

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

17 Jun 2026

### Evaluating the efficacy of Telerehabilitation in comparison to conventional physiotherapy on pain and quality of life of patients with mechanical neck pain

#### Protocol summary

##### Study aim

The aim of this study was to evaluate the effectiveness of remote rehabilitation on pain and quality of life in patients with mechanical neck pain and compare it with conventional physiotherapy.

##### Design

Patients with randomization by Block Randomization method in one of the two groups are treated with physiotherapy in the clinic or physiotherapy through APP. A questionnaire including demographic information, VAS, NDI, SF-12 criteria will be completed by patients and the range of active neck movement will be measured by a goniometer. Patients are evaluated according to the mentioned criteria before the intervention, one month and three months after the start of treatment.

##### Settings and conduct

This interventional study is performed as a clinical trial in patients with mechanical neck pain who are referred to Imam Reza Hospital in Tehran.

##### Participants/Inclusion and exclusion criteria

Inclusion criteria include patients in the age range of 25 to 60 years who have had pain for more than 6 weeks and have been diagnosed with mechanical neck pain, their VAS level is between 3 and 8 and have a phone with Android operating system. Been. Patients who have undergone treatment or other surgery within three months or whose neck pain is due to a known trauma or is a sign of radiculopathy, paresthesia, focal neurological symptoms or danger signs are excluded from the study.

##### Intervention groups

neck muscle stretching exercises and strengthening exercises with emphasis on core stabilizer muscles and endurance exercises were considered. The APP group receives the exercises in the form of a video through the software, The physiotherapy group in the clinic also receives oral and written exercises after a routine cervical physiotherapy course.

#### Main outcome variables

VAS score, NDI, SF-12

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20201007048959N1**

Registration date: **2021-03-01, 1399/12/11**

Registration timing: **registered\_while\_recruiting**

Last update: **2021-03-01, 1399/12/11**

Update count: **0**

##### Registration date

2021-03-01, 1399/12/11

##### Registrant information

##### Name

Seyed Morteza Tabatabaee

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 21 4424 7340

##### Email address

smt.1368@ajaums.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2020-11-15, 1399/08/25

##### Expected recruitment end date

2021-11-16, 1400/08/25

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty  
**Trial completion date**  
empty

**Scientific title**  
Evaluating the efficacy of Telerehabilitation in comparison to conventional physiotherapy on pain and quality of life of patients with mechanical neck pain

**Public title**  
Evaluating the efficacy of Telerehabilitation in patients with mechanical neck pain

**Purpose**  
Treatment

**Inclusion/Exclusion criteria**  
**Inclusion criteria:**  
They have been in pain for more than 6 weeks and have been diagnosed with mechanical neck pain VAS score between 3 and 8 cellphone with Android operating system capable of using smartphone

**Exclusion criteria:**  
Have another treatment or surgery within three months  
Their neck pain is due to a known trauma or symptoms of radiculopathy, paresthesia, focal neurological symptoms red flags such as weight loss, trauma, fever, night sweats, night pain, a history of tuberculosis infections, HIV, cancer, inflammatory diseases, and spinal tenderness

**Age**  
From **25 years** old to **60 years** old

**Gender**  
Both

**Phase**  
N/A

**Groups that have been masked**  
*No information*

**Sample size**  
Target sample size: **50**

**Randomization (investigator's opinion)**  
Randomized

**Randomization description**  
For random allocating of two groups with the same size of 25 participants (50 patients in total) we used block randomization with different block sizes. The sizes of blocks would be a multiple of 2 and a divisor of 40 (2,4,8). At first, the block sizes were selected randomly. Then, for each block, different permutations for equal group size were determined. Finally, one of the permutations was selected randomly. Random numbers were generated in an independent statistical office using Random allocation software.

**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

AJA University of Medical Sciences

##### Street address

Imam Reza hospital, Etemad zade street, Fatemi street

##### City

Tehran

##### Province

Tehran

##### Postal code

1411718546

#### Approval date

2020-11-15, 1399/08/25

#### Ethics committee reference number

IR.AJAUMS.REC.1399.148

## Health conditions studied

### 1

#### Description of health condition studied

Mechanical neck pain

#### ICD-10 code

M54.2

#### ICD-10 code description

Cervicalgia

## Primary outcomes

### 1

#### Description

pain Visual Analogue Scale

#### Timepoint

0, 1, 3 months after intervention

#### Method of measurement

10-point visual analogue scale

### 2

#### Description

disability Visual Analogue Scale

#### Timepoint

0, 1, 3 months after intervention

#### Method of measurement

10-point visual analogue scale

### 3

#### Description

Neck Disability Index score

#### Timepoint

0, 1, 3 months after intervention

## Method of measurement

Based on the Neck Disability Index questionnaire to assess a person's inability to neck pain

## 4

### Description

12-Item Short Form Survey score

### Timepoint

0, 1, 3 months after intervention

### Method of measurement

Based on a questionnaire to assess general health in the last 4 weeks in 8 areas

## Secondary outcomes

empty

## Intervention groups

## 1

### Description

Intervention group: The group that uses the APP receives the exercises in the form of a video through the software, and the software repeatedly reminds the patient to do the exercises. The software also has the feature that the patient communicates with the therapist in video or audio or text and expresses his problems with the therapist.

### Category

Treatment - Other

## 2

### Description

Control group: The physiotherapy group in the clinic also receives oral and written exercises after a routine cervical physiotherapy course.

### Category

Treatment - Other

## Recruitment centers

## 1

### Recruitment center

#### Name of recruitment center

Imam Reza Hospital in Tehran

#### Full name of responsible person

Seyed Morteza Tabatabaee

#### Street address

No 50, 4th Golestan alley, Nahid street, Marzadaran blv

#### City

Tehran

#### Province

Tehran

#### Postal code

1461643744

#### Phone

+98 21 4424 7340

#### Email

Smt.1368@gmail.com

## Sponsors / Funding sources

## 1

### Sponsor

#### Name of organization / entity

Artesh University of Medical Sciences

#### Full name of responsible person

Mojtaba Yousefi Zashk

#### Street address

AJA university, Etemad zade street, Fatemi street

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#### Phone

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#### Email

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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

Artesh 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

Artesh University of Medical Sciences

#### Full name of responsible person

Seyed Morteza Tabatabaee

#### Position

resident

#### Latest degree

Medical doctor

#### Other areas of specialty/work

Physical Medicine

#### Street address

Imam Reza hospital, Etemad zade street, Fatemi street

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Tehran

#### Province

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## Person responsible for scientific inquiries

### Contact

**Name of organization / entity**  
Artesh University of Medical Sciences  
**Full name of responsible person**  
Seyed Morteza Tabatabaee  
**Position**  
resident  
**Latest degree**  
Medical doctor  
**Other areas of specialty/work**  
Physical Medicine  
**Street address**  
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## Person responsible for updating data

### Contact

**Name of organization / entity**  
Artesh University of Medical Sciences  
**Full name of responsible person**  
Seyed Morteza Tabatabaee

**Position**  
resident  
**Latest degree**  
Medical doctor  
**Other areas of specialty/work**  
Physical Medicine  
**Street address**  
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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