Clinical Trial Protocol
Iranian Registry of Clinical Trials

27 Jul 2026

The effect of progressive muscle relaxation technique on fatigue, pain and quality of life patients undergoing dialysis

Protocol summary

Study aim
Determining and comparing the mean total score of fatigue, pain and quality of life in dialysis patients before and three months after the implementation of progressive muscle relaxation technique in the intervention and control groups

Design
The clinical trial has a control group and parallel design and it is performed on 60 patients. Randomization will be done by card.

Settings and conduct
The above project is performed in the dialysis ward of Ali Ibn Abitaleb and Khatam Al-Anbia hospitals in Zahedan and the technique of progressive muscle relaxation is given individually to the intervention group at the patient's home by the researcher

Participants/Inclusion and exclusion criteria
Inclusion criteria: People over 18 years old referred to the dialysis ward of the relevant hospitals; suffering from chronic kidney failure; living in Zahedan; having a minimum level of education; willing to participate in the study. Non-inclusion criterion: Need to be hospitalized

Intervention groups
In the intervention group, progressive muscle relaxation technique individually face to face in 2 to 3 sessions for one hour, on the day after dialysis, the time of which is determined in coordination with the patient and family, in the presence of a first-degree member of the patient (child , Spouse), is taught at the patient's home by the researcher. (If the patient is not able to perform the technique independently during the designated sessions, the training will continue until the learning is complete and the technique is performed independently). These people should do relaxation exercises twice a day (morning and evening) for 12 weeks according to the schedule set at home. In the control group, nothing will be done except routine care.

Main outcome variables
General quality of life, quality of public life, quality of private life, fatigue, pain

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20201021049107N1**
Registration date: **2022-02-14, 1400/11/25**
Registration timing: **registered_while_recruiting**

Last update: **2022-02-14, 1400/11/25**
Update count: **0**

Registration date
2022-02-14, 1400/11/25

Registrant information

Name
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Name of organization / entity

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2021-03-10, 1399/12/20

Expected recruitment end date
2022-03-11, 1400/12/20

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date

empty

Scientific title
The effect of progressive muscle relaxation technique on fatigue, pain and quality of life patients undergoing dialysis

Public title
The effect of progressive muscle relaxation technique on fatigue, pain and quality of life of dialysis patients

Purpose
Supportive

Inclusion/Exclusion criteria

Inclusion criteria:
Age over 18 years Performing dialysis 2 to 3 times a week Ability to access and control the patient during the study Resident of Zahedan Having a cell phone by the participant or a family member or having a landline telephone at home Have a minimum degree of literacy At least 6 months have passed since the first dialysis

Exclusion criteria:
Need to be hospitalized Functional disability (musculoskeletal) Known mental illness

Age
From **18 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
Sampling will be done by available method. Then the selected patients are randomly divided into control and intervention groups. In this way, some envelopes containing the names of the groups are prepared and randomly arranged for the total number of participants. By referring each patient one of the envelops will be assigned to them subsequently.

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 Zahedan University of Medical Sciences

Street address
Campus of Medical School; Dr. Hesabi square

City
Zahedan

Province
Sistan-va-Balouchestan

Postal code
9816743463

Approval date
2021-03-07, 1399/12/17

Ethics committee reference number
IR.ZAUMS.REC.1399.539

Health conditions studied

1

Description of health condition studied
Dialysis patients

ICD-10 code
Y84.1

ICD-10 code description
Kidney dialysis as the cause of abnormal reaction of the patient, or of later complication, without mention of misadventure at the time of the procedure

Primary outcomes

1

Description
Total fatigue score based on the fatigue questionnaire

Timepoint
Before the intervention and three months after the end of the intervention

Method of measurement
The Fatigue Questionnaire is a short questionnaire to measure the level of fatigue, it consists of 9 sentences that each sentence is scored according to the severity of the symptoms. The range of scores for each question is between 7-1. Giving the lowest score, 1 indicates strong opposition to the sentence and 7 indicates strong agreement with the sentence. In order to obtain the total score of the questionnaire, the total score of each question is calculated. A higher score indicates the greater the severity of the respondent's fatigue, and vice versa. This score ranges from 9 to 63. In general, the patient with a total score below 36 indicates no fatigue and if the total score is 36 or above 36, indicates fatigue.

