

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

15 Jul 2026

### The effectiveness of self-esteem and psychological problems educational package in children with scoliosis

#### Protocol summary

##### Study aim

Self-esteem gradually increases in the pre-adolescent years, and with the onset of adolescence due to abstract thinking about physical interpretation, more thoughts about oneself are observed. Social strength is such as graduating from university, marriage, changing jobs. Diseases that change the structure of the body, such as scoliosis, may also change the mental image of the body

##### Design

Clinical trial with control group, with parallel groups, double-blind, randomized, on 60 patients. Excel software rand function was used for randomization.

##### Settings and conduct

Background: Psychological education of patients with scoliosis Location: Shafa Yahyaian Hospital, Tehran Scope and method of work: Educational package for children Blinding: Yes-patient-physician-statistical researcher

##### Participants/Inclusion and exclusion criteria

Inclusion criteria: Patients with idiopathic scoliosis, No need for surgical treatment, Accept brace treatment Age 9-12 years Criteria for non-entry : Congenital scoliosis Secondary scoliosis to other etiologies such as radiotherapy or tumor Age less than 9 and older than 12 years

##### Intervention groups

The experimental group undergoes 12 sessions of 1.5 hours, one session per week for approximately three months under the intervention of self-respect training by a clinical psychologist Demographic, clinical, and radiographic information are obtained using patient records Completion of the body image anxiety questionnaire is done by the participants at the beginning and end of the study at intervals of three months, twice, in both group

##### Main outcome variables

1. A person's dissatisfaction and embarrassment with his appearance, checking and hiding perceived defects 2. The degree to which anxiety about appearance interferes

with a person's social performance

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20210520051351N3**

Registration date: **2022-05-14, 1401/02/24**

Registration timing: **prospective**

Last update: **2022-05-14, 1401/02/24**

Update count: **0**

##### Registration date

2022-05-14, 1401/02/24

##### Registrant information

##### Name

Mehdi Mohammadpour

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 21 4448 2494

##### Email address

mehdi.668491@gmail.com

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2022-05-21, 1401/02/31

##### Expected recruitment end date

2022-09-21, 1401/06/30

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

**Scientific title**  
The effectiveness of self-esteem and psychological problems educational package in children with scoliosis

**Public title**  
The effectiveness of self-esteem and psychological problems educational package in children with scoliosis

**Purpose**  
Education/Guidance

**Inclusion/Exclusion criteria**  
**Inclusion criteria:**  
 Patients with idiopathic scoliosis No need for surgical treatment Accept brace treatment Age 9-12 years  
**Exclusion criteria:**  
 Congenital scoliosis Secondary scoliosis to other etiologies such as radiotherapy or tumor Age less than 9 and older than 12 years

**Age**  
From **9 years** old to **12 years** old

**Gender**  
Both

**Phase**  
N/A

**Groups that have been masked**

- Participant
- Outcome assessor
- Data analyser

**Sample size**  
Target sample size: **60**

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

**Randomization description**  
 Randomization method in the present study: simple randomization so that they will be divided into control and intervention groups one by one. Randomization unit: will be individual. Layers of randomization: Using stratified randomization Patients are randomly placed in different groups and random blocks are used for balance in groups. The samples are classified according to the center of the class and then in each class with the help of software to generate a random sequence.  
 Randomization tool: Random number table The method of constructing a random sequence is selected one by one Explanation of allocation concealment: Patients do not know the type of intervention and the person performing the analysis does not know the type of intervention.

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

**Blinding description**  
 Participant: does not know the type of intervention  
 Clinical caregiver: Knows the type of intervention  
 Researcher: Knows the type of intervention Impact  
 Assessor: Does not know the type of intervention Data Analyzer: Does not know the type of intervention Health personnel (physicians): Do not know the type of intervention Data collectors and those evaluating the outcome: Unaware of the type of intervention

**Placebo**

Not used

**Assignment**  
Parallel

**Other design features**

**Secondary Ids**  
empty

**Ethics committees**

**1**

**Ethics committee**  
**Name of ethics committee**  
 Ethics committee of Iran University of Medical Sciences  
**Street address**  
 Mojahedin Islam St. Shafa Yahyaian Hospital  
**City**  
 Tehran  
**Province**  
 Tehran  
**Postal code**  
 1157637131  
**Approval date**  
 2022-04-15, 1401/01/26  
**Ethics committee reference number**  
 IR.IUMS.REC.1401.040

