

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

02 Jul 2026

### Evaluating the efficacy of therapeutic exercises and trigger points dry needling in patients with forward head posture

#### Protocol summary

##### Study aim

The aim of this study will be to compare effectiveness of exercise therapy and and trigger points dry needling on neck and shoulder angle, pain intensity and quality of life of patients.

##### Design

The study is a phase 3 clinical trial that will be performed on 60 patients. Patients will be randomly assigned to two groups of exercise therapy and Dry Needling using the envelope method.

##### Settings and conduct

This study will be performed as a single (blindness evaluator of intervention outcome) in Besat Hospital in Hamadan.

##### Participants/Inclusion and exclusion criteria

Participants in the study will be patients aged 14 to 65 years with with forward head posture that will be diagnosed based on clinical criteria. comorbidity with other musculoskeletal diseases, spinal diseases, neurological and motor diseases, history of shoulder surgery and vascular diseases are the exclusion criteria.

##### Intervention groups

Intervention: Patients in the exercise therapy group will be under the supervision of the therapist, twice a week for 20 minutes (three stretching exercises and four strength exercises). To increase patients' resistance, all exercises are started lightly, including 2 sets of 15, and gradually the intensity, number of sets and repetition of movements will be increasing. The second group of Dry Needling trigger points (TrPs) will be performed. The neck and shoulder girdle muscles will first be evaluated by a specialist with experience in finding TrPs. Dry Needling is performing on a bed in a quiet room for 10 minutes by inserting an acupuncture needle 0.3 mm in diameter and 50 mm long into the TrPs. Needle is raised and lowered 3 to 5 times and then removed. As with the exercise therapy group, treatment sessions in this group are twice a week for 12 weeks

##### Main outcome variables

The outcomes of the intervention include changes in neck and shoulder angle, pain score and quality of life of patients.

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20151123025202N17**

Registration date: **2021-07-17, 1400/04/26**

Registration timing: **prospective**

Last update: **2021-07-17, 1400/04/26**

Update count: **0**

##### Registration date

2021-07-17, 1400/04/26

##### Registrant information

##### Name

Abbas Moradi

##### Name of organization / entity

Hamedan University of Medical Of Science

##### Country

Iran (Islamic Republic of)

##### Phone

+98 81 3838 0097

##### Email address

a.moradi@umsha.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2021-08-06, 1400/05/15

##### Expected recruitment end date

2022-02-04, 1400/11/15

##### Actual recruitment start date

empty

**Actual recruitment end date**

empty

**Trial completion date**

empty

**Scientific title**

Evaluating the efficacy of therapeutic exercises and trigger points dry needling in patients with forward head posture

**Public title**

Treatment of forward head posture

**Purpose**

Treatment

**Inclusion/Exclusion criteria****Inclusion criteria:**

Diagnosis of forward head posture abnormalities according to clinical criteria Age 65-14 years

**Exclusion criteria:**

Comorbidity of other musculoskeletal diseases, spinal diseases, neurological and motor diseases History of shoulder surgery Vascular diseases

**Age**

From **14 years** old to **65 years** old

**Gender**

Both

**Phase**

3

**Groups that have been masked**

- Outcome assessor

**Sample size**

Target sample size: **60**

**Randomization (investigator's opinion)**

Randomized

**Randomization description**

We made 60 cards and write letter V on 30 for Intervention and on the other 30 letter D for the control group. Then put them inside the envelope with aluminum wrap and put in a box. At the time of patient arrival, one of the envelopes randomly will be selected and will be opened, based on selected letter V or D patients will be assigned to exercises therapy or dry needling group. The sampling process will be continues until all the cards are selected

**Blinding (investigator's opinion)**

Single blinded

**Blinding description**

In this study, the person evaluating the angle of head, neck and shoulders in the image taken by digital camera and analyzed computer software, pain score of patients with visual analog scale and quality of life of patients with SF-12 scale will be blinded regarding to intervention groups .