2

Description
The total pain score based on the pain questionnaire

Timepoint
Before the intervention and three months after the end of the intervention

Method of measurement
Visual Analogue Scale, or VAS, is a scale used to measure pain intensity. It is the most widely used pain

measuring tool in the world. The most important feature of this instrument is its ease of use. The number zero on the left indicates absolute painlessness and the number 10 on the right indicates unbearable pain. A score of 1-3 indicates mild pain, 4-7 indicates moderate pain, and 8-10 indicates severe pain.

3

Description

The total quality of life score that is measured by the quality of life questionnaire

Timepoint

Before the intervention and three months after the end of the intervention

Method of measurement

The standard quality of life questionnaire for kidney patients is a questionnaire of 79 questions and is divided into two subscales, specific and general. General dimension includes 8 areas of general health (6 questions) with a score of 5-1, physical function (10 questions) and a score of 3-1, physical pain (2 questions) with a score of 1-1, playing an emotional role (3 questions) With a score of 2-1, social performance (2 questions) with a score of 1-1, vitality (4 questions) with a score of 6-1, mental health (5 questions) with a score of 6-1 and physical role playing (4 questions) with a score It is 2-1. Specific dimension includes 12 burden areas of kidney disease (4 questions) with a score of 1-5, cognitive function (3 questions) with a score of 1-5, quality of social interactions (3 questions) with a score of 1-5, symptoms (12 questions) with a score of 5-1, Effect of kidney disease (8 questions) with score 5-1, Sexual issues (2 questions) with score 5-1 Sleep (4 questions) with score 5-1, Social support (2 questions) with score 4-1 , Work status (2 questions) with a score of 2-1, Patient satisfaction (1 question) with a score of 1-7, Satisfaction with the care of ward staff (2 questions) with a score of 1-5 and General health rating (1 question) with a score It is 10-0. According to the standard guidelines for quality of life in kidney patients, a score of 0 to 100 is assigned for each dimension. In addition, the total scores from both subscales were classified as poor (0–33), moderate (34–66) and good above 66.

4

Description

General quality of life score that is measured by the quality of life questionnaire and its score range is from 0-100

Timepoint

Before the intervention and three months after the end of the intervention

Method of measurement

The standard quality of life questionnaire for kidney patients is a questionnaire of 79 questions and is in 2 subscales. The general dimension includes 8 areas of general health (6 questions) with a score of 1-1, physical function (10 questions) and a score of 3-1, physical pain (2 questions) with a score of 6-1, playing an emotional role (3 questions) with a score of 2-1, social performance (2 questions) with a score of 5-1, vitality (4 questions) with a score of 6-1, mental health (5 Question) with a score of 1-6 and playing a physical role (4 questions) with a score of 1-2. According to the standard guidelines for quality of life in kidney patients, a score of 0 to 100 is assigned for each dimension. In addition, the total scores from both subscales were classified as poor (0–33), moderate (34–66) and good above 66.

5

Description

Specific quality of life score that is measured by the quality of life questionnaire and its score range is from 0-100

Timepoint

Before the intervention and three months after the end of the intervention

Method of measurement

The standard quality of life questionnaire for kidney patients is a questionnaire of 79 questions and is in 2 subscales, which includes a specific dimension including 12 areas of kidney disease burden (4 questions) with a score of 1-5, cognitive function (3 questions) with a score of 1-5, quality of social interactions (3 questions) with a score of 5-1, symptoms (12 questions) with a score of 1-1, the effect of kidney disease (8 questions) with a score of 1-1, sexual issues (2 questions) with a score of 1-1, sleep (4 questions) With a score of 5-1, social support (2 questions) with a score of 4-1, working status (2 questions) with a score of 1-2, patient satisfaction (1 question) with a score of 7-1, satisfaction with the care of ward staff (2 questions)) With a score of 5-1 and the overall health rating (1 question) with a score of 10-0. According to the standard guidelines for quality of life in kidney patients, a score of 0 to 100 is assigned for each dimension. In addition, the total scores from both subscales were classified as poor (0–33), moderate (34–66) and good above 66.

