Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 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
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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
Ir.umsu.rec.1396.277

Health conditions studied

1

Description of health condition studied
Patients' fatigue under hemodyalisis

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
AyatollahTaleghani hospital

Full name of responsible person
Sara Fooladi

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AyatollahTaleghani Hospital- Kashani street

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Sponsors / Funding sources

1

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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
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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