Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 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 124educable 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(group1 and 2).These people are divided into two groups of 62intervention 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)

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+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 124students 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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2

Recruitment center
Name of recruitment center
Golestan school
Full name of responsible person
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Gaz Borkhar, Tohid Square, Azadi St., Golestan St., Golestan School
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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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Email
pegah.nazarinezhad@gmail.com
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
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Person responsible for updating data

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Position
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Latest degree
Bachelor
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