

Clinical Trial Protocol

Iranian Registry of Clinical Trials

21 Jul 2026

The effect of recreational therapy application on fatigue and depression in hemodialysis patients

Protocol summary

Study aim

Determining the effect of recreational therapy application on fatigue and depression in hemodialysis patients

Design

Clinical trial with an intervention group and a control group in parallel without blinding, randomized using site www.randomization.com; on 60 patients.

Settings and conduct

The study was conducted on hemodialysis patients in Montaseriyeh Hospital and the patients completed the mentioned questionnaires before and after the implementation of the recreational therapy application programs.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Age 18 to 60 years old; having full consciousness; having a mobile phone under the Android operating system; history of at least 2 months of hemodialysis; perform hemodialysis at least 2 to 3 times a week; not taking anti depression or drugs that effect; not having a history of mental illness. Exclusion criteria: unwillingness to participate in the study; occurrence of physical and mental disorders requiring treatment or hospitalization; death or travel of the participant during the research; failure to implement approved programs for at least days; obtaining a score higher than 19 according Beck depression questionnaire.

Intervention groups

Patients personal and medical characteristics, Beck depression and MFI fatigue questionnaires are completed at the beginning of the study. Then the application is installed on the patients mobile phone and patients is taught how to use it. Patients will perform all the programs specified in the application every day for 30 days. The researcher will follow up the patients on a daily basis through phone calls and also in person in term of the full implementation of the determined programs. After 30 days, Becks depression and MFI fatigue questionnaires will be completed again for patients.

Main outcome variables

Depression and Fatigue

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20220803055608N1**

Registration date: **2022-08-29, 1401/06/07**

Registration timing: **prospective**

Last update: **2022-08-29, 1401/06/07**

Update count: **0**

Registration date

2022-08-29, 1401/06/07

Registrant information

Name

Moein Alishahi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 51 5229 0361

Email address

moeinnurse@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-10-23, 1401/08/01

Expected recruitment end date

2022-12-22, 1401/10/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of recreational therapy application on fatigue and depression in hemodialysis patients

Public title

The effect of recreational therapy application on fatigue and depression in hemodialysis patients

Purpose

Supportive

Inclusion/Exclusion criteria**Inclusion criteria:**

Age 18 to 60 years Having full consciousness Having a mobile phone under the Android operating system A history of at least 2 months of hemodialysis Perform hemodialysis at least 2 to 3 times a week Not taking anti depression or drugs that effect Not having a history of mental illness according to the patients statement or a history of taking psychiatric drugs

Exclusion criteria:

Unwillingness to participate in the study Occurrence of physical and mental disorders requiring treatment or hospitalization Death or travel of the participant during the research Failure to implement approved programs for at least 10 days Obtaining a score higher than 19 studies of the Beck depression questionnaire

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: **60**

Randomization (investigator's opinion)

Randomized

Randomization description

Simple randomization is done using the www.randomization.com site and the random sequences determined using a closet envelope are allocated to the study participants.

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 Mashhad School of Nursing and Midwifery

Street address

Qureshi building, Next to hoveyze cinema, Daneshgah street.

City

Mashhad

Province

Razavi Khorasan

Postal code

91388-13944

Approval date

2022-06-22, 1401/04/01

Ethics committee reference number

IR.MUMS.NURSE.REC.1401.021

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

End stage renal disease

ICD-10 code

N18.6

ICD-10 code description

End stage renal disease

2**Description of health condition studied**

Depression

ICD-10 code

F06.31

ICD-10 code description

Mood disorder due to known physiological condition with depressive features

3**Description of health condition studied**

Chronic kidney disease (CKD)

ICD-10 code

N18

ICD-10 code description

Chronic kidney disease (CKD)

Primary outcomes**1****Description**

Depression score in Beck questionnaire

Timepoint

The beginnings of study (Before the start of the intervention) and 30 days after the start of the intervention

Method of measurement

Beck depression questionnaire

2

Description

Fatigue score in Multidimensional Fatigue Inventory (MFI) questionnaire

Timepoint

The beginnings of study (Before the start of the intervention) and 30 days after the start of the intervention

Method of measurement

Multidimensional Fatigue Inventory (MFI) questionnaire

Secondary outcomes

1

Description

Nausea

Timepoint

The beginnings of study (Before the start of the intervention) and 30 days after the start of the intervention

Method of measurement

Verbal numeric rate scale (VNRS)

2

Description

Quality of life

Timepoint

The beginnings of study (Before the start of the intervention) and 30 days after the start of the intervention

Method of measurement

Kidney disease quality of life (KDQOL-SF)

3

Description

Perceived stress

Timepoint

The beginnings of study (Before the start of the intervention) and 30 days after the start of the intervention

Method of measurement

Cohen perceived stress scale

Intervention groups

1

Description

Intervention group: After stating the objectives and obtaining informed consent from the samples, the patients are assured about the confidentiality of the information and publication of the results of the studies. Then the patients personal and medical characteristics, becks depression and MFI fatigue questionnaires are completed. After preparing and confirming the content of the recreational therapy application, in consultation with the informatics engineer the application will be prepared for the smartphone as standard in the android operating system. Then the application is installed on the patients

mobile phone and patients is taught how to use it. Patients will perform all the programs specified in the application every day for 30 days. Using a checklist and based on the characteristics and date of entry into the study, the researcher will follow up the patients on a daily basis through phone calls and also in person in term of the full implementation of the determined programs. After 30 days, Becks depression and MFI fatigue questionnaires will be completed again for patients.

Category

Rehabilitation

2

Description

Control group: After stating the objectives and obtaining informed consent from the samples, the patients are assured about the confidentiality of the information and publication of the results of the studies. Then the patients personal and medical characteristics, becks depression and MFI fatigue questionnaires are completed. In this group, no intervention was performed and only routine hospital nursing interventions were provided, including checking vital signs and injecting prescription drugs. After 30days, Becks depression and MFI fatigue questionnaires are completed.

Category

Rehabilitation

Recruitment centers

1

Recruitment center

Name of recruitment center

Montaseriyeh Hospital

Full name of responsible person

Moein Alishahi

Street address

25 Imam Khomeini Street

City

Mashhad

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Postal code

9137776788

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Email

Moeinnurse@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Mashhad University of Medical Sciences

Full name of responsible person

Seyyed Reza Mazloun

Street address

Daneshgah Street, Doctora Crossroad, Ebne sina Street

City

Mashhad

Province

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Postal code

9137913199

Phone

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Email

mazlomr@mums.ac.ir

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Mashhad 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

Mashhad University of Medical Sciences

Full name of responsible person

Moein Alishahi

Position

Student

Latest degree

Bachelor

Other areas of specialty/work

Nursery

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Person responsible for scientific inquiries

Contact

Name of organization / entity

Mashhad University of Medical Sciences

Full name of responsible person

Moein Alishahi

Position

Student

Latest degree

Bachelor

Other areas of specialty/work

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Person responsible for updating data

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Full name of responsible person

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Position

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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

There is no further information

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
No - There is not a plan to make this available
Analytic Code

No - There is not a plan to make this available
Data Dictionary
No - There is not a plan to make this available