**Placebo**

Not used

**Assignment**

Parallel

**Other design features****Secondary Ids**

empty

**Ethics committees****1****Ethics committee****Name of ethics committee**

Ethics committee of Hamadan University of Medical Science

**Street address**

Shahid Fahmideh Ave

**City**

Hamadan

**Province**

Hamadan

**Postal code**

6517838697

**Approval date**

2021-01-30, 1399/11/11

**Ethics committee reference number**

IR.UMSHA.REC.1399.924

**Health conditions studied****1****Description of health condition studied**

forward head posture

**ICD-10 code**

M95.9

**ICD-10 code description**

Acquired deformity of musculoskeletal system, unspecified

**Primary outcomes****1****Description**

Changes neck and shoulder angle

**Timepoint**

Before the intervention and at the end of week 12 of the intervention

**Method of measurement**

Taking a photo of the profile of the body, analysis with a computer

**2****Description**

Pain severity

**Timepoint**

Before the intervention and at the end of week 12 of the intervention

**Method of measurement**

Visual Analogues Scale

## Secondary outcomes

### 1

#### Description

Quality of life associated with forward head posture

#### Timepoint

Before and 12 weeks after the intervention

#### Method of measurement

Questionnaire SF-12

## Intervention groups

### 1

#### Description

Intervention group: The duration of treatment in this study will be 3 months (12 weeks). Exercise therapy sessions will be performed twice a week for 20 minutes under the supervision of a therapist. The exercise therapy protocol will include three stretching exercises and four strength exercises aimed at correcting the condition of the neck and shoulders position. Strength training is designed for rotator cuff activity, minor fear, infra-spinatus, scapular stabilizing muscles (upper and lower trapezius), rhomboids, and deep neck flexors. Stretching exercises are designed to stretch the shortened pectoralis minor muscles and the SCM neck muscles and the scapula lift. The exercise program is performed under the direct supervision of the therapist to ensure the correctness of the exercises. To increase patients' resistance, all exercises are started lightly, including 2 sets of 15, and gradually increase the intensity, number of sets and repetition of movements. The average duration of exercise will be 20 minutes and the exercise sequence is random.

#### Category

Rehabilitation

### 2

#### Description

Intervention group: For patients in the Dry Needling group of trigger points (TrPs), the neck and shoulder girdle muscles, including the trapezius, SCM, sub-occipital, scapula, scale, pectoralis major, and infra-spinatus muscles, will first be evaluated by a experienced specialist to finding TrPs. . The identified TrPs are marked for each patient in an anatomical shape. For Dry Needling, patients will be asked to lie in a comfortable bed in a quiet room for 10 minutes. Dry Needling is then performed by inserting an acupuncture needle 0.3 mm in diameter and 50 mm in length into the identified TrPs. The needle is raised and lowered for 3-5 times and then removed. As in the exercise therapy group, treatment sessions in this group will be twice a week for 12 weeks.

#### Category

Treatment - Devices

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

Besat Hospital

##### Full name of responsible person

Lobat Majidi

##### Street address

Shahid Beheshti Blv

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Hamedan

##### Province

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6514845411

##### Phone

+98 81 3264 0020

##### Email

besat@umsha.ac.ir

## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

Hamedan University of Medical Sciences

##### Full name of responsible person

Saeid Bashirian

##### Street address

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##### Email

vc\_research@umsha.ac.ir

##### Web page address

##### Grant name

##### Grant code / Reference number

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

Yes

##### Title of funding source

Hamedan 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

**Email**

lobat.majidi@gmail.com

**Person responsible for general inquiries****Contact****Name of organization / entity**

Hamedan University of Medical Sciences

**Full name of responsible person**

Abbas Moradi

**Position**

Coach

**Latest degree**

Master

**Other areas of specialty/work**

Epidemiology

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Physical Medicine

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**Full name of responsible person**

Abbas Moradi

**Position**

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**Latest degree**

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**Other areas of specialty/work**

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**Web page address****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