

Clinical Trial Protocol

Iranian Registry of Clinical Trials

29 Jul 2026

Investigating the Impact of Mothers Empowerment on Aggression score of 6 - 12 Years Old Children with Autism in Al- Nasiriya City at 2021

Protocol summary

Study aim

Determining the effect of mother empowerment on children aggression aged 6-12 years with autism

Design

A randomized clinical trial, without blinding (Only data collector will blind), on 60 mothers of children with Autism in autism centers

Settings and conduct

Mothers of eligible children are selected by available methods and then the centers are divided randomly so that one of them would be the intervention group and the other would be the control group. single-blind (participants and care providers)

Participants/Inclusion and exclusion criteria

Inclusion criteria: Mothers who agree with participation in the study; their children have one of the types of autism; children age between 6 to 12 years; the autistic child should not be diagnosed with other mental illnesses. Exclusion criteria: Mothers who participated in other similar activities.

Intervention groups

Intervention group: based on need assessment and includes the implementation of the family-center empowerment model. Control group: receive routine care from the center.

Main outcome variables

Aggression score

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20210602051482N1**

Registration date: **2021-09-26, 1400/07/04**

Registration timing: **prospective**

Last update: **2021-09-26, 1400/07/04**

Update count: **0**

Registration date

2021-09-26, 1400/07/04

Registrant information

Name

Mohanad Dawood

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 51 3854 2022

Email address

abassmohanad2018@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-10-02, 1400/07/10

Expected recruitment end date

2021-12-16, 1400/09/25

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Investigating the Impact of Mothers Empowerment on Aggression score of 6 - 12 Years Old Children with Autism in Al- Nasiriya City at 2021

Public title

Impact of Mothers Empowerment on Aggression of Children with Autism

Purpose

Education/Guidance

Inclusion/Exclusion criteria

Inclusion criteria:

Their child has one of the types of autism, Children age between 6 to 12 years. Lack of experience of a stressful event in the last six months. Parents agreed with participation in the study. The autistic child should not be diagnosed with other mental illnesses.

Exclusion criteria:

Parents who have participated in other similar activities.

Age

From **6 years** old to **12 years** old

Gender

Both

Phase

N/A

Groups that have been masked

- Data analyser

Sample size

Target sample size: **60**

Randomization (investigator's opinion)

Randomized

Randomization description

The sampling method (entry of research participants from the community to the sample) will be non-random (convenient sampling). Mothers of children with autism in the Iraqi city of Nasiriyah are selected from special care centers for children with autism. The Iraqi city of Nasiriyah has two autistic children's centers. With a simple randomization method, lottery, one center will be assigned to the intervention group and another center to the control group. Then, for each of the intervention and control groups, 30 people from each center will be selected by lot.

Blinding (investigator's opinion)

Single blinded

Blinding description

All the goals and methods of the study will be explained to the participants in the study when obtaining informed consent. Interventions and evaluations will also be performed by the researcher. Therefore, in this study, only the person responsible for data analysis can be blind.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Mashhad University of Medical Sciences

Street address

Mashhad, Ph.D. Crossroads, Mashhad School of

Nursing and Midwifery, Ethics Committee

City

Mashhad

Province

Razavi Khorasan

Postal code

9137913199

Approval date

2021-07-27, 1400/05/05

Ethics committee reference number

IR.MUMS.NURSE.REC.1400.042

Health conditions studied

1

Description of health condition studied

Autism

ICD-10 code

F84.0

ICD-10 code description

Autistic disorder

Primary outcomes

1

Description

aggressive behavior score towards oneself.aggressive behavior score towards others.aggressive behavior score towards property.

Timepoint

before intervention and 4 weeks after intervention

Method of measurement

demographic data questionnaire and aggression questionnaire. This questionnaire would be an assessment tool for aggression of the children aged 6-12 years and consists of 40 questions that measure the dimensions of aggression, including aggression towards oneself, towards others and towards properties.

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: empowerment model in 4 stages
Content: threat perception (1) To increasing knowledge and awareness in association with the disease. In first session introduce with mothers and assessment problems with child's autism. The researcher guides mothers to identify effective thoughts and feelings in stressful and aggressive situations for children. Problem solving (2) to increase participation in order to increase self-esteem and self-efficacy of the individual in coping with problems. Create a group discussion among the participants to exchange experiences (with the researcher's assistance) to solve problems. Educational

participation (3) Participate the mothers in care giving. The researcher mothers the stressful conditions and the resulting changes in children with autism. The researcher teaches people to make positive mental changes. The researcher presents relaxation patterns in stressful and aggressive situations for children. Teaching stress management skills and how to deal with aggressive and stubbornness situations in children. The researcher teaches attention and focus techniques for autistic children. Training on the use of movement activities (such as playing a small ball, zigzag walking between cones) for children to direct the behavior towards a specific task and move from a random state to a purposeful state of behavior (Discharging the excess energy and random movements and employing them in purposeful, organized and positive activities). It reinforces and supports the desired behaviors of the aggressive child. Training skills on the acquired skills and the need to apply these skills when dealing with aggressive situations for autistic children provided presentations in the previous sessions were given to the mothers as CD-face-to-face training educational pamphlets. Evaluation (4) to determine learning rate and participation of the individuals. An evaluation at the end of each session and an evaluation also which will done finally.

Category

Other

2

Description

Control group: For children in the control group in autistic children's centers in Nasiriyah, a series of pamphlets are delivered to parents that contain trainings such as the behaviors of these children and how to deal with it. They usually do not have classes and face-to-face meetings with their parents. These pamphlets will also be provided to the participants of the intervention group.

Category

Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Al Nasiriyah autism center

Full name of responsible person

Dr. Naama Al-Tamimi

Street address

Nasiriyah City , Al Shaibani Street

City

Nasiriyah

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Mashhad University of Medical Sciences

Full name of responsible person

Ms. Dr. Latif Nejad

Street address

Faculty of Nursing and Midwifery, Mashhad, Daneshgah St., Ibn Sina Crossroads

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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

Mashhad 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

Mashhad University of Medical Sciences

Full name of responsible person

Hamidreza Behnam vashani

Position

Faculty member

Latest degree

Master

Other areas of specialty/work

Pediatrics

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Person responsible for scientific inquiries

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Person responsible for updating data

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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

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

Yes - There is a plan to make this available

Analytic Code

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

Data Dictionary

Not applicable

Title and more details about the data/document

Investigating the Impact of Mothers Empowerment on Aggression score of 6 – 12 Years Old Children with Autism in Al- Nasiriya City at 2021. Only part of the data, such as information about the main outcome or the like, can be shared.

When the data will become available and for how long

e.g., starting 6 months after publication

To whom data/document is available

is this only available for people working in academic institutions

Under which criteria data/document could be used

This should be within the scope of the researcher's work for scientific purposes. The conditions that Mashhad University of Medical Sciences pursues in the field of acquiring medical knowledge

From where data/document is obtainable

abddavoudm982@mums.ac.ir

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

Every week, applications are reviewed by the above-mentioned e-mail. Respond to them and send the required information as possible.

Comments

The charity of knowledge is spreading it