

Clinical Trial Protocol

Iranian Registry of Clinical Trials

02 Jun 2026

The effect of jacobson relaxation on fatigue and happiness among family Caregivers of hemodialysis Patients

Protocol summary

Study aim

The effect of Jacobson's relaxation on fatigue and happiness of family caregivers in hemodialysis patients

Design

The research units will be selected by available sampling method and then randomly divided into two experimental (even days) and control (odd days) groups by coin toss.

Settings and conduct

Relaxation in the experimental group will be taught face to face in 1 session to the experimental group for 30-45 minutes by the researcher, in the patients' rest room, and caregivers will be asked to perform the relaxation method again for the researcher. Participants in the experimental group will be asked to perform relaxation techniques three times a week (one day in between), 12 times over 30 days for 30 to 45 minutes at home or in the rest room, the time of referral for their patient's hemodialysis will be done and a checklist will be given according to which the date of relaxation, the duration of it and the reason for not doing it, will be ticked by the caregiver

Participants/Inclusion and exclusion criteria

The age range of 18 to 60 years - taking on the role of primary caregiver - being a family member - performing at least six months of patient care - receiving three dialysis times a week by the patient under care - having read and write literacy No history of psychological disorders (self-declaration) No drug abuse and sedatives Not having a history of training and implementing Jacobson's method No history of crisis in the last 4 weeks

Intervention groups

There is a group in this study and all participants receive one type of intervention

Main outcome variables

Fatigue and happiness

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20210808052114N1**

Registration date: **2021-08-14, 1400/05/23**

Registration timing: **prospective**

Last update: **2021-08-14, 1400/05/23**

Update count: **0**

Registration date

2021-08-14, 1400/05/23

Registrant information

Name

Farzaneh Ravash

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 3324 9537

Email address

afsaneh.ravash@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-09-10, 1400/06/19

Expected recruitment end date

2021-12-10, 1400/09/19

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of jacobson relaxation on fatigue and happiness among family Caregivers of hemodialysis Patients

Public title

The effect of jacobson relaxation onfamily Caregivers

Purpose

Prevention

Inclusion/Exclusion criteria**Inclusion criteria:**

- Age range of 18 to 60 years- taking on the role of primary caregiver - being a family member - performing at least six months of patient care - receiving three dialysis times a week by the patient under care - having read and write literacy

Exclusion criteria:

No history of psychological disorders (self-reported) no drug abuse and sedatives, no history of education and implementation of Jacobson method, no history of crisis during the last 4 weeks

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: **70**

Randomization (investigator's opinion)

Randomized

Randomization description

The research units will be selected by available sampling method and then randomly divided into two groups: experimental (even days) and control (odd days) by coin toss.

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 Army Medical Sciences
University

Street address

Pine Street

City

tehran

Province

Tehran

Postal code

1615116139

Approval date

2021-03-15, 1399/12/25

Ethics committee reference number

IR.AJAUMS.REC.1399.263

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

Gentrification by Jacobson Method

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

Fatigue and happiness

Timepoint

Before the intervention and 2 and 4 weeks after jacobson relaxation

Method of measurement

Fatigue and Happiness Questionnaire

Secondary outcomes

empty

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

Intervention group: Intervention group: In this method, the muscles contract for approximately 5 seconds and then slowly release (expand) for 20 to 30 seconds. First, he sits in a relaxing chair and thinks of a relaxing subject, preferablThe first step takes a slow and deep breath and then slowly exits up to 5 numbers to repeat 5 times.The second and third stages, first the right wrist contracts and then expands, then the forearm and arms contract into figurative position and then expand. All the steps in the left hand are repeated as well.The fourth step, first we raise the eyebrows and then let go, then press the eyes tightly, then slowly release, with the mouth closed, create a smile line and then go to y a view he likes and has never been to before. We release slowly, at the end we bring the chin forward and then let go.Step five, we put the abdomen forward with the waist and then we release the abdomen and then let go of the abdomen and then let go. We will.And then we put the abdomen in and then we release it, the sixth and seventh stages, first we hang the right leg, pull the fingers forward and then let go, we give up the para wrist, then we release the para, from the fingertip to the shin, and then we hold it to 90 degrees with the body,

and then we release it. Para from fingertip to shin to 90 degrees with the body and then release and at the end of the foot to the abdomen and then release all the steps in the left leg is repeated.1 The following points should be observed:1. Breathing during contraction and expansion of muscles is done normally and the breath is not kept at all.2. During contraction and expansion of muscles, it is tried to feel the difference between these two good operations. Of course, if this feeling doesn't touch the person at first, after a while, it will feel the difference.3. During muscle expansion, focus your senses on the muscles and the muscles are gradually released.4 . Practice is performed once for 45 minutes

Category

Prevention

Recruitment centers

1

Recruitment center

Name of recruitment center

chamran hospital

Full name of responsible person

frazaneh ravash

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Artesh University of Medical Sciences

Full name of responsible person

Dr. Mojtaba Yousefi Zeshk

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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

Artesh 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

Artesh University of Medical Sciences

Full name of responsible person

Vice Chancellor for Research and Technology, AJA
University of Medical Sciences

Position

Senior Student of Special Nursing

Latest degree

Bachelor

Other areas of specialty/work

Nursery

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Person responsible for scientific inquiries

Contact

Name of organization / entity

Artesh University of Medical Sciences

Full name of responsible person

Farzaneh Ravash

Position

Nurse

Latest degree

Bachelor

Other areas of specialty/work

Nursery

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Person responsible for updating data

Contact

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Undecided - It is not yet known if there will be a plan to make this available

Study Protocol

Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan

Undecided - It is not yet known if there will be a plan to make this available

Informed Consent Form

Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report

Undecided - It is not yet known if there will be a plan to make this available

Analytic Code

Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary

Undecided - It is not yet known if there will be a plan to make this available