**

Ayatollah Taleghani hospital

Full name of responsible person

Sara Fooladi

Street address

Ayatollah Taleghani Hospital- Kashani street

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Sponsors / Funding sources

1

Sponsor

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Grant name

Grant code / Reference number

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

Yes

Title of funding source

Oroumia University of Medical Sciences

Proportion provided by this source

100

Public or private sector

Public

Domestic or foreign origin

Domestic

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

Academic

Person responsible for general inquiries

Contact

Name of organization / entity
Oroumia University of Medical Sciences

Full name of responsible person

Sara Fooladi

Position

MSc student

Latest degree

Bachelor

Other areas of specialty/work

Nursery

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Person responsible for scientific inquiries

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Nader Aghakhani

Position

Assistant professor

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Person responsible for updating data

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Latest degree

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD

Relied on the principle of secrecy and not misuse of others

Study Protocol

No - There is not a plan to make this available

Statistical Analysis Plan

No - There is not a plan to make this available

Informed Consent Form

No - There is not a plan to make this available

Clinical Study Report

Not applicable

Analytic Code

Not applicable

Data Dictionary

Not applicable