## Health conditions studied

**1**

**Description of health condition studied**  
Scoliosis

**ICD-10 code**  
M41.11

**ICD-10 code description**  
Juvenile idiopathic scoliosis

## Primary outcomes

**1**

**Description**  
Theoretical questionnaire score from body image.

**Timepoint**  
Evaluation of psychological problems with body image concern questionnaire before and three months after self-esteem training

**Method of measurement**  
Body Image Concern Questionnaire

**2**

**Description**  
Beck Anxiety Questionnaire score

**Timepoint**  
Evaluation of psychological problems with Beck Anxiety Questionnaire before and after three months of self-esteem training

**Method of measurement**  
Beck Anxiety Questionnaire

## Secondary outcomes

empty

## Intervention groups

### 1

#### Description

Intervention group: Self-esteem package training - This group, which is tested in 12 sessions of 1.5 hours, one session per week, for approximately three months under the intervention of self-esteem package training, by a clinical psychologist. Collecting demographic, clinical and radiographic information of patients using patient records and completing a body image concern questionnaire is performed by study participants three months apart, twice, once before the start of the package, and once at the end of treatment. Be.

#### Category

Rehabilitation

### 2

#### Description

Control group: Lack of training in your honor package-  
Control group: Lack of self-esteem training - This group is also patients with scoliosis who are asked to fill out the desired questionnaire twice in three months.

#### Category

Other

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

Shafa Yahyaian Hospital

##### Full name of responsible person

Hasan Ghandehari

##### Street address

Shafa yahyaiehian Educational and Medical Center,  
Mojahedin-e-Islam St., Baharestan Square, Tehran

##### City

Tehran

##### Province

Tehran

##### Postal code

1157637131

##### Phone

+98 21 3354 2041

##### Email

mehdi.668491@gmail.com

## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

Iran University of Medical Sciences

##### Full name of responsible person

سید عباس متولیان

##### Street address

Shahid Hemmat Highway between Sheikh Fazl ...  
Nouri and Shahid Chamran Iran University of Medical  
Sciences

##### City

Tehran

##### Province

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##### Postal code

۱۳۴۹۶۱۴۵۳۵

##### Phone

+98 21 86701

##### Email

admins@iums.ac.ir

#### Grant name

#### Grant code / Reference number

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

Yes

#### Title of funding source

Iran 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

Iran University of Medical Sciences

##### Full name of responsible person

Hasan Ghandehari

##### Position

Associate professor

##### Latest degree

Specialist

##### Other areas of specialty/work

Orthopedics

##### Street address

Mojahedin-e-Islam Street

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##### Province

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##### Phone

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**Email**

Ghandhari.h@iums.ac.ir

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

Iran University of Medical Sciences

**Full name of responsible person**

Mehdi Mohammadpour

**Position**

Non-faculty specialist physician

**Latest degree**

Specialist

**Other areas of specialty/work**

Orthopedics

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Punak Square, Sardar Jangal St., Bahar Sharghi St.,  
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**Person responsible for updating data****Contact****Name of organization / entity**

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**Position**

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**Latest degree**

Specialist

**Other areas of specialty/work**

Orthopedics

**Street address**

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**Province**

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**Phone**

+98 21 3354 2041

**Email**

mehdi.668491@gmail.com

**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**

Yes - There is a plan to make this available

**Statistical Analysis Plan**

Yes - There is a plan to make this available

**Informed Consent Form**

Yes - There is a plan to make this available

**Clinical Study Report**

Yes - There is a plan to make this available

**Analytic Code**

Yes - There is a plan to make this available

**Data Dictionary**

Yes - There is a plan to make this available

**Title and more details about the data/document**

All variables and all potential data can be shared after identifying individuals

**When the data will become available and for how long**

Access period starts 6 months after the results are published

**To whom data/document is available**

It will be available to researchers working in academic institutions, and people in industry can apply for it.

**Under which criteria data/document could be used**

The data can be reviewed and used to improve clinical conditions and maintain patient health and perform meta-analyses.

**From where data/document is obtainable**

They can request the author's email or from the research center or university.

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

Apply by email or post to Iran University of Medical Sciences or Shafa Yahyaian Bone and Joint Reconstruction Research Center.

**Comments**