

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

06 Jun 2026

### The self-care education and stabilizing exercise in pain, disability and muscle activities in mothers with chronic low back pain having children with cerebral palsy

#### Protocol summary

##### Summary

This study aims to evaluate the effectiveness of self-care education and stabilizing exercise on pain, disability and muscle activity in mothers with chronic low back having children with cerebral palsy, for this purpose the mothers with chronic low back pain having children with cerebral palsy divided into two groups of experimental group and control group. In control group mothers will be received self-care education for 8 weeks, and in experimental group mothers in additional the self-care education they will be received stabilizing exercise for 8 weeks 3 times a week, the first assessment will be done before the intervention and secondary assessment will be done after the intervention and then 4 weeks after the end of interventions the assessment will be done in order to follow up the effects of the interventions

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT2015041121686N1**

Registration date: **2015-06-25, 1394/04/04**

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

Last update:

Update count: **0**

##### Registration date

2015-06-25, 1394/04/04

##### Registrant information

###### Name

Zahra Ahmadizadeh

###### Name of organization / entity

Semnan University of Medical Sciences

###### Country

Iran (Islamic Republic of)

##### Phone

+98 23 3365 4180

##### Email address

ahmadizadeh.z@semums.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

Semnan University of Medical Sciences

##### Expected recruitment start date

2015-06-20, 1394/03/30

##### Expected recruitment end date

2016-01-20, 1394/10/30

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

The self-care education and stabilizing exercise in pain, disability and muscle activities in mothers with chronic low back pain having children with cerebral palsy

##### Public title

The self-care education and stabilizing exercise in pain, disability and muscle activities in mothers with chronic low back pain having children with cerebral palsy

##### Purpose

Treatment

##### Inclusion/Exclusion criteria

Inclusion criteria: Having a child with cerebral palsy; mother was the primary caregiver for children with cerebral palsy; having low back pain for at least three months Exclusion criteria: a history of trauma in low back; reported the history of vertebral column fractures and hip fractures; report any neurological diseases such as multiple sclerosis, Parkinson's, etc.; report systemic

diseases such as diabetes or Rheumatoid arthritis, tuberculosis, etc.; scoliosis and kyphosis of vertebral column and report any signs of serious disease in spinal included: Non-mechanical pain (without regard to time or activity); chest pain, wide paresthesia in the limbs, severe muscle weakness in lower limb, unexplained weight loss, fever, history of recently surgery, previous history of carcinoma, reported human immunodeficiency virus infection and substance abuse

#### **Age**

From **18 years** old to **60 years** old

#### **Gender**

Female

#### **Phase**

N/A

#### **Groups that have been masked**

*No information*

#### **Sample size**

Target sample size: **60**

#### **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**

Semnan University of Medical Sciences

###### **Street address**

Semnan University of Medical Sciences, Km 5 Semnan to Damghan Road, Semnan

###### **City**

Semnan

###### **Postal code**

##### **Approval date**

2015-05-19, 1394/02/29

##### **Ethics committee reference number**

ir.semums.rec.1394.12

### **Health conditions studied**

#### **1**

##### **Description of health condition studied**

Women with chronic low back pain having children with cerebral palsy

##### **ICD-10 code**

M70.8, M70

##### **ICD-10 code description**

Other soft tissue disorders related to use, overuse and pressure, Unspecified soft tissue disorder related to use, overuse and pressure, Low back pain

### **Primary outcomes**

#### **1**

##### **Description**

Muscle activities

##### **Timepoint**

Before intervention, after 8 weeks intervention and 4 weeks after the end of intervention

##### **Method of measurement**

Ultrasonography

#### **2**

##### **Description**

Disability

##### **Timepoint**

Before intervention, after 8 weeks intervention and 4 weeks after the end of intervention

##### **Method of measurement**

Roland-Morris Questionnaire

#### **3**

##### **Description**

Pain

##### **Timepoint**

Before intervention, after 8 weeks intervention and 4 weeks after the end of intervention

##### **Method of measurement**

Visual Analogue Scale for pain

### **Secondary outcomes**

#### **1**

##### **Description**

Depression

##### **Timepoint**

Before intervention, after 8 weeks intervention and 4 weeks after the end of intervention

##### **Method of measurement**

Beck depression questionnaire

### **Intervention groups**

#### **1**

##### **Description**

Control group: the self-care education will be trained and the mothers will be received the booklet

##### **Category**

N/A

## 2

### Description

Experimental group: in addition to self-care education they will be received muscle stabilization training for 8 week 3 times per week

### Category

N/A

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

Neuromuscular Rehabilitation Research Center

##### Full name of responsible person

Zahra Ahmadizadeh

##### Street address

No.24, Neuromuscular Rehabilitation Research Center, Ghods Blvd, Mashahir square, Semnan, Iran

##### City

Semnan

## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

Deputy of research and technology of Semnan University of Medical Sciences

##### Full name of responsible person

Dr. Ali Rashidy pour

##### Street address

deputy of research and technology of Semnan university of medical sciences, No.47, Semnan university of medical sciences, Basij Blvd, Semnan, Iran

##### City

Semnan

#### Grant name

#### Grant code / Reference number

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

Yes

#### Title of funding source

Deputy of research and technology of Semnan University of Medical Sciences

#### 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

### Contact

#### Name of organization / entity

Semnan University of Medical Sciences

#### Full name of responsible person

Zahra Ahmadizadeh

#### Position

Master degree/ Faculty member

#### Other areas of specialty/work

#### Street address

school of Rehabilitation, Semnan University of Medical Sciences, Km 5 Semnan to Damghan Road, Semnan, Iran

#### City

Semnan

#### Postal code

#### Phone

+98 23 3365 4180

#### Fax

#### Email

ahmadizadeh.z@semums.ac.ir

#### Web page address

## Person responsible for scientific inquiries

### Contact

#### Name of organization / entity

Semnan University of Medical Sciences

#### Full name of responsible person

Zahra Ahmadizadeh

#### Position

Master degree

#### Other areas of specialty/work

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## Person responsible for updating data

### Contact

#### Name of organization / entity

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#### Full name of responsible person

Zahra Ahmadizadeh

#### Position

Master degree/ Lecturer

#### Other areas of specialty/work

#### Street address

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**Web page address**

## **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*