Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 2026

Comparing the effect of home-based synchronous tele-exercise on balance, fall risk, postural abnormalities, quality of life, physical activity level, and functional status in hemodialysis patients

Protocol summary

Study aim

To investigate the effect of 12 weeks of home-based corrective exercises with and without remote synchronous supervision on balance, fall risk, postural abnormalities, quality of life, physical activity level, and functional status in hemodialysis patients

Design

Randomized controlled clinical trial; parallel-group design; single-blind (outcome assessor); simple randomization using sealed opaque envelopes; sample size of 60 participants (30 per group); study duration of 5 months.

Settings and conduct

The study will be conducted at the dialysis center of Khorshid Hospital, Isfahan. Patients will be randomly assigned to two groups after informed consent. Assessments of balance, fall risk, walking ability, postural abnormalities, quality of life, and physical activity will be performed before and after the intervention. The intervention group will perform home exercises on non-dialysis days with online supervision by a trainer, and the outcome assessor will be unaware of the patient grouping.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Patients referred to Khorshid Hospital Dialysis Center; age 40-60 years; at least 3 months dialysis history; 3 times weekly hemodialysis; no recent heart attack/stroke; able to communicate; physician permission; exclusion: unstable cardiac status; active infection; unstable blood sugar; unable to exercise; severe musculoskeletal pain; shortness of breath at rest/daily activities

Intervention groups

Intervention group: 12 weeks, 3 sessions/week home exercises (warm-up 5 min, corrective/strength 15-30 min, cool-down 10 min) with synchronous online supervision via WhatsApp; Control group: same exercises via printed booklet without supervision; both groups continue usual care

Main outcome variables

Balance (assessed by Berg Balance Scale); fall risk (assessed by Tinetti Performance-Oriented Mobility Assessment); forward head posture (assessed by craniovertebral angle from digital photography); kyphosis (assessed by spinal angle measurement using a flexible ruler); quality of life; physical activity level; functional status (assessed by six-minute walking test)

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20200819048461N5**
Registration date: **2026-08-08, 1405/05/17**
Registration timing: **prospective**

Last update: **2026-08-08, 1405/05/17**
Update count: **0**

Registration date

2026-08-08, 1405/05/17

Registrant information

Name

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Name of organization / entity

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Recruitment status

recruiting

Funding source

Expected recruitment start date
2026-09-23, 1405/07/01
Expected recruitment end date
2027-02-20, 1405/12/01
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Comparing the effect of home-based synchronous tele-exercise on balance, fall risk, postural abnormalities, quality of life, physical activity level, and functional status in hemodialysis patients

Public title
The effect of home-based synchronous tele-exercise on balance, risk of fall, abnormality of posture, quality of life, level of physical activity and physical function in dialysis patients
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Age between 40 and 60 years At least three months of dialysis history Receiving hemodialysis three times per week No heart attack and stroke in the last three months Ability to communicate with others Doctor's permission for exercise
Exclusion criteria:
Unstable cardiac status (angina, congestive heart failure, severe arterial stenosis, uncontrolled arrhythmias, etc.) Active infection or acute medical disease Individuals with medically diagnosed unstable blood glucose levels (fluctuations between hypoglycemia and hyperglycemia) Unable to exercise (lower limb amputation without prosthesis) Severe musculoskeletal pain at rest or minimal activity Shortness of breath at rest or with daily activities
Age
From **40 years** old to **60 years** old
Gender
Both

Phase
N/A
Groups that have been masked

- Outcome assessor

Sample size
Target sample size: **60**
Randomization (investigator's opinion)
Randomized
Randomization description
A simple random allocation sequence will be generated by an independent person using a random number generator software. Each allocation will be placed in a sequentially numbered, opaque, sealed envelope. After obtaining informed consent, the next envelope will be opened and the patient will be assigned to either the intervention or control group according to its content. Therefore, neither the researcher nor the patient is aware of the group assignment until the envelope is opened.
Blinding (investigator's opinion)
Single blinded
Blinding description
The study is single-blind, and the collaborator who takes the functional tests from the patients and measures postural abnormalities with a flexible ruler and digital photography and completes the questionnaires will not be aware of the patient grouping
Placebo
Not used
Assignment
Parallel
Other design features
This study is a randomized controlled clinical trial with a parallel-group design and blinded outcome assessment. The unique feature of this trial is the comparison of home-based corrective exercise with synchronous online coach supervision in the intervention group versus the same exercise program without online supervision in the control group. Participants will be allocated using simple randomization with concealed allocation through opaque sealed envelopes.

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics Committee of Isfahan University of Medical Sciences
Street address
Isfahan University of Medical Sciences, Hezar Jerib Street, Isfahan, Iran
City
Isfahan
Province
Isfehan
Postal code
8174673461
Approval date
2022-10-22, 1401/07/30
Ethics committee reference number
IR.ARI.MUI.REC.1401.209

Health conditions studied

1

Description of health condition studied
End-stage renal disease requiring hemodialysis
ICD-10 code
N18.6
ICD-10 code description

End stage renal disease

Primary outcomes

1

Description
Balance
Timepoint
Before intervention; after 12 weeks
Method of measurement
Berg Balance Scale (BBS), a 14-item performance-based instrument (e.g., sit-to-stand, unsupported standing, 360° turn, single-leg stance), each item scored 0 (unable) to 4 (independent); total score range 0–56, with lower scores indicating greater balance impairment and fall risk. Administered by a trained, blinded assessor in a clinical setting over approximately 15–20 minutes.

