

Clinical Trial Protocol

Iranian Registry of Clinical Trials

04 Aug 2026

The effect of yoga on aggression and anxiety in girls with educable mental retardation

Protocol summary

Study aim

Determining the effect of yoga on aggression and anxiety of educable mentally retarded girls

Design

Randomized clinical trial, with control group, without blinding, with parallel groups, on 124 educable mentally retarded female students

Settings and conduct

124 educable mentally retarded girls with eligibility criteria are entered into the study after completing the Spence Anxiety Questionnaire by the student and the Ghezel Seflo Aggression Questionnaire by the parent / student guardian. The type of randomization was block randomization with classification on groups (group 1 and 2). These people are divided into two groups of 62 intervention and control using random block size with the size of four blocks. Students are trained in 20 virtual 45-minute yoga sessions. Classes are held 4 times a week for 5 weeks. One month after the end of the sessions, the Spence Anxiety Questionnaire is completed by the student and the Ghezel Seflo Aggression Questionnaire is completed by the student / student's supervisor. The study is not blind.

Participants/Inclusion and exclusion criteria

be female Have mental retardation be educable No movement restrictions Got a Score in the questionnaires used

Intervention groups

These people will be trained in 20 sessions of 45 minutes of online yoga training. In each yoga session, exercises (asana) which includes 27 movements, will be trained. First the special exercises for warming up the body and then the positions of the butterfly, the hello to the sun, and other movements, that will be taught in each session. Breathing exercises (pranayama) will also be performed, which include full inhalation breathing, complete exhalation breathing, and cooling breathing. The control group will not receive any intervention.

Main outcome variables

The main outcome studied in this study is the anxiety and aggression of educable mentally retarded girls

General information

Reason for update

Modify the number of samples. correction of the maximum age of the samples

Acronym

IRCT registration information

IRCT registration number: **IRCT20210222050460N1**

Registration date: **2021-07-31, 1400/05/09**

Registration timing: **prospective**

Last update: **2021-08-15, 1400/05/24**

Update count: **1**

Registration date

2021-07-31, 1400/05/09

Registrant information

Name

Pegah Nazarinezhad

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 31 4536 4220

Email address

pegah.nazarinezhad@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-08-01, 1400/05/10

Expected recruitment end date

2021-08-06, 1400/05/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of yoga on aggression and anxiety in girls with educable mental retardation

Public title

The effect of yoga on aggression and anxiety in girls with educable mental retardation

Purpose

Diagnostic

Inclusion/Exclusion criteria**Inclusion criteria:**

be FEMALE Have mental retardation be educable No movement restrictions Got a Score in the questionnaires used

Exclusion criteria:

Reluctance of the participant or his / her supervisor to participate in the study Failure to attend 2 or more online training sessions

Age

From **6 years** old to **20 years** old

Gender

Female

Phase

N/A

Groups that have been masked*No information***Sample size**Target sample size: **124**

More than 1 sample in each individual

Number of samples in each individual: **1**

For each mentally retarded person participating in the study, at least one parent or guardian enters the study to complete the questionnaire.

Randomization (investigator's opinion)

Randomized

Randomization description

This study will be performed on 124 educable mentally retarded girls in an intervention group and a control group. Random assignment of these 124 students is done using a random block size of four blocks into a 62-member intervention group (group1 and 2) and a 62-member control group (group1 and 2). The type of randomization was block randomization with classification on groups (group1 and 2). For random allocation by block method and assigning individuals to 2 intervention groups (T) and control group (c), there are six modes for blocks, Includes: TTCC, TCTC, TCCT, CCTT, CTTC and CTTC. We create random numbers using a computer. For number 1 of combination 1 (CTTC), for number 2 of combination 2 (CCTT), for number 3 of combination 3 (TCCT), for number 4 of combination 4 (TCTC), for number 5 of combination 5 (CTTC) and for Number 6 We use combination 6 (TTCC).

Blinding (investigator's opinion)

Not blinded

Blinding description**Placebo**

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

کمیته اخلاق در پژوهش دانشکده پرستاری و مامایی دانشگاه علوم پزشکی تهران

Street address

Tohid Square, Dr. Mirkhani St., School of Nursing and Midwifery

City

Tehran

Province

Tehran

Postal code

1419733171

Approval date

2020-09-19, 1399/06/29

Ethics committee reference number

IR.TUMS.MEDICINE.REC.13991459

Health conditions studied**1****Description of health condition studied**

aggression

ICD-10 code

R45.6

ICD-10 code description

Violent behavior

2**Description of health condition studied**

anxiety

ICD-10 code

F41.1

ICD-10 code description

Generalized anxiety disorder

3**Description of health condition studied**

mental retardation

ICD-10 code

F70

ICD-10 code description

Mild intellectual disabilities

Primary outcomes

1

Description

aggression

Timepoint

Before study and 1 month after study

Method of measurement

Ghezel Seflo Aggression Questionnaire

2

Description

anxiety

Timepoint

Before study and 1 month after study

Method of measurement

Spence Anxiety Scale

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: These people will be trained in 20 sessions of 45 minutes of online yoga training (for 5 weeks, 4 sessions per week). in each yoga session, exercises (asana) which includes 27 movements, Will be trained. First the special exercises for warming up the body and then the positions of the butterfly, the wooden horse, the cat pull, the hello to the sun, the angular balance, the boat, the shooter, the bow, the bridge, the camel, the chest pull, the chair, the cobra, the candle, the relaxation. It is a set of stagnation, twisted leaves, cow's head, eagle, fish, lotus, sleeping screw, tree, mountain, stork, swan, triangle, cart that will be taught in each session. Breathing exercises (pranayama) will also be performed, which include full inhalation breathing, complete exhalation breathing, and cooling breathing. At the end of each session, students will participate in a relaxation program that will include relaxation and visualizing an imaginary trip to the beach, sea, forest, and space.

Category

Prevention

2

Description

Control group: Students who do not receive any intervention

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center

Boostan school

Full name of responsible person

Nakisa Goodarzi

Street address

Shahin Shahr, Shahid Beheshti St., Side 6 West, Bustan School

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Esfahan

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2

Recruitment center

Name of recruitment center

Golestan school

Full name of responsible person

Aghdas Jazayeri

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Mohammad Ali Sahraeian

Street address

Department of Reproductive Health, Tehran University of Medical Sciences, Nosrat St., Tohid Square

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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

Tehran 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**

Tehran University of Medical Sciences

Full name of responsible person

Pegah Nazari NEZHAD

Position

Master student of midwifery

Latest degree

Bachelor

Other areas of specialty/work

Midwifery

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

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Full name of responsible person

Ziba TaghiZade

Position

PhD in Reproductive Health

Latest degree

Ph.D.

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

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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)**

No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD

We intend to publish the results and will not distribute the data

Study Protocol

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

Statistical Analysis Plan

No - There is not a plan to make this available

Informed Consent Form

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

Clinical Study Report

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

Analytic Code

No - There is not a plan to make this available

Data Dictionary

No - There is not a plan to make this available