Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 2026

Tele exercise for patients with failed back surgery syndrome: Randomized clinical trial

Protocol summary

Study aim

Determining the effectiveness of the researcher made exercises and Williams on pain intensity, quality of life and range of motion of the back after 4 and 8 weeks in patients with failed back surgery syndrome.

Design

The clinical trial has a control group, with parallel groups, a blind strain, randomized, simple method is used for randomization.

Settings and conduct

The first session will be in person at the Neuroscience Clinic of Khatam Hospital, all exercises will be explained and taught, and then the sessions will continue at home. Also, the objectives are fully explained. For the purpose of blinding, all measurements are performed by a physiotherapist who is not aware of the placement of people in the 2 groups.

Participants/Inclusion and exclusion criteria

164 patients (age< 65 years) who has failed back surgery syndrome and have been referred by a surgeon to a pain specialist in Khatam al-Anbia Hospital and do not have surgical problems are selected, and after performing initial evaluations, they are randomly selected (simple randomization) are placed in two groups of 82 subjects. Patients are initially screened for symptoms of failed back surgery syndrome, including pain in the back, neck, or legs. Additionally, screen patients for RED FLAGS, including excessive mechanical pain that may indicate pseudarthrosis or nonunion, that may indicate infectious spine problems.

Intervention groups

In the intervention group, each exercise should be performed 3 times a day for 4 weeks for 20 sets with a set duration of 10 seconds (for each leg/arm). The intervention group has three exercises defined by a pain specialist, including Hip abduction exercise, Shoulder abduction and concurrent hip and shoulder abduction exercise.

Main outcome variables

Pain intensity (Numeric Pain Rating Scale); Health-related quality of life; Lumbar range of motion (bending forward and backward).

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20240608062042N1**
Registration date: **2024-07-09, 1403/04/19**
Registration timing: **registered_while_recruiting**

Last update: **2024-07-09, 1403/04/19**
Update count: **0**

Registration date

2024-07-09, 1403/04/19

Registrant information

Name
Ardalan Shariat
Name of organization / entity
Country
Iran (Islamic Republic of)
Phone
+98 939 861 4772
Email address
ardalansh2002@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2024-07-09, 1403/04/19

Expected recruitment end date

2025-07-10, 1404/04/19

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Tele exercise for patients with failed back surgery syndrome: Randomized clinical trial

Public title

Teleexercise for failed back surgery syndrome

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Age: <65 years old Patients with failed back surgery syndrome They have been referred by a surgeon to a pain specialist in Khatam al-Anbia Hospital.

Exclusion criteria:

Lack of ability to do the exercises. Lack of intention for participation. Having red flags.

Age

To **65 years** old

Gender

Both

Phase

N/A

Groups that have been masked

- Outcome assessor
- Data analyser

Sample size

Target sample size: **164**

Randomization (investigator's opinion)

Randomized

Randomization description

Simple randomization: Using random numbers generated by Google, subjects will be divided into intervention group (doing researcher-made exercises) and control group (doing Williams exercises) with equal numbers and subjects have equal chance to choose. It was agreed from the beginning that the intervention group will be given odd numbers and the control group will be given even numbers. In the random numbers generated by Google, the minimum defined number is 1 and the maximum is set to 164. At the time of using this program, the person who is going to do this process is not aware of the distribution of subjects in these two groups and will not participate in any other phase of the research.

Blinding (investigator's opinion)

Single blinded

Blinding description

Investigator is blind about the randomization.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Tehran University of Medical Sciences

Street address

Tehran University Of Medical Sciences

City

Tehran

Province

Tehran

Postal code

1936893813

Approval date

2024-05-28, 1403/03/08

Ethics committee reference number

IR.TUMS.MEDICINE.REC.1403.108

Health conditions studied

1

Description of health condition studied

Failed back surgery syndrome

ICD-10 code

M54.5

ICD-10 code description

Low back pain

Primary outcomes

1

Description

Range of motion

Timepoint

Before intervention and 1, 2 months after intervention

Method of measurement

Modified-modified Schober Test

2

Description

Pain intensity

Timepoint

Before intervention and 1, 2 months after intervention

Method of measurement

Numeric Pain Rating Scale

3

Description

Quality of life

Timepoint

Before intervention and 1, 2 months after intervention

Method of measurement

Health-related quality of life

Secondary outcomes

1

Description
Clinical changes
Timepoint
Before intervention and after 1 and 2 month.
Method of measurement
MRI

