

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 2026

Evaluate the effectiveness of mindfulness-based training to improve the resilience and quality of life in adolescents with idiopathic scoliosis brace treatment and their parents

Protocol summary

Study aim

The purpose of this study was to investigate the effectiveness of bench-based methods on improving resilience and quality of life in adolescents with idiopathic scoliosis treated with brace and their parents.

Design

The plan includes two groups of parents and teens. Which is a case study. Finally, it will be examined whether this training is more effective than adolescents or parents.

Settings and conduct

A cohort of cognitive therapy package for children and adolescents (Sample & Lee, 2007) for adolescent group and parental group also teaches cognitive techniques (Kabat Zein, 1999). The intervention will be held at the Shahid Beheshti University Psychological Consulting and Services Center.

Participants/Inclusion and exclusion criteria

Adolescent group (Entry requirements) -Does not have any physical and medical illness. -Have at least 10 years and maximum 18 years of age.. Parents group(Entry requirements) -Have at least a diploma or higher education. Adolescent group(Conditions of failure to enter) -Patient's opposition to cooperation at any time from research.

Intervention groups

This study consists of two groups. A group in which adolescents with scoliosis attend. And the second group, which can include parents whose child was involved in intervention, and can include parents whose son was scoliosis but who did not participate in the intervention.

Main outcome variables

Improve the quality of life and quality of life for teens using brace, as well as their parents. Because the disease and the type of treatment affect the various dimensions of quality of life.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20180221038817N1**

Registration date: **2018-05-29, 1397/03/08**

Registration timing: **retrospective**

Last update: **2018-05-29, 1397/03/08**

Update count: **0**

Registration date

2018-05-29, 1397/03/08

Registrant information

Name

Mehrnaz Tisheh zan

Name of organization / entity

Shahid Beheshti University Of Tehran

Country

Iran (Islamic Republic of)

Phone

+98 41 3544 5244

Email address

m.tishehzan@mail.sbu.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-02-20, 1396/12/01

Expected recruitment end date

2018-05-05, 1397/02/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluate the effectiveness of mindfulness-based training to improve the resilience and quality of life in adolescents with idiopathic scoliosis brace treatment and their parents

Public title

The Effectiveness of Mindfulness Education in adolescent with scoliosis and their parents

Purpose

Education/Guidance

Inclusion/Exclusion criteria

Inclusion criteria:

does not have other physical and medical illness Use brace and exercise at the same time At least three months from the start of treatment.

Exclusion criteria:

Age

From **10 years** old to **18 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **14**

Randomization (investigator's opinion)

N/A

Randomization description

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Other

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Shahid Beheshti University

Street address

Family Research Institute, Shahid Beheshti University, Shahid shahriari Sq, Yaman St, Shahid Chamran Hwy.

City

Tehran

Province

Tehran

Postal code

1983969411

Approval date

2016-11-27, 1395/09/07

Ethics committee reference number

850/2/ص

Health conditions studied

1

Description of health condition studied

Idiopathic Scoliosis

ICD-10 code

M41

ICD-10 code description

Scoliosis

Primary outcomes

1

Description

Resonance Score in Conner and Davidson Questionnaire

Timepoint

Prior to training, the resilience score is measured by Conner and Davidson's questionnaire. After one month after completion of the intervention, samples are monitored by measuring instruments.

Method of measurement

Conner and Davidson Suspension Questionnaire

2

Description

The score of the questionnaire (BrQ) measures the quality of life of adolescents with scoliosis who are treated with brace.

Timepoint

Before starting the training, the quality of life score is measured by the Brace Questionnaire and after one month after completion of the intervention, samples are monitored by measuring instruments.

Method of measurement

Brace Questionnaire

3

Description

Quality of Life Score in the WHO Quality of Life Questionnaire for Parents Group

Timepoint

Before starting the training of Mindfulness techniques, the quality of life score is measured by the World Health Organization's Quality of Life questionnaire and after one month after completion of the intervention, samples are monitored by measuring instruments.

Method of measurement

World Health Organization Quality of Life Questionnaire

Secondary outcomes

empty

Intervention groups

1

Description

Group 1: Adolescents with braided Idiopathic scoliosis,
Group II: Parents of juvenile idiopathic scoliosis treated with brace

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center

Technical Orthopedics Dr. Kamyab

Full name of responsible person

Dr. Mojtaba Kamyab

Street address

unit 1,koohe noor building,infront of koohe noor st,
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2

Recruitment center

Name of recruitment center

Dr. Ganjavian office

Full name of responsible person

Dr. Mohammad Saleh Ganjavian

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shahid Beheshti University

Full name of responsible person

Dr. Babak Shokri

Street address

assistance of Research and Technology, presidential
building, Shahid Beheshti University,Evin.

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Grant name

Grant code / Reference number

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

Yes

Title of funding source

Shahid Beheshti University

Proportion provided by this source

100

Public or private sector

Private

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

Shahid Beheshti University Of Tehran

Full name of responsible person

Mehrnaz Tishehzan

Position

M.A student

Latest degree

Bachelor

Other areas of specialty/work

Psychology

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Person responsible for scientific inquiries

Contact

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Full name of responsible person

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Person responsible for updating data

Contact

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Position

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Latest degree

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Other areas of specialty/work

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is a plan to make this available

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

Not applicable

Informed Consent Form

Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

No - There is not a plan to make this available

Data Dictionary

Not applicable

Title and more details about the data/document

After the intervention, the findings of the study were followed up and the results of the questionnaires were distributed to each person participating in this study. Also, techniques that are appropriate to the sample conditions will be selected and implemented, and will also be introduced.

When the data will become available and for how long

Starting the access period from September 2018

To whom data/document is available

All researchers and graduate and postgraduate students whose interventions they use in research are good.

Under which criteria data/document could be used

Only for researchers who work on the field of this research (Scoliosis & Mindfulness)

From where data/document is obtainable

1-send the email to this address: mehr.tn@gmail.com and in the text of the email, mention which parts of the data and the results and what research is required.

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

After sending the email to mehr.tn@gmail, according to your request, a weekly container will be sent to your email address.

Comments