Clinical Trial Protocol
Iranian Registry of Clinical Trials

26 May 2026

Evaluation of multimedia mobile application effects on patients with Thoracic Outlet Syndrome and Low Back Pain comparing with control group - a randomized controlled trial

Protocol summary

Study aim

Designing, implementing and evaluating a multimedia application for patients with Thoracic Outlet Syndrome and low back pain.

Design

This study is a randomized trial with intervention and control groups, that will be performed as a parallel method. The application will be installed on 88 patients' smartphones suffering from low back pain or thoracic outlet syndrome and the improvement of symptoms will be measured after a certain period of time compared to the control group.

Settings and conduct

This study will be performed on patients with low back pain and thoracic outlet syndrome. analyzer and patients will be blind. The study sampling will be performed in Khatam Al Anbia medical center.

Participants/Inclusion and exclusion criteria

Inclusion criteria: 1- Minimum age 18 and maximum age 65 years 2-Participants should have low back pain or thoracic outlet syndrome 3. Patients in the intervention group should have a smartphone 4. Patients in the intervention group should have the ability to work with the smartphone Exclusion criteria: 1- If the patient has additional disease 2. The patient has had surgery on the back or shoulder and neck in the last 6 months

Intervention groups

44 patients with Thoracic Outlet Syndrome will be allocated to the intervention group 44 patients with Thoracic Outlet Syndrome will be allocated to the control group 44 patients with low back pain will be allocated to the intervention group 44 patients with low back pain will be allocated to the control group

Main outcome variables

Disability questionnaire for patients with TOS; EAST test; Roland-Morris Questionnaire; Pain severity

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20141221020380N3**
Registration date: **2018-07-14, 1397/04/23**
Registration timing: **prospective**

Last update: **2019-05-23, 1398/03/02**
Update count: **2**

Registration date

2018-07-14, 1397/04/23

Registrant information

Name

Afshin Sarafinejad

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 34 3261 5849

Email address

asarafinejad@kmu.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-04-01, 1398/01/12

Expected recruitment end date

2019-07-15, 1398/04/24

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title
Evaluation of multimedia mobile application effects on patients with Thoracic Outlet Syndrome and Low Back Pain comparing with control group - a randomized controlled trial

Public title
Evaluation of a multimedia app for patients with Thoracic Outlet Syndrome and Low Back Pain

Purpose
Supportive

Inclusion/Exclusion criteria

Inclusion criteria:
People's willingness to complete the questionnaire and use the software The patient has an adequate level of cognitive and physical literacy familiar with how the smartphone works.

Exclusion criteria:
Patients with any other illness will exclude from the study

Age
From **18 years** old to **65 years** old

Gender
Both

Phase
3

Groups that have been masked

- Participant
- Data analyser

Sample size
Target sample size: **176**

Randomization (investigator's opinion)
Randomized

Randomization description
In this study, simple randomization method will be used based on random number table.

Blinding (investigator's opinion)
Double blinded

Blinding description
The participants do not know in which group, intervention or control, will be allocated. The data analyst does not know which patient will be allocated to intervention or control groups.

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics committee of Kerman University of Medical Sciences

Street address
Seven Alavi Gardens, Kerman University of Medical Sciences

City
Kerman

Province
Kerman

Postal code
7616913555

Approval date
2018-04-29, 1397/02/09

Ethics committee reference number
IR.KMU.REC.1397.036

Health conditions studied

1

Description of health condition studied
low back pain

ICD-10 code
M54.5

ICD-10 code description
Low back pain

2

Description of health condition studied
thoracic outlet syndrome

ICD-10 code
G54.0

ICD-10 code description
Brachial plexus disorders

Primary outcomes

1

Description
The Severity of Pain

Timepoint
At the beginning of the study (before the intervention) and 6 weeks after the intervention (use of the application)

Method of measurement
Numeric Rating Scale

2

Description
EAST Test

Timepoint
At the beginning of the study (before the intervention) and 6 weeks after the intervention (use of the application)

Method of measurement
By specialist: Record the amount of time a patient can hold his/her hands above the head

3

Description

Disability of Low Back Pain Patients

Timepoint

At the beginning of the study (before the intervention) and 6 weeks after the intervention (use of the application)

Method of measurement

Roland Morris Disability Questionnaire

4

Description

Thoracic Outlet Syndrome Disability Questionnaire

Timepoint

At the beginning of the study (before the intervention) and 6 weeks after the intervention (use of the application)

Method of measurement

Questionnaire

Secondary outcomes

empty

Intervention groups

1

Description

Intervention Group: In the intervention group, the application install on the patient's mobile phone and the patient uses the application for 6 weeks.

Category

Rehabilitation

2

Description

Control Group: This group does not install the app and continue normal treatment

Category

Rehabilitation

Recruitment centers

1

Recruitment center

Name of recruitment center

Khatam Al Anbia Physicians' Building.

Full name of responsible person

Mohammad Naeim Ahrari

Street address

Shariati Street, near to Tahmasb-Abad Cross.

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Kerman University of Medical Sciences

Full name of responsible person

Abbas Pardakhty

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Kerman University of Medical Sciences, Medical University Campus,Haft-Bagh Highway, Kerman, Iran

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Email

abpardakhty@kmu.ac.ir

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Kerman University of Medical Sciences

Proportion provided by this source

80

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

2

Sponsor

Name of organization / entity

شرکت پژوهشگران داده پرداز ابن سینا حکیم

Full name of responsible person

افشین صرافی نژاد

Street address

Pezeshk Blvd.

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Province

Kerman

Postal code

7618447951

Phone

+98 34 3261 5849

Email
a.sarafi@gmail.com
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
شرکت پژوهشگران داده پرداز ابن سینا حکیم
Proportion provided by this source
20
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
Name of organization / entity
Kerman University of Medical Sciences
Full name of responsible person
Saeideh Goharinejad
Position
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Medical Informatics
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Person responsible for updating data

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Position
MSc. Student
Latest degree
Bachelor
Other areas of specialty/work
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Postal code
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gohari.2490@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
To get the required permission from the patient and/or physician
Study Protocol
Yes - There is a plan to make this available
Statistical Analysis Plan
Not applicable
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
No - There is not 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
We will publish a scientific paper about main outcome
When the data will become available and for how

long

Access to information about the main outcome will be postponed until publication of articles

To whom data/document is available

The data will be available under certain condition to people who need them, after accepting and publishing the main article

Under which criteria data/document could be used

Part of data can be used for scientific and research purposes and as a valid document for screening and related executing jobs.

From where data/document is obtainable

Published articles will be available through journals.

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

People can access to articles through journal subscriptions.

Comments