Intervention groups

1

Description
Intervention group: distance exercises. After 1-2 face-to-face training sessions, a face-to-face visit is performed, ideally with the patient's caregiver or companion, who may later assist the patient with FBSS at home. Then an educational video and poster is sent electronically to the patient and his companion can assist in viewing. After this, remote exercise sessions will begin. The participation of the therapist during the video therapy sessions allows for appropriate intervention and feedback to ensure that the patient performs the exercises safely and effectively. Then the online sessions can continue, focusing on the gradual transition of the patient to perform the exercises alone or with the help of a companion at home. In the intervention group, each exercise should be performed 3 times a day for 4 weeks for 20 sets with a set duration of 10 seconds. (for each leg/hand) The intervention group will perform three exercises defined by the pain specialist, including Hip abduction exercise, Shoulder abduction exercise, and Hip and shoulder abduction exercise.
Category
Treatment - Other

2

Description
The control group will only do Williams exercises. The first session, with movement training, will be attended at the pain clinic of Khatam Hospital in Tehran, and pamphlets and videos on the correct way to perform movements will be provided to the patients. Movements are performed at home for 4 weeks, and after 4 weeks, re-evaluations will be done in person, then to monitor the patient, the patient will perform the movements at home for another 4 weeks (according to the previous instructions) and will be re-evaluated. While a companion is essential for these exercises, we will demonstrate these routines through an online consultation.
Category
Treatment - Other

Recruitment centers

1

Recruitment center
Name of recruitment center
Khatammanbia hospital
Full name of responsible person
Dr.Reza Alizadeh
Street address
Tehran Province, Tehran، Rashid Yasemi Street، Upper than Mirdamad St.، Vali- Asr St.، QC95+J5G
City
Tehran
Province
Tehran
Postal code
1456887157
Phone
+98 21 8888 4040
Email
ardalansh2002@gmail.com

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Tehran University of Medical Sciences
Full name of responsible person
Ardalan Shariat
Street address
Tehran University Of Medical Sciences
City
Tehran
Province
Tehran
Postal code
1936893813
Phone
+98 939 861 4772
Email
ardalansh2002@gmail.com
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Tehran 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

Tehran University of Medical Sciences

Full name of responsible person
Ardalan Shariat

Position
Assistant Professor

Latest degree
Ph.D.

Other areas of specialty/work
Telehealth

Street address
Tehran University Of Medical Sciences

City
Tehran

Province
Tehran

Postal code
1936893813

Phone
+98 939 861 4772

Email
ardalansh2002@gmail.com

Person responsible for scientific inquiries

Contact

Name of organization / entity
Tehran University of Medical Sciences

Full name of responsible person
Ardalan Shariat

Position
Assistant Professor

Latest degree
Ph.D.

Other areas of specialty/work
Telehealth

Street address
Tehran University Of Medical Sciences

City
Tehran

Province
Tehran

Postal code
1936893813

Phone
+98 939 861 4772

Email
ardalansh2002@gmail.com

Person responsible for updating data

Contact

Name of organization / entity
Tehran University of Medical Sciences

Full name of responsible person
Ardalan Shariat

Position
Assistant Professor

Latest degree
Ph.D.

Other areas of specialty/work
Telehealth

Street address
Tehran University Of Medical Sciences

City
Tehran

Province
Tehran

Postal code
1936893813

Phone
+98 939 861 4772

Fax

Email
ardalansh2002@gmail.com

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
No more data.

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
No - There is not a plan to make this available

Clinical Study Report
Yes - There is 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
No - There is not a plan to make this available

Title and more details about the data/document
All the data will be shared after removing identification details of participants. We will publish the results as a scientific article without any name from participants.

When the data will become available and for how long
After finish the study, results will be published and will be available permanently.

To whom data/document is available
Data is only available for people working in academic institutions.

Under which criteria data/document could be used
For academic purpose.

From where data/document is obtainable
Ardalansh2002@gmail.com Dr.Ardalan Shariat

What processes are involved for a request to access data/document
Contact me using email.

Comments