The effect of adding Temporomandibular joint manual therapy to routine physiotherapy on the improvement of patients with non-specific chronic neck pain

Protocol summary

Summary
The aim of this study is to evaluate the effect of adding Temporomandibular joint manual therapy to routine physiotherapy on the improvement of patients with non-specific chronic neck pain. This is an experimental study and interventional clinical trial that is randomized, parallel and double-blind. For inclusion, people with non-specific chronic neck pain, which they are also suffering from the Temporomandibular joint disorders have to be present. In this case, there are pain and limitations in range of motion of the Temporomandibular joint and pain and tenderness in at least two related muscles. Patients with neurological disorders, absence of pain in the Temporomandibular joint, malignancy and infection and acute muscle trauma were excluded. The number of 20 was determined for each group. Initially, patients will randomly divided into two groups: group A (They will receive routine physiotherapy treatments for neck pain) and group B (They will receive Temporomandibular joint manual therapy in addition to routine physiotherapy treatments for neck pain). Then both groups will receive their treatments in six sessions for two days a week over a period of 21 days. In order to evaluate the effects of intervention, we will use the visual analogue scale of pain, neck disability index and the range of motion of neck without pain. The assessments for all patients will take place at the first session, at the last session and one month after treatment as follow-up.

General information

Acronym
IRCT registration information
IRCT registration number: IRCT2017012732221N1
Registration date: 2017-02-13, 1395/11/25
Registration timing: registered_while_recruiting

Last update:
Update count: 0
Registration date
2017-02-13, 1395/11/25
Registrant information
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Recruitment status
Recruitment complete
Funding source
University of Social Welfare and Rehabilitation Sciences

Expected recruitment start date
2017-01-03, 1395/10/14
Expected recruitment end date
2017-02-16, 1395/11/28
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
The effect of adding Temporomandibular joint manual therapy to routine physiotherapy on the improvement of patients with non-specific chronic neck pain

Public title
The effect of Temporomandibular joint manual therapy on the improvement of patients with non-specific chronic neck pain

**Purpose**
Treatment

**Inclusion/Exclusion criteria**
Inclusion criteria: People with non-specific chronic neck pain, which they are also suffering from the Temporomandibular joint disorders. In this case, there are the pain and limitations in range of motion of the Temporomandibular joint and pain and tenderness in at least two related muscles. Exclusion criteria: Neurological disorders; Absence of pain in the Temporomandibular joint; Malignancy and infection; Acute muscle trauma

**Age**
From **18 years** old to **55 years** old

**Gender**
Both

**Phase**
N/A

**Groups that have been masked**
No information

**Sample size**
Target sample size: **40**

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

**Randomization description**

**Blinding (investigator's opinion)**
Double blinded

**Blinding description**

**Placebo**
Not used

**Assignment**
Parallel

**Other design features**

**Secondary Ids**
empty

**Ethics committees**

1

**Ethics committee**
Name of ethics committee
The University of Social Welfare and Rehabilitation Sciences (USWRS)

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kodafone Ave., Daneshjo Blvd.,Evin

City
Tehran

Postal code
1985713834

Approval date
2017-01-02, 1395/10/13

Ethics committee reference number
IR.uswr.rec.1395.355

**Health conditions studied**

1

**Description of health condition studied**
Temporomandibular joint disorders

**ICD-10 code**
K07.6

**ICD-10 code description**
Temporomandibular joint disorders

2

**Description of health condition studied**
non-specific chronic neck pain

**ICD-10 code**
R52.2

**ICD-10 code description**
Other chronic pain

**Primary outcomes**

1

**Description**
Neck disability index (NDI)

**Timepoint**
At the first session, at the last session and one month after

**Method of measurement**
Neck disability index (NDI)

2

**Description**
The pain

**Timepoint**
At the first session, at the last session and one month after

**Method of measurement**
Visual Analogue Scale(VAS)

3

**Description**
The range of motion of neck flexion

**Timepoint**
At the first session, at the last session and one month after

**Method of measurement**
Goniometer

4

**Description**
The range of motion of neck extention

**Timepoint**
At the first session, at the last session and one month after

**Method of measurement**
Goniometer
5
Description
The range of motion of neck side bending

Timepoint
At the first session, at the last session and one month after

Method of measurement
Goniometer

6
Description
The range of motion of neck rotation

Timepoint
At the first session, at the last session and one month after

Method of measurement
Goniometer

Secondary outcomes

1
Description
General questionnaire

Timepoint
At the first assessment session

Method of measurement
questionnaire

Intervention groups

1
Description
Common physical therapy treatment interventions for neck pain, which is the same for both groups, include the following: Soft tissue release, muscle energy techniques and exercise therapy

Category
Rehabilitation

2
Description
In the intervention group, manual therapy of the temporomandibular joint includes the following: Muscle energy techniques, mobilization and tongue movements and related training in the TMJ

Category
Rehabilitation

Recruitment centers

1
Recruitment center
Name of recruitment center
University of Social Welfare and Rehabilitation Sciences

Full name of responsible person

Sponsors / Funding sources

1
Sponsor

Name of organization / entity
The University of Social Welfare and Rehabilitation Sciences (USWRS)

Full name of responsible person
Negar Akhavan

Street address
kodakyar Ave., daneshjo Blvd., Evin, Tehran, Iran

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Tehran

Grant name

Grant code / Reference number

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

Title of funding source
The University of Social Welfare and Rehabilitation Sciences (USWRS)

Proportion provided by this source
100

Public or private sector
empty

Domestic or foreign origin
empty

Category of foreign source of funding
empty

Country of origin

Type of organization providing the funding
empty

Person responsible for general inquiries

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Sharing plan
Deidentified Individual Participant Data Set (IPD)
empty
Study Protocol
empty
Statistical Analysis Plan
empty
Informed Consent Form
empty
Clinical Study Report
empty
Analytic Code
empty
Data Dictionary
empty