

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

04 Aug 2026

### The Effect of Supportive- Educational Program on Parenting Stress and Sense of Competence for Mothers Who have Children With Hyperactivity Disorder in Two Groups of Control and Intervention.

#### Protocol summary

##### Summary

The aim of this survey was to find out the effects of an educational-supportive program on parenting stress and a sense of competence of mothers who have kids with Attention Deficit Hyper Activity Disorder( ADHD). The type of this research is Parallel clinical trial. The studied population included of educated mothers, as it takes about 6 months that the ADHD disorder has been diagnosed in their children with an age range of 7-11 years old. Implementation method was based on available sampling and random selection of treatment centers As determined by lottery, which hospital Can be in the control group and Which hospital for the intervention group. This program is going to be performed for groups containing 5-12 mothers with a kid (at 6 months took from the diagnosis the problem of ADHD) in selected psychiatric centers of Iran University of Medical Sciences in Tehran, including Children's Psychiatric Clinic of Ali Asghar Hospital and Tehran Psychiatric Institute. Three months after submitting the pretest, the post - test procedure will be conducted via completion of questionnaires. This field is about designing an educational-supportive program for female parents of hyperactive children. Intervention time is composed of 8 sessions, each session held on; one hour and one day of the week. Inclusion criteria: women should live in Tehran, mothers should be physiologic, families should not be a single parent-typed, and mother does not have another sick kid. Exclusion criteria: Physical and psychological problems identified with the mother, participating in less than 4 sessions of educational funding program. The intervention is Parallel clinical trial, and for the intervention group, an educational-supportive program is selected based on the Denforth and Barclay's behavior management program. after end of the intervention, the capacity of the educational program is driven home to them.

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT2015081923683N1**

Registration date: **2016-09-19, 1395/06/29**

Registration timing: **retrospective**

Last update:

Update count: **0**

##### Registration date

2016-09-19, 1395/06/29

##### Registrant information

##### Name

Naiemeh Seyedfatemi

##### Name of organization / entity

Iran University of Medical Sciences

##### Country

Iran (Islamic Republic of)

##### Phone

+98 21 8820 1880

##### Email address

seyedfatemi.n@iums.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

Governmental

##### Expected recruitment start date

2015-09-23, 1394/07/01

##### Expected recruitment end date

2016-03-18, 1394/12/28

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

**Scientific title**  
The Effect of Supportive- Educational Program on Parenting Stress and Sense of Competence for Mothers Who have Children With Hyperactivity Disorder in Two Groups of Control and Intervention.

**Public title**  
The Effect of Supportive- Educational Program on Stress and Sense of Competence for Mothers Who have Children With Hyperactivity Disorder.

**Purpose**  
Supportive

**Inclusion/Exclusion criteria**  
Inclusion criteria: Mothers should live in Tehran, mothers should be physiologic, families should not be a single parent-typed, and mother does not have another sick kid. Exclusion criteria: Physical and psychological problems identified with the mother, participating in less than 4 sessions of educational funding program.

**Age**  
From **7 years** old to **11 years** old

**Gender**  
Female

**Phase**  
2-3

**Groups that have been masked**  
*No information*

**Sample size**  
Target sample size: **100**

**Randomization (investigator's opinion)**  
Randomized

**Randomization description**

**Blinding (investigator's opinion)**  
Not blinded

**Blinding description**

**Placebo**  
Not used

**Assignment**  
Parallel

**Other design features**  
The type of this research is Parallel clinical trial. Implementation method was based on available sampling and random selection of treatment centers As determined by lottery, which hospital Can be in the control group and Which hospital for the intervention group.

## Secondary Ids

empty

## Ethics committees

### 1

#### Ethics committee

##### Name of ethics committee

Ethics Committee of Iran University of Medical Science

##### Street address

Shahid Hemmat Highway, Iran University of Medical Science

##### City

Tehran

##### Postal code

14565-345

##### Approval date

2015-05-26, 1394/03/05

##### Ethics committee reference number

IR.IUMS.REC.1394.9211196241

## Health conditions studied

### 1

#### Description of health condition studied

Mothers with children of hyperactivity

#### ICD-10 code

F90

#### ICD-10 code description

Disturbance of Activity and Attention

## Primary outcomes

### 1

#### Description

parenting stress

#### Timepoint

Before and three months after the pre-test

#### Method of measurement

Parenting stress index-short form

### 2

#### Description

sense of competence

#### Timepoint

Before and three months after the pre-test

#### Method of measurement

parenting sense of competence

## Secondary outcomes

empty

## Intervention groups

### 1

#### Description

1 Intervention: The type of research is parallel clinical trial and for mothers of the intervention group, an educational-supportive program is selected based on the Denforth and Barclay's behavioural management program. Intervention time is composed of 8 sessions, each session held on; one hour and one day of the week.

#### Category

Behavior

## 2

### Description

2 Intervention: No intervention is made in the control group and later re-filling the questionnaires; after three months, they will be offered by educational contents.

### Category

Behavior

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

Tehran Psychological Institute

##### Full name of responsible person

Nazi Abdollahpour

##### Street address

No1,Mansori Street,Sattarkhan Avenue,Tehran Iran

##### City

Tehran

### 2

#### Recruitment center

##### Name of recruitment center

Aliasghar Hospital

##### Full name of responsible person

Nazi Abdollahpour

##### Street address

Tehran, Zafar Street

##### City

Tehran

## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

Vice chancellor for research, Iran University of Medical Science

##### Full name of responsible person

Dr Haj Miresmaeil

##### Street address

Shahid Hemmat Highway,University of Iran Medical ScienceTehran,IRAN

##### City

Tehran

##### Grant name

##### Grant code / Reference number

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

Yes

##### Title of funding source

Vice chancellor for research, Iran University of Medical Science

##### Proportion provided by this source

100

##### Public or private sector

empty

##### Domestic or foreign origin

empty

##### Category of foreign source of funding

empty

##### Country of origin

##### Type of organization providing the funding

empty

## Person responsible for general inquiries

### Contact

#### Name of organization / entity

University of Iran Medical Science, School of Nursing and Midwifery

#### Full name of responsible person

Mrs. Doctor Naima Seyedfatemi

#### Position

Doctor / Head of Graduate

#### Other areas of specialty/work

#### Street address

Tehran

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88201978

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nseydfatemi@yahoo.com

#### Web page address

## Person responsible for scientific inquiries

### Contact

#### Name of organization / entity

University of Iran Medical Science, School of Nursing and Midwifery

#### Full name of responsible person

Nazi Abdollahpour

#### Position

msc/student

#### Other areas of specialty/work

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Rashid Yasami Avenue, Valiyeasr Street,Vank Square,Tehran Iran

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#### Web page address

## Person responsible for updating data

### Contact

**Name of organization / entity**

University of Iran Medical Science, School of Nursing  
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**Full name of responsible person**

Nazi Abdollahpour

**Position**

msc/ student

**Other areas of specialty/work****Street address**

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**Web page address****Sharing plan****Deidentified Individual Participant Data Set (IPD)**

*empty*

**Study Protocol**

*empty*

**Statistical Analysis Plan**

*empty*

**Informed Consent Form**

*empty*

**Clinical Study Report**

*empty*

**Analytic Code**

*empty*

**Data Dictionary**

*empty*