

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

Tehran

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

City

Tehran

Province

Tehran

Postal code

1157637131

Phone

+98 21 3354 2041

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

Street address

Punak Square, Sardar Jangal St., Bahar Sharghi St.,
Fajr Alley, No. 29, Unit 3, Postal Code 1476954974

City

TEHRAN

Province

Tehran

Postal code

1157637131

Phone

+98 21 3354 2041

Fax**Email**

mehdi.668491@gmail.com

Person responsible for updating data**Contact****Name of organization / entity**

Iran University of Medical Sciences

Full name of responsible person

Mehdi Mohammadpour

Position

Fellowship

Latest degree

Specialist

Other areas of specialty/work

Orthopedics

Street address

Mojahedin-e-Islam Street

City

Tehran

Province

Tehran

Postal code

1157637131

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