Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 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
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Iran (Islamic Republic of)
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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
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2

Recruitment center
Name of recruitment center
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Full name of responsible person
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Shahid Beheshti University
Full name of responsible person
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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
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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