2

Description
Fall risk
Timepoint
Before intervention; after 12 weeks
Method of measurement
Tinetti Performance-Oriented Mobility Assessment (POMA), comprising a balance subscale (9 items, max 16 points) and a gait subscale (7 items, max 12 points); total score 0–28, with <19 indicating high fall risk, 19–23 moderate risk, and ≥24 low risk. Administered via direct observation by an assessor blinded to group allocation.

3

Description
Forward head posture
Timepoint
Before intervention; after 12 weeks
Method of measurement
Craniovertebral angle (CVA) measured from a lateral-view digital photograph taken in natural standing posture; anatomical landmarks (spinous process of C7 and the tragus of the ear) are marked on the skin, and the angle between the horizontal line through the tragus and the line connecting the tragus to the C7 spinous process is calculated using AutoCAD (or equivalent angle-measurement software); a smaller angle indicates greater forward head posture severity (normal typically >50°).

4

Description
Kyphosis
Timepoint
Before intervention; after 12 weeks
Method of measurement
Thoracic kyphosis angle measured using a Flexible Ruler; the ruler is molded over the T1–T12 spinous processes with the patient in natural standing posture and the spinal curve traced onto paper; the kyphosis angle is then calculated from the traced curve using the trigonometric formula Kyphosis Angle = arctan(4H/L), where H is the height of the curve and L is the baseline length; higher values indicate greater kyphotic curvature.

5

Description
Quality of life
Timepoint
Before intervention; after 12 weeks
Method of measurement
Kidney Disease Quality of Life – Short Form (KDQOL-36), comprising the generic SF-12 core plus kidney disease–specific components (symptoms/problems, effects of kidney disease on daily life, burden of kidney disease); each domain is scored 0–100, with higher scores indicating better quality of life. Self-administered by the patient after the dialysis session, with assistance from the research collaborator if needed.

6

Description
Physical activity level
Timepoint
Before intervention; after 12 weeks
Method of measurement
Community Healthy Activities Model Program for Seniors (CHAMPS) questionnaire, covering approximately 41 physical and social activities; participants report frequency and duration of each activity over the past week; output is expressed as estimated weekly caloric expenditure (kcal/kg/week) and weekly hours of moderate-to-vigorous activity, with higher scores indicating greater physical activity. Administered as an interviewer-based questionnaire by a blinded research collaborator.

7

Description
Functional status
Timepoint
Before intervention; after 12 weeks
Method of measurement
Six-Minute Walk Test (6MWT), conducted per the American Thoracic Society (ATS) standard protocol; the patient walks at maximal comfortable pace along a flat 30-meter corridor for 6 minutes, and the total distance covered (in meters) is recorded; a greater distance indicates better functional exercise capacity. Performed on a non-dialysis day by a blinded assessor.

Secondary outcomes

1

Description
Hospitalization
Timepoint
During the study (5 months)
Method of measurement

Number and cause of hospital admissions during the 5-month study period, recorded via a researcher-made checklist based on medical record review and patient self-report at each dialysis session.

2

Description
Mortality
Timepoint
During the study (5 months)
Method of measurement
Recording of mortality cases and cause of death during the 5-month study period, via a researcher-made checklist based on review of the dialysis center's medical records.

Intervention groups

1

Description
Intervention group:Experimental group (with coach supervision): 12 weeks; 3 sessions/week exercise program at home on non-dialysis days with synchronous online supervision by coach via WhatsApp. The exercise program includes: general warm-up (5 minutes), corrective and strength exercises (15 minutes) and general cool-down (10 minutes), with the main exercise body starting at 15 minutes and gradually increasing by adding sets and repetitions to 30 minutes over three months. After each exercise, a 30 to 60 second rest is given to the patient.
Category
Rehabilitation

2

Description
Control group (without supervision): Participants receive the same home exercise program in a printed booklet but perform the exercises independently without synchronous online supervision. Both groups continue to receive usual medical care.
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Khorshid Hospital Dialysis Center
Full name of responsible person
Shahrzad Shahidi
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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
Pardis Specialized Wellness Institute
Proportion provided by this source
100
Public or private sector
Private
Domestic or foreign origin
Domestic
Category of foreign source of funding
empty
Country of origin
Type of organization providing the funding
Persons

Person responsible for general inquiries

Contact
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Web page address

Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is a plan to make this available
Study Protocol
Yes - There is a plan to make this available
Statistical Analysis Plan
Yes - There is a plan to make this available
Informed Consent Form
Yes - There is a plan to make this available
Clinical Study Report
Yes - There is a plan to make this available
Analytic Code
Yes - There is a plan to make this available
Data Dictionary
Yes - There is a plan to make this available
Title and more details about the data/document
The results of the study group are made available
When the data will become available and for how long
After publication of the main results
To whom data/document is available
Only academics are allowed
Under which criteria data/document could be used
If the data is used for the purpose of research in the field of variables and providing new solutions, it can be used by mentioning the source
From where data/document is obtainable
Dr. Mohammad Ali Tabibi via email address m.tabibi@ut.ac.ir
What processes are involved for a request to access data/document
It will be answered within one month after receiving the email
Comments