

Clinical Trial Protocol

Iranian Registry of Clinical Trials

17 Sep 2026

Effectiveness of Stretching Exercises and Leg Massage on the Severity of Restless Legs Syndrome for Hemodialysis Patients

Protocol summary

Study aim

To assess the effectiveness of stretching exercises and leg massage on the severity of restless leg syndrome for hemodialysis patients

Design

Quasi experimental design with Two intervention groups : stretching exercises and leg massage, and one control group, and with 90 sample size with 30 for each of the three groups selected purposively was used to conduct a study that started from 10 October 2022 and ended in May 31 2023, while the data collection specifically started on January 1, 2023 and ended on March 14, 2023

Settings and conduct

Wasit Hemodialysis centers (Al-zahraa Teaching Hospital and Martyr Fairouz Hospital) and Thi-Qar dialysis centers (Al-Nasiriya General Hospital, Al-Refaai General Hospital, and Al-Hussein Teaching Hospital).

Participants/Inclusion and exclusion criteria

Hemodialysis Patients who are above 18 and without infection or injuries in the legs

Intervention groups

Stretching exercises and legs massage and control group

Main outcome variables

Severity of restless legs syndrome

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20221121056569N1**

Registration date: **2023-08-19, 1402/05/28**

Registration timing: **retrospective**

Last update: **2023-08-19, 1402/05/28**

Update count: **0**

Registration date

2023-08-19, 1402/05/28

Registrant information

Name

Samaa Aljasani

Name of organization / entity

The University of Baghdad

Country

Iraq

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Email address

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-01-01, 1401/10/11

Expected recruitment end date

2023-03-14, 1401/12/23

Actual recruitment start date

2023-01-01, 1401/10/11

Actual recruitment end date

2023-03-14, 1401/12/23

Trial completion date

2023-03-14, 1401/12/23

Scientific title

Effectiveness of Stretching Exercises and Leg Massage on the Severity of Restless Legs Syndrome for Hemodialysis Patients

Public title

Effectiveness of Nonpharmacological interventions to Reduce the Severity of Restless Legs Syndrome

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria:

Hemodialysis Adults with restless legs syndrome who are above 18 years old Without any other problems in the legs Stable mental status

Exclusion criteria:
 Patients with restless legs syndrome who are below 18 years old
 Patients with infection or injuries in the leg
 Unstable mental state

Age
 From **18 years** old

Gender
 Female

Phase
 N/A

Groups that have been masked
No information

Sample size
 Target sample size: **90**
 Actual sample size reached: **90**

Randomization (investigator's opinion)
 Not randomized

Randomization description

Blinding (investigator's opinion)
 Not blinded

Blinding description

Placebo
 Used

Assignment
 Other

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Research Ethical Approval committee at the College of Nursing

Street address

Bab Al-Muadum

City

Baghdad

Postal code

10001

Approval date

2022-10-10, 1401/07/18

Ethics committee reference number

2395

Health conditions studied

1

Description of health condition studied

Restless legs syndrome patients who have an urgent desire to move their legs in order to acquire slight relief

ICD-10 code

G25.81

ICD-10 code description

Restless legs syndrome

Primary outcomes

1

Description

Severity of restless legs syndrome

Timepoint

before intervention, and 1, 2 weeks after intervention

Method of measurement

International restless legs syndrome study group rating scale

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group 1: this intervention group received pretest then stretching exercises three times a week and for two weeks then a posttest at the end of the first week and second posttest at the end of the second week

Category

Other

2

Description

Intervention group 2: this intervention group received pretest then leg massage three times a week then a first posttest at the end of the first week then a second posttest at the end of the second week.

Category

Other

3

Description

Control group: group 3: received no intervention

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

AL-Zahra Teaching Hospital

Full name of responsible person

samaa ali zhamis

Street address

alzahra

City

Wasit

Postal code

52001

Phone

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Email
samaa.ali2102m@conursing.uobaghdad.edu.iq
Web page address

2

Recruitment center

Name of recruitment center
Martyr Fairouz Hospital
Full name of responsible person
Prof. Dr. Wissam Jabbar Qasim
Street address
Al-Hay
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3

Recruitment center

Name of recruitment center
AL-Refaai General Hospital
Full name of responsible person
samaa ali zhamis
Street address
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64001
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4

Recruitment center

Name of recruitment center
Al-Hussein Teaching Hospital
Full name of responsible person
samaa ali zhamis
Street address
Alnasriya
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5

Recruitment center

Name of recruitment center
Al-Nasriya General Hospital

Full name of responsible person
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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
College of Nursing/University of Baghdad
Full name of responsible person
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Bab Al-Muadum
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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
College of Nursing/University of Baghdad
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
College of Nursing/University of Baghdad
Full name of responsible person
Prof. Dr. Wissam Jabbar Qasim
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**

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Person responsible for updating data**Contact****Name of organization / entity**

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Latest degree

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Other areas of specialty/work

Nursery

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Sharing plan**Deidentified Individual Participant Data Set (IPD)**

Yes - There is 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

Yes - There is 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

Title and more details about the data/document

The researcher will share the primary outcomes for the effectiveness of stretching exercises and leg massage on the severity of restless legs syndrome in the form of tables

When the data will become available and for how long

God willing, once finishing the process of data collection, analysis, and successfully publishing the manuscript, all the related files will become available for 6 months after publications

To whom data/document is available

Researchers

Under which criteria data/document could be used

it may be used after seeking the author's permission and acknowledging her contribution

From where data/document is obtainable

the official email of samaa ali which is (samaa.ali2102m@conursing.uobaghdad.edu.iq)

What processes are involved for a request to access data/document

Just mailing the author as the email will be in the published article

Comments

Nothing