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: First, a questionnaire of demographic characteristics, fatigue, pain and quality of life for patients is completed by the researcher. Then, the technique of progressive muscle relaxation individually face to face in 2 to 3 sessions for one hour, on the day after dialysis, the time of which is determined in coordination with the patient and family, in the presence of a first-degree member of the patient (child, spouse) is taught at the patient's home by the researcher (If the patient is not able to perform the technique independently during the designated sessions, the training will continue until the learning is complete and the technique is performed independently). The first session will be technique training; the second session will be performing the technique by the patient in the

presence of the researcher and the repetition of the technique training if necessary. The third session will be training with questions from the patient and answers to his questions during practice relaxation technique at home and performance and performing technique by the patient in the presence of the researcher. The audio file is provided to the intervention group through a compact disc with the researcher's own voice and an educational booklet containing images of the first and second steps of relaxation. The intervention group is asked to do relaxation exercises twice a day (morning and evening) for 12 weeks according to the schedule set at home. Each relaxation step takes about 20 minutes. The family member is also asked to supervise the patient performing the technique at home. Prior to the intervention, the researcher will undergo theoretical and practical training in relaxation techniques in several stages under the full supervision of a clinical psychologist. The technique is performed by first closing the patient's eyes, relaxing them as much as possible, and focusing all their attention on their breathing, taking five deep breaths, and each time filling the lungs with air and empty slowly. After this stage, patients perform muscle contraction and expansion for 14 groups of facial muscles (forehead, eyelids, jaws, and lips), neck muscles, fingers and palms, forearms, arms and shoulders, back and chest, abdomen, buttock, thighs, legs and soles of the feet. Each muscle contracts for 5 seconds and expands for 10 seconds. Also, when the muscles contract, they should not tighten too much, and shouldn't put pressure on themselves rather, normal contraction will be sufficient. Finally, the patient relaxes his whole body, takes 5 deep breaths, opens his eyes slowly, and returns to normal. During this period, to ensure the implementation of the relaxation technique on the prescribed days, a checklist is provided to the patient's family member to record the day, hour and duration of the technique by the patient and if not, the cause. Also, in order to solve possible problems in the implementation of the technique, during the research, the researcher made telephone calls to the patient or family member twice a week to ensure the implementation of the technique and the completion of the checklist. After 12 weeks, the researcher completes the fatigue, pain and quality of life questionnaire for the intervention group.

Category

Rehabilitation

2

Description

Control group: First, to start the pre-test, a questionnaire of demographic information, fatigue, pain and quality of life was completed by the researcher. This group does not receive any intervention except for routine care. The post-test is completed within 12 weeks during a telephone call by the researcher whose time and place are based on the wishes and opinions of the patient and his family. At the end of the intervention, the audio file on a CD with the researcher's own voice and an educational booklet with an image containing the first and second steps of relaxation will be provided to patients in the control group and family.

Category

Rehabilitation

Recruitment centers

1

Recruitment center

Name of recruitment center

Ali Ibn Abitaleb Hospital; Zahedan University of Medical Sciences

Full name of responsible person

Mahnaz Ghaljeh

Street address

Ali Ibn Abitaleb Hospital; Salamat Boulevard; Khalij-e-Fars Highway; Zahedan

City

Zahedan

Province

Sistan-va-Balouchestan

Postal code

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Email

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2

Recruitment center

Name of recruitment center

Khatam Al-Anbia Hospital, Zahedan University of Medical Sciences

Full name of responsible person

Mahnaz Ghaljeh

Street address

Khatam Al-Anbia Hospital; Khatam Square; Jam Jam Boulevard; Zahedan

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Province

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Zahedan University of Medical Sciences

Full name of responsible person

Noor Mohammad Bakhshani

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Campus of Medical School; Dr. Hesabi square

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public@zaums.ac.ir

Grant name

Grant code / Reference number

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

Title of funding source
Zahedan 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
Zahedan University of Medical Sciences

Full name of responsible person
Mahnaz Ghaljeh

Position
University faculty member, assistant professor

Latest degree
Ph.D.

Other areas of specialty/work
Nursery

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Medical Sciences Campus; Dr. Hesabi Square; Zahedan

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Person responsible for scientific inquiries

Contact

Name of organization / entity
Zahedan University of Medical Sciences

Full name of responsible person
Mahnaz Ghaljeh

Position
University faculty member, assistant professor

Latest degree
Ph.D.

Other areas of specialty/work
Nursery

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Medical Sciences Campus; Dr. Hesabi Square; Zahedan

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Person responsible for updating data

Contact

Name of organization / entity
Zahedan University of Medical Sciences

Full name of responsible person
Mahnaz Ghaljeh

Position
University faculty member, assistant professor

Latest degree
Ph.D.

Other areas of specialty/work
Nursery

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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